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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**AMENDMENT NO. 2**  
**TO**  
**Form S-1**  
**REGISTRATION STATEMENT**  
**UNDER**  
**THE SECURITIES ACT OF 1933**

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**OCULUS INNOVATIVE SCIENCES, INC.**

*(Exact name of registrant as specified in its charter)*

**California (prior to reincorporation)**  
**Delaware (after reincorporation)**  
*(State or other jurisdiction of  
incorporation or organization)*

**3841**  
*(Primary Standard Industrial  
Classification Code Number)*

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

**1129 N. McDowell Blvd.**  
**Petaluma, CA 94954**  
**(707) 782-0792**

*(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)*

**Hojabr Alimi**  
**Chief Executive Officer and President**  
**1129 N. McDowell Blvd.**  
**Petaluma, CA 94954**  
**(707) 782-0792**

*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting any offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED NOVEMBER 13, 2006**

**PRELIMINARY PROSPECTUS**

**Shares**



**Oculus Innovative Sciences, Inc.**

**Common Stock**

We are offering \_\_\_\_\_ shares of our common stock. This is our initial public offering, and no public market currently exists for our shares. We anticipate that the initial public offering price will be between \$12.00 and \$14.00 per share. We have applied for quotation of our common stock on the Nasdaq Global Market under the symbol "OCLS."

**Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully consider the risk factors described in "Risk Factors" beginning on page 9 of this prospectus.**

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$	\$
Underwriting discount	\$	\$
Proceeds, before expenses, to Oculus Innovative Sciences, Inc.	\$	\$

The underwriters may also purchase up to an additional \_\_\_\_\_ shares from us at the public offering price, less the underwriting discount, within 30 days after the date of this prospectus to cover over-allotments. The underwriters will have the right to purchase from us, at a nominal price, warrants to purchase up to 7% of the total number of shares sold in this offering.

All information in this prospectus reflects a one-for-four reverse stock split to our common stock and our reincorporation in Delaware from California to be effected immediately prior to the completion of this offering.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The underwriters expect to deliver the shares on or about \_\_\_\_\_, 2006.

**ROTH CAPITAL PARTNERS**

**MAXIM GROUP LLC**

**BROOKSTREET SECURITIES CORPORATION**

The date of this prospectus is \_\_\_\_\_, 2006



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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. We are not making an offer to sell these securities in any jurisdiction where the offer is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the respective dates as of which the information is given.

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## PROSPECTUS SUMMARY

*Before you decide whether to invest in our common stock, you should carefully read this entire prospectus, including "Risk Factors" and the consolidated financial statements and related notes. In this prospectus, "we," "us," "our" and "Oculus" refer to Oculus Innovative Sciences, Inc. and its consolidated subsidiaries unless the context requires otherwise.*

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

We have developed, and manufacture and market, a family of products intended to help prevent and treat infections in chronic and acute wounds. Infection is a serious potential complication in both chronic and acute wounds, and controlling infection is a critical step in wound healing. Our platform technology, called Microcyn, is a non-toxic, super-oxidized water-based solution that is designed to treat a wide range of pathogens, including 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. We do not have the necessary regulatory approvals to market Microcyn in the United States as a drug. However, in clinical testing and studies, our products were effective against a wide range of pathogens and were found to be non-toxic, easy to use and complementary to most existing treatment methods in wound care. Our experience and clinical data indicate that the use of Microcyn may shorten hospital stays, lower aggregate patient care costs and, in certain cases, reduce the need for systemic antibiotics. Microcyn also has potential applications in several other large markets, including respiratory, dermatology, dental and veterinary markets.

We believe Microcyn provides significant advantages over current methods of care in the treatment of a wide range of chronic and acute wounds throughout all stages of treatment. We believe that Microcyn is the first topical product that is effective against a broad range of bacteria and other infectious microbes, including antibiotic resistant strains, such as MRSA and VRE, without causing toxic side effects on, or irritation of, healthy tissue. Unlike most antibiotics, we believe Microcyn does not target specific strains of bacteria, a practice which has been shown to promote the development of resistant bacteria. In addition, our products are shelf stable, require no special preparation, and are easy to use.

Our products have received CE Mark approval for wound cleaning and reduction of microbial load, three U.S. Food and Drug Administration, or FDA, 510(k) clearances as a medical device in wound debridement, lubricating, moistening and dressing and have been granted approvals for use as an antiseptic, disinfectant and sterilant in Mexico, for use in cleaning and debriding in wound management in India and for moistening, irrigating, cleansing and debriding skin lesions in Canada. Physicians in several countries have conducted studies in which Microcyn was used to treat infection in a variety of wounds, including hard-to-treat wounds such as diabetic ulcers and burns, and, in some cases, reduced the need for systemic antibiotics. In July 2006, we completed a controlled clinical trial for pre-operative skin preparation. After completion of this trial, the Federal Drug Administration, or FDA, advised us that it is considering adopting new heightened performance requirements for evaluating efficacy of products designed to be used in pre-operative skin preparation such as ours. In discussions with the FDA, the FDA has not provided us with the definitive timing for, or parameters of, any such new requirements, and has informally stated that it is uncertain during what time frame it will be able to do so. We plan to continue our discussions with the FDA regarding the possible timing and parameters of any new guidelines for evaluating efficacy for pre-operative skin preparations. Depending on the ultimate position of the FDA regarding performance criteria for pre-operative skin preparations, we may reassess our priorities, clinical timelines and schedules for pursuing a pre-operative skin preparation indication or may decide not to pursue this indication.

We intend to conduct a pilot study in early 2007 to evaluate the effectiveness of Microcyn in patients with infections in open wounds. Following completion of the pilot study, we intend to establish a protocol for a Phase IIb clinical trial in a similar patient population, which we intend to begin in mid to late 2007. We anticipate this trial to last approximately 12 months.

We own one issued U.S. patent, 12 pending U.S. patent applications and 18 foreign pending patent applications relating to super-oxidized water, methods of using super-oxidized water-based solution, and aspects of the method and apparatus for manufacturing super-oxidized water.

We began selling our Microcyn-based product in July 2004 in Mexico, where we sell through a dedicated contract sales force, and in October 2004 in Europe, where we have a direct sales force and exclusive distribution agreements with distributors which we believe are experienced in supplying the wound care market. We began selling our products in the United States in June 2005 and have established a network of one national and five regional distributors, who are supported by our commercial team and clinical support staff. We began selling our product in India in July 2006 through a national distributor, and in Canada, we have entered into a distribution agreement under which distribution is expected to commence by late 2007.

We currently offer the following products:

<b>Geographic Region</b>	<b>Brand Name</b>	<b>Indication</b>
United States	Dermacyn Wound Care	A medical device product intended for moistening absorbent wound dressings and cleaning, moistening, lubricating and debriding specified types of wounds.
	Vetericyn Wound Care	A product used for the management of traumatic wounds, cuts, abrasions, skin irritations, post-surgical incisions and minor burns in animals.
European Union	Dermacyn Wound Care	A product intended for the reduction of microbial load for use in debriding, irrigating and moistening specified types of wounds.
Mexico	Oculus Microcyn Disinfectant	A disinfectant solution for medical devices.
	Microcyn60	A product used for the antiseptic treatment of wounds and infected areas and for the disinfection of medical instruments and equipment and clean-rooms.
Canada	Dermacyn Wound Care	A product used in moistening, irrigating, cleansing and debriding skin lesions.
India	Oxum	A product intended for use in cleaning and debriding in wound management.

The indications for our products vary from country to country due to different regulatory requirements and standards from jurisdiction to jurisdiction. The indications above are summaries of the indications approved by the regulatory authority or authorities in the listed jurisdictions. The similarly named products have similar formulations; however, they may not have identical specifications due to the varying requirements of different jurisdictions' regulatory agencies.

If we successfully complete additional clinical studies and receipt of the necessary FDA regulatory approvals, we plan to market Microcyn in the United States as a drug.

#### **Market Opportunity**

According to Medtech Insight, a Division of Windhover Information, there were over 90 million incidents of wounds in the United States during 2004. Of these, over 6 million were chronic wounds, including arterial, diabetic, pressure and venous ulcers. The remaining 84 million incidents were acute wounds, which follow the normal process of healing and commonly include burns, traumatic wounds and approximately 67 million surgical incisions. Key trends in wound care include a large and increasing at-risk population, primarily of elderly, diabetic and obese people, increased emphasis on controlling the cost of patient care, technological product and treatment innovation, increased focus on improving the patient experience and advancements in combination treatment methods.

When infection is present in a wound, standard treatments include cleansing, debridement and systemic antibiotics. Although there are a number of topical antiseptics and antibiotics currently used to treat acute and chronic wounds, their overall effectiveness is limited. For example:

- 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 allergic reactions and bacterial resistance; and
- the increase in antibiotic resistant bacterial strains, such as MRSA and VRE, have compromised the efficacy of some widely used topical antibiotics, including Neosporin and Bacitracin.

#### **Our Solution**

We believe our products have the following key features:

- **Efficacy.** In both laboratory testing and physician clinical studies, our products were 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 that 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 where Microcyn was used both independent of and in conjunction with other wound care therapeutic products, data supported that patients generally experienced less pain, improved mobility and physical activity levels and better quality of life.
- **Safety.** Preclinical and clinical data shows that Microcyn is non-toxic. Throughout all our clinical trials and physician clinical studies to date and since commercialization in 2004, we have received no reports of serious adverse events related to the use of Microcyn products.
- **Ease of Use.** 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 and does not require any specific handling procedures. Unlike other super-oxidized water 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 complementary to most advanced technologies used 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 Microcyn has the potential to help treat infection, accelerate wound healing time and, in certain cases, may help reduce the need for systemic antibiotics, thereby lowering overall patient cost.

#### **Our Strategy**

Our goal is to become a worldwide leader in wound care by establishing Microcyn as the standard of care for helping to prevent and treat chronic and acute wounds. We also intend to leverage our expertise in wound care into additional market opportunities. The key elements of our strategy include the following:

- drive adoption of Microcyn as the standard of care in the wound care market to help prevent and treat infection;
- obtain additional regulatory approvals in the United States;
- expand our direct sales force and distribution networks;
- pursue opportunities to combine Microcyn with other treatments;

- develop strategic collaborations in the wound care market; and
- leverage our Microcyn platform to address additional markets.

#### **Principal Risks**

There are significant risks and challenges relating to our business and industry that may materially and adversely affect our ability to execute our strategy and achieve our objectives, including the following risks:

- we have a history of losses, expect to continue to incur losses and may never achieve profitability;
- all of our current products are based on our Microcyn platform technology;
- we do not have regulatory approval to market Microcyn as a drug in the United States;
- we are required to conduct lengthy and expensive clinical trials, which may not be successful or lead to regulatory approvals;
- even if our products receive regulatory approval, our products may not gain market acceptance;
- one of our Microcyn based products was recently found to be ineffective as a high level disinfectant in killing certain strains of pathogens under current U.S. Environmental Protection Agency testing protocols;
- we may be unable to protect our intellectual property and we may be subject to infringement claims from third parties; and
- in connection with their dismissal in April 2006, our former independent registered public accounting firm has notified us of a number of reportable events it deemed to constitute material weaknesses over financial reporting that could impact our ability to develop reliable financial statements in a timely manner.

#### **Recent Developments**

On September 14, 2006, we sold 84,539 units, consisting of 84,539 shares of our Series C convertible preferred stock and warrants to purchase 16,907 shares of our common stock at an exercise price of \$18.00 per share, at a per unit price of \$18.00 for aggregate gross proceeds of \$1,521,702. On October 20, 2006, we sold 108,486 units, consisting of 108,486 shares of our Series C convertible preferred stock and warrants to purchase 21,697 shares of our common stock at an exercise price of \$18.00 per share, at a per unit price of \$18.00 for aggregate gross proceeds of \$1,952,748. In connection with the first closing, we paid to Brookstreet Securities Corporation, or Brookstreet, as placement agent, an aggregate of \$152,170 in commissions and issued to Brookstreet fully vested warrants to purchase an aggregate of 10,567 shares of our common stock at an exercise price of \$18.00 per share. In connection with the second closing, we paid to Brookstreet, an aggregate of \$195,274 in commissions and issued to Brookstreet fully vested warrants to purchase an aggregate of 13,560 shares of our common stock at an exercise price of \$18.00 per share. We refer to these transactions collectively as the Series C Financing elsewhere in this prospectus.

On November 7, 2006, we signed a loan agreement with Robert Burlingame under which Mr. Burlingame agreed to advance to us \$4.0 million, which accrues interest at an annual rate of 7%. The principal and all accrued interest under the loan agreement will become due and payable in full on the earlier of November 10, 2007 or five days after the completion of an initial public offering of our common stock resulting in gross proceeds to us of at least \$30.0 million. The loan is secured by all of our assets, other than our intellectual property, but is subordinate to the security interest held by our secured lender. At the time the principal is advanced to us, Brookstreet will be paid a fee in the amount of \$50,000 and will be granted a warrant to purchase 25,000 shares of our common stock at an exercise price of \$18.00 per share. We refer to this transaction as the Bridge Loan elsewhere in this prospectus. Mr. Burlingame was elected to our board of directors on November 7, 2006.

#### **Corporate Information**

We were incorporated in California in 1999 as Micromed Laboratories, Inc. In August 2001, we changed our name to Oculus Innovative Sciences, Inc. In connection with this offering, we intend to reincorporate in



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. Our website is [www.oculusis.com](http://www.oculusis.com). Information that is included on our website is not a part of this prospectus.

We use several trademarks in our business, including Microcyn, Dermacyn and Vetericyn. We own trademark registrations for these and other marks in the United States and in other countries, and we are currently seeking to register our Cidalcyn, Dentricyn and other marks in the United States and in other countries. All other trademarks, trade names or services marks appearing in this prospectus are the property of their respective owners.

Our human wound treatment product is marketed under the name Dermacyn in the United States, the European Union and Canada, under the name Microcyn60 in Mexico and under the name Oxum in India. We have agreed to cease marketing our product in Mexico under the name Microcyn60 by September 2007 as a result of the settlement of a trademark confusion claim in Mexico. All references in this prospectus to Microcyn as a product are to the products marketed under their respective names. Other references to Microcyn are to our platform technology used in producing our products for wound care and for other markets.

A glossary of technical, medical and industry terms appears on page 78.

**The Offering**

Common stock to be offered by us	3,076,923 shares
Common stock to be outstanding after the offering	11,476,132 shares
Assumed initial public offering price per share	\$13.00
Use of proceeds	We intend to use the net proceeds from this offering to expand our sales and marketing capabilities, to fund clinical trials and related research, to repay the principal and interest of our Bridge Loan and for general corporate purposes, including working capital. See "Use of Proceeds."
Proposed Nasdaq Global Market symbol	OCLS

The number of shares of common stock that will be outstanding immediately after this offering:

- includes 4,222,731 shares of common stock outstanding as of September 30, 2006;
- includes the automatic conversion of all outstanding shares of our convertible preferred stock into 4,176,478 shares of our common stock;
- excludes 2,260,263 shares of our common stock issuable upon the exercise of outstanding stock options, options to be granted in connection with this offering and options to be granted to a new board member, at a weighted-average exercise price of \$4.60 per share;
- excludes 1,098,301 shares of our common stock issuable upon the exercise of outstanding warrants, at a weighted average exercise price of \$10.18 per share;
- excludes 215,385 shares of our common stock issuable upon the exercise of warrants to be issued to the underwriters in connection with this offering at an exercise price equal to 165% of the offering price; and
- excludes up to 1,250,000 additional shares of our common stock reserved for future grants under our 2006 Stock Incentive Plan.

Unless we indicate otherwise, all information in this prospectus:

- gives effect to the automatic conversion of all outstanding shares of our preferred stock into shares of our common stock upon the completion of this offering;
- does not reflect the exercise of outstanding warrants or options to purchase shares of our common stock;
- assumes that the underwriters do not exercise their over-allotment option to purchase up to 461,538 additional shares in this offering and related warrants to purchase up to 32,307 additional shares of our common stock are not issued;
- reflects a one-for-four reverse split of our common stock to be effected before completion of this offering;
- reflects our reincorporation in Delaware from California; and
- reflects the amendment of our certificate of incorporation in connection with this offering to, among other things, change the number of shares authorized for issuance.

**Summary Consolidated Financial Data**

The following tables present our summary consolidated financial data. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read this information together with our audited consolidated financial statements and related notes and the information under "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

The following tables present our summary consolidated financial data:

- on an actual basis;
- on a pro forma, as adjusted, basis to give effect to:
  - the conversion of all outstanding shares of our convertible preferred stock into 4,176,478 shares of our common stock upon closing of this offering;
  - the sale of 3,076,923 shares of common stock in this offering at an assumed initial public offering price of \$13.00 per share, which is the midpoint of our expected offering range on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us; and
  - the Bridge Loan net of fees resulting in net proceeds of \$3,950,000.

	Year Ended March 31,			Six Months Ended September 30,	
	2004	2005	2006	2005	2006
(unaudited)					
(In thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
Revenues					
Product	\$ 95	\$ 473	\$ 1,966	\$ 807	\$ 1,942
Service	807	883	618	275	388
Total revenues	<u>902</u>	<u>1,356</u>	<u>2,584</u>	<u>1,082</u>	<u>2,330</u>
Cost of revenues					
Product(1)	1,403	2,211	3,899	1,350	1,043
Service(1)	1,265	1,311	1,003	497	422
Total cost of revenues	<u>2,668</u>	<u>3,522</u>	<u>4,902</u>	<u>1,847</u>	<u>1,465</u>
Gross profit (loss)	(1,766)	(2,166)	(2,318)	(765)	865
Operating expenses					
Research and development(1)	1,413	1,654	2,600	965	1,595
Selling, general and administrative(1)	3,918	12,492	15,933	7,704	7,867
Total operating expenses	<u>5,331</u>	<u>14,146</u>	<u>18,533</u>	<u>8,669</u>	<u>9,462</u>
Loss from operations	(7,097)	(16,312)	(20,851)	(9,434)	(8,597)
Interest expense	(178)	(372)	(172)	(103)	(261)
Interest income	3	8	282	68	100
Other income (expense), net	(26)	146	(377)	(101)	92
Net loss from continuing operations	(7,298)	(16,530)	(21,118)	(9,570)	(8,666)
Loss on discontinued operations	—	—	(1,981)	(174)	—
Net loss	(7,298)	(16,530)	(23,099)	(9,744)	(8,666)
Preferred stock dividends	—	—	(121)	—	(242)
Net loss available to common stockholders	<u>\$ (7,298)</u>	<u>\$ (16,530)</u>	<u>\$ (23,220)</u>	<u>\$ (9,744)</u>	<u>\$ (8,908)</u>
Net loss per common share: basic and diluted	<u>\$ (1.87)</u>	<u>\$ (4.22)</u>	<u>\$ (5.60)</u>	<u>\$ (2.38)</u>	<u>\$ (2.11)</u>
Weighted-average number of shares used in per common share calculations: basic and diluted	<u>3,911</u>	<u>3,914</u>	<u>4,150</u>	<u>4,086</u>	<u>4,221</u>
Pro forma net loss per common share: basic and diluted			<u>\$ (2.16)</u>		<u>\$ (0.79)</u>
Pro forma weighted-average number of shares used in per common share calculations: basic and diluted			<u>10,759</u>		<u>11,283</u>

(1) Includes the following stock-based compensation charges:

	<u>Year Ended March 31,</u>			<u>Six Months Ended</u>	
	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>September 30,</u>	<u>2006</u>
	(In thousands)				
<b>Cost of revenues</b>					
Product	\$ —	\$ 2	\$ 2	\$ 1	\$ —
Service	10	3	1	—	1
<b>Operating expenses</b>					
Research and development	56	5	52	12	40
Selling, general and administrative	358	2,339	542	253	229
<b>As of September 30, 2006</b>					
	<b>Actual</b>		<b>Pro Forma As Adjusted (unaudited)</b>		
	(In thousands, except per share data)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents <sup>(1)</sup>			\$ 2,269	\$	44,776
Working capital (deficiency) <sup>(1)</sup>			(797)		37,710
Total assets <sup>(1)</sup>			10,056		51,158
Total liabilities			9,082		13,082
Total stockholders' equity <sup>(1)</sup>			974		38,076

(1) A \$1.00 increase or decrease in the assumed initial public offering price of \$13.00 per share (the midpoint of our expected offering range on the cover of this prospectus) would increase or decrease, as applicable, this amount on a pro forma as adjusted basis by approximately \$2,831 assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and our estimated offering expenses.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below with all of the other information included in this prospectus before making an investment decision. If any of the following risks actually occur, our business, results of operations or financial condition would likely suffer. In that case, the market price of our common stock could decline and you could lose all or part of your investment in our common stock. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.*

### 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 have incurred significant net losses in each fiscal year since our inception, including losses of \$7.3 million, \$16.5 million, \$23.1 million and \$8.7 million for the years ended March 31, 2004, 2005 and 2006 and the six months ended September 30, 2006, respectively. Our accumulated deficit as of September 30, 2006 was \$59.3 million. We have yet to demonstrate that we can generate sufficient sales of our products to become profitable. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve profitability. Even if we do generate significant revenues from our product sales, we expect that increased operating expenses will result in significant operating losses in the near term as we, among other things:

- expand our sales and marketing capabilities in the United States and internationally;
- conduct preclinical studies and clinical trials on our products and product candidates;
- seek U.S. Food and Drug Administration, or FDA, clearance to market Microcyn as a drug in the United States;
- increase our research and development efforts to enhance our existing products, commercialize new products and develop new product candidates; and
- establish additional and expand existing manufacturing facilities.

As a result of these activities, we will need to generate significant revenue in order to achieve profitability and may never become profitable. We must also maintain specified cash reserves in connection with our loan and security agreement which may limit our investment opportunities. Failure to maintain these reserves could result in our lender foreclosing against our assets or imposing significant restrictions on our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We believe that the net proceeds from this offering, the Series C Financing and the Bridge Loan, together with our future revenues, cash and cash equivalent balances and interest we earn on these balances will be sufficient to meet our anticipated cash requirements through at least the next 12 months. Without completion of this offering, or the raise of capital through an alternate funding source, we would curtail certain operational activities in order to reduce costs. These activities may include clinical and regulatory trials, sales and marketing activities, and international operations. In the event that we are required to raise additional capital, we cannot provide any assurance that we will secure any commitments for new financing on acceptable terms, if at all.

**Because all of our products are based on our Microcyn platform technology, we will need to generate sufficient revenues from the sale of Microcyn to execute our business plan.**

All of our products are based on our Microcyn platform technology, and we do not have any non-Microcyn product candidates that will generate revenues in the foreseeable future. Accordingly, we expect to derive substantially all of our future revenues from sales of our current Microcyn products. We have only been selling our products since July 2004, and substantially all of our historical product revenues have been from

sales of Microcyn in Mexico. Although we began selling in Europe in October 2004, in the United States in June 2005, and in India in July 2006, our product revenues outside of Mexico were not significant prior to our last fiscal quarter. For example, product revenues from countries outside of Mexico were just 9.1% of our product revenues for the year ended March 31, 2006, but 45.5% of our product revenues for the six months ended September 30, 2006 were from countries outside Mexico. Microcyn has not been adopted as a standard of care for wound treatment in any country and may not gain acceptance among physicians, nurses, patients, third-party payors and the medical community. Existing protocols for wound care are well established within the medical community and tend to vary geographically, and healthcare providers may be reluctant to alter their protocols to include the use of Microcyn. If Microcyn does not achieve an adequate level of acceptance, we will not generate sufficient revenues to become profitable.

**One of our non-commercialized products, when recently tested by the U.S. Environmental Protection Agency, or EPA, did not meet certain efficacy standards based on an EPA test protocol that used parameters that differed from those parameters previously used by us when we originally registered this product as an EPA registered disinfectant product. As a result, we have discontinued sampling, promotion and all distribution of this non-commercialized product.**

In October 2004, after EPA review of our registration filing, including the results of disinfectant efficacy testing conducted by an independent laboratory retained by us, we obtained EPA authorization, or registration, for the distribution and sale of our Microcyn-based product, which we call Cidalcyn, as a hospital grade disinfectant. Although we have not commercialized Cidalcyn, we previously provided samples to potential marketing partners and other entities for product evaluation. Subsequently, in July 2006, we were informed by the EPA that in more recent tests conducted by the EPA, Cidalcyn did not meet efficacy standards when tested against three specified pathogens (*Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Mycobacterium tuberculosis*) when used according to label directions. These new results prevent us from marketing Cidalcyn as a hospital grade disinfectant. We believe the EPA test protocol utilizes a bacterial culture to challenge a disinfectant in a test method which does not replicate a human wound environment and which is not used to evaluate the safety or efficacy of wound care products by the FDA or CE Mark. We believe the EPA test made use of a bacterial culture which contained a significantly higher concentration of pathogens than the culture used in the independent test, the results of which we submitted to the EPA for registration purposes. This increased concentration of bacteria might have overwhelmed our Cidalcyn product. Subsequent testing we have conducted appears to have confirmed the EPA's results against two of the three microorganisms. Based on the EPA's own testing, the EPA strongly recommended that we immediately recall all Cidalcyn distributed on and after September 28, 2005. Accordingly, we promptly and voluntarily ceased all distribution of Cidalcyn to end users, and we are not providing the product to distributors or retailers for re-distribution to third parties or end users; we have ceased promoting Cidalcyn; and we have contacted the entities and small number of individuals in the United States who are not our employees, to whom the Cidalcyn product had been provided for evaluation purposes during the one-year period (the product's shelf-life) prior to our receipt of the EPA's recent notification to ensure they have been informed not to use any remaining quantities they might have in their possession. In August 2006, we received a "show cause" letter from the EPA stating that it was prepared to file a civil administrative complaint against us for violation of federal pesticide legislation in connection with the sale or distribution of a pesticide that did not meet the label's efficacy claims, and it gave us the opportunity to advise the EPA of any factors we believe the EPA should consider before issuing a civil complaint. We have engaged in discussions with the EPA since that time and are working cooperatively with the EPA to resolve this matter. We believe that any civil penalties that might be assessed against us in connection with such a civil complaint would not be in a material amount. Unless and until we provide new information to support the original label claims of Cidalcyn to the EPA, there will not be any sales or other distributions of the product in the United States as a hospital grade disinfectant.

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

We have obtained three 510(k) clearances in the United States that permit us to sell Microcyn as a medical device to clean, moisten and debride wounds. However, we do not have the necessary regulatory approvals to market Microcyn in the United States as a drug, which we will need to obtain in order to execute

our business plan. 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, or NDA, to the FDA and obtain FDA approval. In July 2006, we completed a controlled clinical trial for pre-operative skin preparation. After completion of this trial, the FDA advised us that it is considering adopting new heightened performance requirements for evaluating efficacy of products designed to be used in pre-operative skin preparation such as ours. In discussions with the FDA, the FDA has not provided us with the definitive timing for, or parameters of, any such requirements, and has informally stated that it is uncertain during what time frame it will be able to do so. We plan to continue our discussions with the FDA regarding the possible timing and parameters of any new guidelines for evaluating efficacy for pre-operative skin preparations. Depending on the ultimate position of the FDA regarding performance criteria for pre-operative skin preparations, we may reassess our priorities, clinical timelines and schedules for pursuing a pre-operative skin preparation indication or may decide not to pursue this indication. We also intend to seek FDA approval for the use of Microcyn to treat infections in wounds.

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. We do not know whether we will obtain favorable results in our preclinical and clinical studies or whether we will obtain the necessary regulatory approvals to market Microcyn as a drug in the United States. We anticipate that obtaining approval for the use of Microcyn to treat infections in wounds in the United States will take several years. 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 products.

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

We expect capital outlays and operating expenditures to increase over the next several years as we work to commercialize our products and expand our infrastructure and research and development activities. We have entered into debt financing arrangements which are secured by all of our assets. We may need to raise additional capital to, among other things:

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

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

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

- competing technological and market developments; and
- changes in regulatory policies or laws that affect our operations.

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

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

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

- FDA requirements for approval, including requirements for testing efficacy or safety, may change;
- the FDA or other regulatory authorities do not approve a clinical trial protocol;
- patients do not enroll 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 do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or the third party organizations do not perform data collection and analysis in a timely or accurate manner;
- governmental regulations or administrative actions are changed; and
- insufficient funds to continue our clinical trials.

We do not know whether our existing or any future clinical trials will demonstrate safety and efficacy sufficiently to result in additional FDA approvals. While a number of physicians have conducted clinical studies assessing the safety and efficacy of Microcyn for various indications, the data from these studies is not sufficient to support approval of Microcyn as a drug in the United States. We will be required to conduct additional clinical trials prior to seeking approval of Microcyn for additional indications. Our failure to adequately demonstrate the safety and efficacy of our product candidates to the satisfaction of the FDA will prevent our receipt of FDA approval for additional indications and, ultimately, impact commercialization of our products in the United States. If we experience significant delays or adverse results in clinical trials, our financial results and the commercial prospects for products based on Microcyn will be harmed, our costs would increase and our ability to generate revenue would be delayed.



**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.**

Developing, testing, manufacturing, marketing and selling of medical technology products are subject to extensive regulation by numerous governmental authorities in the United States and other countries. The process of obtaining regulatory clearance and approval of medical technology products is costly and time consuming. Even though the underlying product formulation may be the same or similar, our products are subject to different regulations and approval processes depending upon their intended use. In the United States, use of Microcyn to cleanse and debride a wound comes within the medical device regulation framework, while use of Microcyn to treat infections in wounds will require us to seek FDA approval of Microcyn as a drug in the United States.

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

We do not know whether our products based on Microcyn will receive approval from the FDA as a drug. The data from clinical studies of Microcyn conducted by physicians to date will not satisfy the FDA's regulatory criteria for approval of an NDA. In order for us to seek approval for the use of Microcyn as a drug in the treatment of infections in wounds, we will be required to conduct additional preclinical and clinical trials and submit applications for approval to the FDA. For example, we are currently planning to conduct a pilot study of Microcyn for the treatment of wound infections, and we will need to conduct additional non-clinical and well-controlled clinical trials in order to generate data to support FDA approval of Microcyn for this indication.

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 or clinical testing that could adversely affect the time to market and sale of products as drugs. If we do not obtain the requisite regulatory clearances and approvals, we will be unable to commercialize our products as drugs or devices and may never recover any of the substantial costs we have invested in the development of Microcyn.

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

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

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

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

- the effectiveness of our sales and marketing efforts.

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

**We may incur significant liabilities in connection with our relationship with a former distributor in Mexico, and our results of operations may be negatively affected by the termination of this relationship.**

On June 16, 2005, we entered into a series of agreements with Quimica Pasteur, or QP, a Mexico-based distributor of pharmaceutical products to hospitals and health care entities owned or operated by the Mexican Ministry of Health, or MOH. These agreements provided, among other things, for QP to act as our exclusive distributor of Microcyn to the MOH for a period of three years. We were granted an option to acquire all except a minority share of the equity of QP directly from its principals. In addition, two of our employees were appointed as officers of QP, which resulted in the establishment of financial control of QP by our company under applicable accounting literature.

As a result of our agreements, we were required to consolidate QP's operations with our financial results. In connection with our audit of QP's financial statements in late 2005, we were made aware of a number of facts that suggested that QP or its principals may have engaged in some form of tax avoidance practice prior to the execution of the agreements between our company and QP. We did not discover these facts prior to our execution of these agreements or for several months thereafter. Our prior independent auditors informed us that we did not have effective anti-fraud programs designed to detect the type of activities in which QP's principals engaged or the personnel to effectively evaluate and determine the appropriate accounting for non-routine or complex accounting transactions. Our audit committee engaged an outside law firm to conduct an investigation whose findings implicated QP's principals in a systemic tax avoidance practice prior to June 16, 2005. We estimate that QP's liability for taxes, interest and penalties related to these practices could amount to \$7 million or more. Based on the results of this investigation, we terminated our agreements with QP effective March 26, 2006.

Although we do not believe that we are responsible for any tax avoidance practices of QP's principals prior to June 16, 2005, the Mexican taxing authority could make a claim against us or our Mexican subsidiary. We have been informed by counsel in Mexico that the statute of limitations, including for actions for fraud, is five years from the date of our last tax return, which was March 31, 2006. QP had a well-established relationship with the MOH. We lost the benefit of this relationship when we terminated our agreements with QP. Although we currently market Microcyn in Mexico through a dedicated contract sales force and continue to market Microcyn to the MOH, which has recently increased its purchases of Microcyn, we do not know whether our future sales in Mexico will decline as a result of the termination of our relationship with QP.

**Our former independent registered public accounting firm has notified us of a number of reportable events constituting a material weakness over financial reporting which, if not successfully remedied, may among other things, impact our ability to develop reliable financial statements and comply with our reporting obligations as a public company.**

In August 2006, our former independent registered public accounting firm, PricewaterhouseCoopers LLP, or PWC, notified us of a number of deficiencies it believes comprise reportable events that may, among other things, impact our ability to develop reliable financial statements. In its letter, PWC stated that it had advised our audit committee of the following:

- the absence of financial accounting personnel with sufficient skills and experience to effectively evaluate and determine the appropriate accounting for non-routine and/or complex accounting transactions consistent with accounting principles generally accepted in the United States, which resulted in a number of material audit adjustments to the financial statements during the course of audit procedures;
- the failure to maintain effective controls to ensure the identification of accounting issues related to and the proper accounting for stock options with the right of rescission that were granted under certain stock option plans that required registration or qualification under federal and state securities laws

primarily due to insufficient oversight and lack of personnel in the accounting and finance organization with the appropriate level of accounting knowledge, experience and training;

- the failure to maintain an effective anti-fraud program designed to detect and prevent fraudulent activities in QP;
- the need to expand significantly the scope of the audit of QP to assess the impact of identified fraudulent activities on our financial statements, in which regard PWC advised our audit committee that the results of the fraud investigation may cause PWC to be unwilling to be associated with our financial statements;
- the “tone at the top” set by our senior management does not appear to encourage an attitude within our company that controls are important or that established controls cannot be circumvented;
- we did not have the appropriate financial management and reporting infrastructure in place to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act of 2002, and that we will be unable to report our financial results accurately or in a timely manner; and
- significant control deficiencies, when considered in the aggregate, constituted a material weakness over financial reporting.

We have filed a copy of the letter from PWC as an exhibit to the registration statement of which this prospectus forms a part. For additional information, please see “Change in Independent Registered Public Accounting Firm.”

**We have agreed to change the brand name of our product in Mexico, which may result in the loss of any brand recognition that we have established with users of our products.**

In accordance with the settlement of a trademark infringement lawsuit filed against us in Mexico, we have agreed to stop using the name Microcyn60 in Mexico by September 2007. In addition, in May 2006, a complaint was filed against us for trademark confusion in connection with the same tradename, and we are in settlement negotiations concerning such claim. We have marketed our products in Mexico under the brand name of Microcyn60 since 2004. In the six months ended September 30, 2006, 54.5% of our product revenues were derived from Mexico. As a result of our agreement to change our product name, we may lose the benefit of the brand name recognition we have generated in the region and our product sales in Mexico could decline. In locations where we have distributed our products, we believe that the brand names of those products have developed name recognition among consumers who purchase them. Any change to the brand name of our other products may cause us to lose such name recognition, which may lead to confusion in the marketplace and a decline in sales of our products.

**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 as 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.

**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 currently sell Microcyn in the United States through a network of one national and five regional distributors and our medical and clinical employees. We plan to sell directly into the United States markets and we plan to expand our domestic sales force. 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 distributors for sales could limit or prevent us from selling our products and from realizing long-term revenue growth.**

We currently depend on distributors to sell Microcyn in the United States, Europe and other countries and intend to continue to sell our products primarily through distributors in Europe and the United States for the foreseeable future. In addition, if we are unable to expand our direct sales force, we will continue to rely on distributors to sell Microcyn. Our existing distribution agreements are generally short-term in duration, and we may need to pursue alternate distributors if the other parties to these agreements terminate or elect not to renew their agreements. If we are unable to retain our current distributors for any reason, we must replace them with alternate 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.

**We depend on a contract sales force to sell our products in Mexico.**

We currently depend on a contract sales force to sell Microcyn in Mexico. Our existing agreement is short-term in duration and can be terminated by either party upon 30 days written notice. If we are unable to retain our current agreement for any reason, we may need to build our own internal sales force or find an alternate source for contract sales people. We may be unable to find an alternate source, or the alternate source's sales force may not generate sufficient revenue. If our current or future contract sales force does not perform adequately, we may not realize long-term revenue growth in Mexico.

**We intend to license or collaborate with third parties in various potential markets, and events involving these strategic partners or any future collaborations 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 a direct sales force in each market. To penetrate our target markets, we may need to enter into additional collaborative agreements to assist in the development and commercialization of future 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. 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 a 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 fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.**

Regulatory approvals or clearances that we currently have and that we may receive in the future are subject to limitations on the indicated uses for which the products may be marketed, and any future approvals could contain requirements for potentially costly post-marketing follow-up studies. If the FDA determines that our promotional materials or activities constitute promotion of an unapproved use or we otherwise fail to comply with FDA regulations, we may be subject to regulatory enforcement actions, including a warning letter, injunction, seizure, civil fine or criminal penalties. In addition, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record-keeping for approved products are subject to extensive regulation. Our manufacturing facilities, processes and specifications are subject to periodic inspection by the FDA, European and other regulatory authorities and from time to time, we may receive notices of deficiencies from these agencies as a result of such inspections. Our failure to continue to meet regulatory standards or to remedy any deficiencies could result in restrictions being imposed on products or manufacturing processes, fines, suspension or loss of regulatory approvals or clearances, product recalls, termination of distribution or 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, 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 EPA, European notified bodies, Mexican regulatory agencies and other foreign regulatory bodies, which may result in lot failures or product recalls. In August 2006, we received a “show cause” letter from the EPA, which stated that, in tests conducted by the EPA, Cidalcyn was found to be ineffective in killing specified pathogens when used according to label directions. We have begun gathering records for review to determine if there might have been any problems in production of the lot tested by the EPA. We have also quarantined all remaining quantities of the production lot in question. 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 our clinical test 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 under a loan and security agreement. The security interest extends to our intellectual property in the event we fail to maintain specified cash reserves under the loan. If we do not protect our rights adequately, third parties could use our technology, and our ability to compete in the market would be reduced.

Although we have filed U.S. and foreign patent applications related to our Microcyn based products, the manufacturing technology for making the products, and their uses, only one patent has 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 issue 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.

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, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States. For example, one of our former contract partners, Nofil Corporation, whom we relied upon to manufacture our proprietary machines had access to our proprietary information and we believe undertook the development and manufacture of the machines to be sold to third parties in violation of our agreement with such company. We have brought a claim against Nofil Corporation in the U.S. District Court for the Northern District of California. We believe that a former officer of our Mexico subsidiary collaborated in these acts, misappropriated our trade secrets, and is currently selling products in Mexico that are competitive with our products. In addition, we believe that, through the licensor of the patents that we in-license and who has also assigned patents to us, a company in Japan obtained one of our patent applications, translated it into Hangul and filed it under such company's and the licensor's name in South Korea. These and any other leak of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets.

**We are in a dispute with the Japanese entity that licenses to us certain rights under Japanese patents, which could result in our losing such rights and may have a material adverse impact on our business opportunities in Japan.**

In March 2003, we obtained an exclusive license to six issued Japanese patents and five Japanese published pending patent applications owned by Coherent Technologies. The issued Japanese patents and pending Japanese patent applications relate to an earlier generation of super-oxidized water product with an acidic pH and not the current commercialized Microcyn. The patents that cover the method and apparatus for the production of the earlier generation of super-oxidized water will expire between 2011 and 2014. In June 2006, we received written notice from Coherent Technologies advising us that the patent license was terminated, citing various reasons with which we disagree. Since that time we have engaged Coherent Technologies in discussions concerning the license agreement and our continued business relationship. Although we do not believe Coherent Technologies has grounds to terminate the license, we may have to take legal action to preserve our rights under the license and to enjoin Coherent Technologies from breaching its terms. We do not know whether we would prevail in any such action, which would be costly and time consuming, and we could lose our rights under the license, which could have a material adverse impact on our business opportunities in Japan. In addition, we could have to defend ourselves against infringement claims from Coherent Technologies in Japan based on their position on termination of the license.

**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.**

From time to time, 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. Some claims received from third parties may lead to litigation. We cannot assure you that we will prevail in these actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or the validity of our patents, will not be asserted or prosecuted against us. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. 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 include the non-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.

In September 2005, a complaint was filed against us in Mexico claiming trademark infringement with respect to our Microcyn60 mark. To settle this claim we have agreed to cease marketing our product in Mexico under the name Microcyn60 by September 2007. A second unrelated claim was filed against us in Mexico in May 2006, claiming trademark infringement with respect to our Microcyn60 mark in Mexico. We are in discussions with the claimant to settle the matter.

In addition to the infringement claims in Mexico, we are currently involved in several pending trademark opposition proceedings in connection with our applications to register the marks *Microcyn*, *Oculus Microcyn* and *Dermacyn* in the European Union, Argentina, Guatemala, Honduras, Nicaragua and Paraguay. If we are unable to settle these disputes or prevail in these opposition proceedings, we will not be able to obtain registrations for the *Microcyn*, *Oculus Microcyn* and *Dermacyn* marks in those countries, and that may impair

our ability to enforce our trademark rights against infringers in those countries. Although no such legal proceedings have been brought or threats of such legal proceedings have been made, we cannot rule out the possibility that any of these opposing parties will also file a trademark infringement lawsuit seeking to prevent our use and seek monetary damages based on our use of the *Microcyn*, *Oculus Microcyn* and *Dermacyn* marks in the European Union, Argentina, Guatemala, Honduras, Nicaragua and Paraguay.

We have also entered into agreements with third parties to settle trademark opposition proceedings in which we have agreed to certain restrictions on our use and registration of certain marks. In March 2006, we entered into an agreement with an opposing party that places restrictions on the manner in which we can use and register our *Microcyn* and *Microcyn60* marks in countries where the opposing party has superior rights, including in Europe and Singapore. These restrictions include always using *Microcyn* along with the word “technology” and another distinctive trademark such as *Cidalcyn*, *Dermacyn* and *Vetericyn*. In addition, we have entered into an agreement with an opposing party in which we agreed to limit our use and registration of the *Microcyn* mark in Uruguay to disinfectant, antiseptic and sterilizing agents. Moreover, we have entered into an agreement with an opposing party in Europe in which we agreed to specifically exclude ophthalmologic products for our *Oculus Microcyn* application in the European Union.

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

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

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

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

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

Some of our distribution agreements contain commitments to indemnify our distributors against liability arising from infringement of third party intellectual property such as patents. We may be required to indemnify our customers for claims made against them or 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. For the fiscal years ended March 31, 2004, 2005 and 2006 and the six months ended September 30, 2006, approximately 10%, 35%, 75% and 81%, respectively, of our total revenue was generated from sales outside of the United States. Our business is highly regulated for the use, marketing and manufacturing of our Microcyn 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 expand internationally to respond to customer requirements and market opportunities. We currently have international manufacturing facilities in Mexico and The Netherlands. Establishing operations in any foreign country or region presents risks such as those described above as well as risks specific to the particular country or region. In addition, until a payment history is established over time with customers in a new geography or region, the likelihood of collecting receivables generated by such operations could be less than our expectations. As a result, there is a greater risk that reserves set with respect to the collection of such receivables may be inadequate. If our international expansion efforts 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. We incurred foreign currency exchange losses of \$4,000, \$283,000 and \$119,000 for the fiscal years ended March 31, 2004 and 2006 and the six months ended September 30, 2006, respectively, and a gain of \$134,000 for the fiscal year ended March 31, 2005. The functional currency of our Mexican subsidiary is the Mexican Peso, and the functional currency of our subsidiary in The Netherlands is the Euro. For the preparation of our consolidated financial statements, the financial results of our foreign subsidiaries are translated into U.S. dollars on average exchange rates during the applicable period. If the U.S. dollar appreciates against the Mexican Peso or the Euro, as applicable, the revenues we recognize from sales by our subsidiaries will be adversely impacted. Foreign exchange gains or losses as a result of exchange rate fluctuations in any given period could harm our operating results and negatively impact our revenues. Additionally, if the effective price of our products were to increase as a result of fluctuations in foreign

currency exchange rates, demand for our products could decline and adversely affect our results of operations and financial condition.

**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 Akihisa Akao, a member of our Board of Directors and one of our consultants. The efforts of these people will be critical to us as we continue to develop our products and attempt to commercialize products in the chronic and acute wound care market. If we were to lose one or more of these individuals, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

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

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

**We may be unable to manage our future growth effectively, which would make it difficult to execute our business strategy.**

We may experience periods of rapid growth as we expand our business, which will likely place a significant strain on our limited personnel and other resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our commercialization goals.

Furthermore, we conduct business in a number of geographic regions and are seeking to expand to other regions. We have not established a physical presence in many of the international regions in which we conduct or plan to conduct business, but rather we manage our business from our headquarters in Northern California. As a result, we conduct business at all times of the day and night with limited personnel. If we fail to appropriately target and increase our presence in these geographic regions, we may not be able to effectively market and sell our Microcyn products in these locations or we may not meet our customers' needs in a timely manner, which could negatively affect our operating results.

Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place strain on our administrative and operational infrastructure, including sales and marketing and clinical and regulatory personnel. Our ability to manage our operations and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy.

**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.**

The wound care industry is highly competitive and subject to rapid technological change. 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 that while we may initially seek to conduct initial clinical trials on our drug candidates, we may need to seek collaborators for a number of our potential products because of the expense, effort and expertise required to continue additional clinical trials and further develop those potential products candidates. Because collaboration arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. 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 of 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.

**We may acquire other businesses or form joint ventures that could harm our operating results, dilute your ownership of us, increase our debt or cause us to incur significant expense.**

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, as well as technology licensing arrangements. We also intend to pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings or distribution. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of collaborations, strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your ownership interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

**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, or 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, or the OIG, 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.

We have agreements to pay compensation to our advisory board members and physicians who conduct clinical trials or provide other services for us. The agreements may be subject to challenge to the extent they do not fall within relevant safe harbors under federal and similar state anti-kickback laws. If our past or present operations, including, but not limited to, our consulting arrangements with our advisory board members or physicians conducting clinical trials on our behalf, or our promotional or discount programs, are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from government healthcare program participation, including Medicare and Medicaid.

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 have increased significantly in recent years and have 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 whom 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. At the present time, we have one Microcyn-based drug candidate in clinical trials. We also have a non-Microcyn-based compound in the research and development phase. We believe this compound has potential applications in oncology. Discovery and development of potential drug candidates are expensive and time-consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. If our efforts do not lead to the discovery of a suitable drug candidate, we may be unable to grow our clinical pipeline or we may be unable to enter into agreements with collaborators who are willing to develop our drug candidates.

**We must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements, which will increase our costs and require additional management resources.**

As a public reporting company, we will be required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, or the Commission, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and other requirements will increase our costs and require additional management resources. In a letter following their dismissal, our prior independent auditors informed us that we did not have the appropriate financial management and reporting structure in place to meet the demands of a public company and that our accounting and financial personnel lacked the appropriate level of accounting knowledge, experience and training. We recently have been upgrading our finance and accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization, enter into complex business transactions and take actions designed to satisfy new reporting requirements. Specifically, our experience with QP indicated that we need to better plan for complex transactions and the application of complex accounting principles relating to those transactions. If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting, if we fail to maintain or implement adequate controls, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of our first Annual Report on Form 10-K for which compliance is required and thereafter, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Securities Exchange Act of 1934. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

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

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

## Risks Related to Our Common Stock

### **Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.**

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock immediately after this offering. Therefore, if you purchase our common stock in this offering, you will incur an immediate dilution of \$9.68 in net tangible book value per share from the price you paid, based on the assumed initial public offering price of \$13.00 per share. The exercise of outstanding options will result in further dilution of your investment. For additional information, please see “Dilution.”

### **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 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 products in large clinical trials conducted by others;
- actual and anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- issues in manufacturing our product candidates or products;
- new or less expensive products and services or new technology introduced or offered by our competitors or us;
- the development and commercialization of product enhancements;
- changes in the regulatory environment;
- delays in establishing new strategic relationships;
- 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 Global 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 initial offering price.**

Prior to this offering, there has not been a public market for our common stock. Although we have applied to have our common stock listed on the Nasdaq Global Market, an active and liquid trading market for our common stock may not develop or be sustained following this offering. You may not be able to sell your shares quickly or at or above the initial offering price if trading in our stock is not active. The initial public offering price may not be indicative of prices that will prevail in the trading market. See “Underwriting” for more information regarding the factors that will be considered in determining the initial public offering price.

**Future sales of shares by our stockholders could cause the market price of our common stock to drop significantly, even if our business is doing well.**

After this offering, we will have 11,476,132 outstanding shares of common stock based on the number of shares outstanding at October 31, 2006. This includes the 3,076,923 shares we are selling in this offering, which (other than shares purchased by our affiliates) may be resold in the public market immediately. The remaining shares will become available for resale in the public market as shown in the chart below.

**Number of Restricted Shares and % of Total Outstanding Following Offering**

	<b>Date Available for Sale Into Public Market</b>
229,025 shares, or 2%	Immediately
7,976,604 shares, or 70%	Immediately upon expiration of the 180-day lock up period
193,580 shares, or 2%	At some point after the expiration of the 180-day lock up period

**We do not expect to pay dividends in the foreseeable future. As a result, you must rely on stock appreciation, if any, for a return on your investment.**

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, you will have to rely on appreciation in the price of our common stock, if any, to earn a return on your investment in our common stock. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends.

**We may allocate net proceeds from this offering in ways with which you may not agree.**

Our management will have broad discretion in using the proceeds from this offering and may use the proceeds in ways with which you may disagree. Because we are not required to allocate the net proceeds from this offering to any specific investment or transaction, you cannot determine at this time the value or propriety of our application of the proceeds. Moreover, you will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use our proceeds. We may use the proceeds for corporate purposes that do not immediately enhance our prospects for the future or increase the value of your investment. As a result, you and other stockholders may not agree with our decisions.

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

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

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

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- 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 an annual meeting of stockholders.

These provisions might discourage, delay or prevent a change of control or 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.

**Purchasers in this offering may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock.**

Our charter documents allow us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 5,000,000 shares of 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 preferred stock, these securities may provide for rights, preferences or privileges senior to those of holders of our common stock.



## INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties, such as statements about our plans, objectives, expectations, assumptions, and future events. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “estimate,” “plan,” “project,” “continue,” “ongoing,” “potential,” “expect,” “predict,” “believe,” “intend,” “may,” “will,” “should,” “could,” “would,” and similar expressions. These statements involve estimates, assumptions, known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from any future results, performances, or achievements expressed or implied by the forward-looking statements. Consequently, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading “Risk Factors” above.

Forward-looking statements include, but are not limited to, statements about:

- the progress and timing of our development programs and regulatory approvals for our products;
- the benefits and effectiveness of our products;
- the progress and timing of clinical trials;
- our expectations and capabilities relating to the sales and marketing of our current products and our product candidates;
- our expectations related to the use of our proceeds from this offering;
- our ability to manufacture sufficient amounts of our product candidates for clinical trials and products for commercialization activities;
- the content and timing of submissions to, and decisions made by, the FDA and other regulatory agencies, including demonstrating to the satisfaction of the FDA the safety and efficacy of our products;
- the rate and causes of infection;
- the accuracy of our estimates of the size and characteristics of the markets which may be addressed by our products;
- the timing of commercializing our products;
- our ability to protect our intellectual property and operate our business without infringing on the intellectual property of others;
- our relationship with, and consolidation for accounting purposes of, Quimica Pasteur;
- our ability to compete with other companies that are developing or selling products that are competitive with our products;
- the ability of our products to become the standard of care for controlling infection in chronic and acute wounds;
- our estimates regarding future operating performance, earnings and capital requirements;
- our expectations relating to the concentration of our revenue from international sales; and
- the impact of the Sarbanes-Oxley Act of 2002 and any future changes in accounting regulations or practices in general with respect to public companies.

The forward-looking statements speak only as of the date on which they are made, and, except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

This prospectus contains market data that we obtained from industry sources. These sources do not guarantee the accuracy or completeness of the information. Although we believe that the industry sources are reliable, we have not independently verified the information.

## USE OF PROCEEDS

We expect to receive net proceeds of approximately \$36.8 million from this offering, based on an assumed initial public offering price of \$13.00 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, our estimated net proceeds will be approximately \$42.4 million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A \$1.00 increase or decrease in the assumed initial public offering price of \$13.00 per share (the midpoint of the range on the cover page of this prospectus) would increase or decrease, as applicable, the net proceeds to us by approximately \$2.8 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and our estimated offering expenses.

We currently intend to use the proceeds of this offering as follows:

- approximately \$14.3 million to expand our sales and marketing capabilities, including the expansion of our direct sales force in Europe and the United States;
- approximately \$13.0 million to fund clinical trials and related research;
- repayment of the principal and interest of our Bridge Loan; and
- the remaining proceeds for general corporate purposes, including working capital.

While we have estimated the particular uses for the net proceeds to be received upon the completion of this offering, the actual amounts and timing of any expenditures will depend upon the rate of growth, if any, of our business, the amount of cash generated by our operations, status of our research and development efforts, competitive and technological developments and the amount of proceeds actually raised in this offering. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products, although we have no agreements with respect to any such transactions as of the date of this prospectus. Accordingly, our management will have significant flexibility in applying the net proceeds from this offering. Pending these uses described above, we intend to invest the net proceeds in short-term, investment grade securities.

We believe that the net proceeds from this offering, the Series C Financing and the Bridge Loan, together with our future revenues, cash and cash equivalent balances and interest we earn on these balances will be sufficient to meet our anticipated cash requirements through at least the next 12 months.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. Upon the completion of this offering, we anticipate that any earnings will be retained for development and expansion of our business, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Our board of directors has sole discretion to pay cash dividends based on our financial condition, results of operations, capital requirements, contractual obligations and other relevant factors. In the future, we may also obtain loans or other credit facilities that may restrict our ability to declare or pay dividends.

**CAPITALIZATION**

The following table describes our capitalization as of September 30, 2006:

- on an actual basis;
- on a pro forma, as adjusted, basis to give effect to:
  - the conversion of all outstanding shares of our convertible preferred stock into 4,176,478 shares of our common stock upon closing of this offering;
  - the sale of 3,076,923 shares of common stock in this offering at an assumed initial public offering price of \$13.00 per share, which is the midpoint of our expected offering range on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us; and
  - the Bridge Loan net of fees resulting in net proceeds of \$3,950,000.

You should read this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

	<b>As of September 30, 2006</b>	
	<b>Actual</b>	<b>Pro Forma As Adjusted (unaudited)</b>
	<b>(In thousands, except share and per share data)</b>	
Short-term debt	\$ 1,776	\$ 5,776
Long-term debt, less current portion	\$ 2,852	\$ 2,852
Stockholders’ equity (deficit):		
Convertible preferred stock, no par value; 7,500,000 shares authorized, 4,067,992 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma, as adjusted	51,760	—
Common Stock, no par value; 25,000,000 shares authorized, 4,222,731 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma, as adjusted	3,399	—
Preferred stock, \$0.0001 par value; no shares authorized, issued and outstanding, actual; 5,000,000 shares authorized, no shares issued and outstanding, pro forma, as adjusted	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized, 11,476,132 shares issued and outstanding, pro forma, as adjusted	—	1
Additional paid-in capital <sup>(1)</sup>	5,163	97,473
Accumulated other comprehensive gain (loss)	(140)	(140)
Accumulated deficit	(59,208)	(59,258)
Total stockholders’ equity <sup>(1)</sup>	974	38,076
Total capitalization <sup>(1)</sup>	<u>\$ 5,602</u>	<u>\$ 46,704</u>

(1) A \$1.00 increase or decrease in the assumed initial public offering price of \$13.00 per share (the midpoint of our expected offering range on the cover page of this prospectus) would increase or decrease, as applicable, this amount on a pro forma, as adjusted, basis by approximately \$2,831, assuming the number of

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shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and our estimated offering expenses.

The information set forth in the table excludes as of September 30, 2006:

- 2,260,263 shares of our common stock issuable upon the exercise of outstanding stock options, options to be granted in connection with this offering and options to be granted to a new board member, at a weighted average exercise price of \$4.60 per share;
- 1,098,301 shares of our common stock issuable upon the exercise of outstanding warrants, at a weighted average exercise price of \$11.15 per share;
- 215,385 shares of our common stock issuable upon the exercise of warrants to be issued to the underwriters in connection with this offering at an exercise price equal to 165% of the offering price; and
- up to 1,250,000 additional shares of our common stock reserved for future grant under our 2006 Stock Incentive Plan.

## DILUTION

Our pro forma net tangible book value as of September 30, 2006 was approximately \$2.7 million, or \$0.32 per share of common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets less total liabilities, including the close of the Bridge Loan net of fees resulting in net proceeds of \$3,950,000, divided by the number of shares of common stock which includes 4,222,731 shares of common stock outstanding as of September 30, 2006 and the conversion of all shares of our convertible preferred stock into 4,176,478 shares of our common stock upon the closing of this offering. Dilution of pro forma net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after completion of this offering. After giving effect to the sale of 3,076,923 shares of common stock at an assumed initial public offering price of \$13.00 per share, which is the midpoint of our expected offering range, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2006 would have been \$38,000,000, or \$3.32 per share of common stock. This represents an immediate increase in net tangible book value of \$3.00 per share of common stock to existing common stockholders and an immediate dilution in pro forma as adjusted net tangible book value of \$9.68 per share to new investors purchasing shares of common stock in this offering. The following table illustrates this per share dilution:

Assumed offering price per share of common stock	\$ 13.00
Pro forma net tangible book value per share at September 30, 2006	\$ 0.32
Increase in pro forma net tangible book value per share attributable to this offering	<u>\$ 3.00</u>
Pro forma as adjusted net tangible book value per share after this offering	<u>\$ 3.32</u>
Dilution in pro forma net tangible book value per share to investors in this offering	<u>\$ 9.68</u>

A \$1.00 increase or decrease in the assumed initial public offering price of \$13.00 per share (the midpoint of our expected offering range on the cover of this prospectus) would increase or decrease, as applicable, our pro forma as adjusted net tangible book value by \$2.8 million, pro forma as adjusted net tangible book value per share by \$0.25 per share and the dilution to investors in this offering by \$0.75 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of September 30, 2006, on the pro forma basis described above, the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid to us by existing and new investors purchasing shares of common stock in this offering assuming an initial public offering price of \$13.00 per share, which is the midpoint of our expected offering range, before deducting the estimated underwriting discounts and commissions and estimated offering expenses.

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders	8,399,209	73%	\$ 62,384,772	61%	\$ 7.43
New investors	3,076,923	27%	40,000,000	39%	13.00
<b>Total</b>	<u>11,476,132</u>	<u>100.0%</u>	<u>102,384,772</u>	<u>100.0%</u>	

A \$1.00 increase or decrease in the assumed initial public offering price of \$13.00 per share (the midpoint of our expected offering range on the cover of this prospectus) would increase or decrease, as applicable, total consideration paid by new investors and total consideration paid by all stockholders by \$2.8 million, assuming the number of shares offered by us, as set forth on the cover of this prospectus, remains the same.

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If the underwriters exercise their over-allotment option in full, our existing stockholders would own 70% and our new investors would own 30% of the total number of shares of our common stock outstanding after this offering.

The number of shares of our common stock referred to above that will be outstanding immediately after completion of this offering is based on 4,222,731 shares of our common stock outstanding as of September 30, 2006 and reflects the automatic conversion of our preferred stock into 4,176,478 shares of common stock and excludes:

- 2,260,263 shares of our common stock issuable upon the exercise of outstanding stock options and options to be granted in connection with this offering, and options to be granted to a new board member, at a weighted-average exercise price of \$4.60 per share;
- 1,098,301 shares of our common stock issuable upon the exercise of outstanding warrants, at a weighted average exercise price of \$10.18 per share;
- 215,385 shares of our common stock issuable upon the exercise of warrants to be issued to the underwriters in connection with this offering at an exercise price equal to 165% of the offering price; and
- up to 1,250,000 additional shares of our common stock reserved for issuance under our 2006 Stock Incentive Plan.

If all of our outstanding options and warrants as of September 30, 2006 were exercised, our pro forma, as adjusted, net tangible book value per share after this offering would be \$4.29 per share, representing an increase attributable to new investors of \$1.84 per share, and there would be an immediate dilution of \$8.71 per share to new investors.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

**SELECTED CONSOLIDATED FINANCIAL DATA**

You should read the following selected consolidated financial data together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes included elsewhere in this prospectus. The selected consolidated statements of operations data for the six months ended September 30, 2005 and 2006 and the selected consolidated balance sheet data as of September 30, 2006 are derived from our unaudited consolidated financial statements and related notes included elsewhere in this prospectus. The selected consolidated statements of operations data for each of the years ended March 31, 2004, 2005 and 2006 and the selected consolidated balance sheet data as of March 31, 2005 and 2006 have been derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The selected consolidated statements of operations data for the years ended March 31, 2002 and 2003 and the selected consolidated balance sheet data as of March 31, 2002, 2003 and 2004 have been derived from our consolidated financial statements and related notes not included in this prospectus. The selected consolidated statement of operations data for the year ended March 31, 2003 and the selected consolidated balance sheet data as of March 31, 2003 have not been audited. The unaudited financial statements include, in the opinion of management, all adjustments that management considers necessary for the fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended March 31,					Six Months Ended	
	2002	2003	2004	2005	2006	2005	2006
	(unaudited)					(unaudited)	
(In thousands, except per share data)							
<b>Consolidated Statements of Operations Data:</b>							
Revenues							
Product	\$ —	\$ —	\$ 95	\$ 473	\$ 1,966	\$ 807	\$ 1,942
Service	2,000	2,470	807	883	618	275	388
Total revenues	<u>2,000</u>	<u>2,470</u>	<u>902</u>	<u>1,356</u>	<u>2,584</u>	<u>1,082</u>	<u>2,330</u>
Cost of revenues							
Product <sup>(1)</sup>	—	—	1,403	2,211	3,899	1,350	1,043
Service <sup>(1)</sup>	815	1,768	1,265	1,311	1,003	497	422
Total cost of revenues	<u>815</u>	<u>1,768</u>	<u>2,668</u>	<u>3,522</u>	<u>4,902</u>	<u>1,847</u>	<u>1,465</u>
Gross profit (loss)	1,185	702	(1,766)	(2,166)	(2,318)	(765)	865
Operating expenses							
Research and development <sup>(1)</sup>	6	68	1,413	1,654	2,600	965	1,595
Selling, general and administrative <sup>(1)</sup>	1,326	2,102	3,918	12,492	15,933	7,704	7,867
Total operating expenses	<u>1,332</u>	<u>2,170</u>	<u>5,331</u>	<u>14,146</u>	<u>18,533</u>	<u>8,669</u>	<u>9,462</u>
Loss from operations	(147)	(1,468)	(7,097)	(16,312)	(20,851)	(9,434)	(8,597)
Interest expense	(24)	(123)	(178)	(372)	(172)	(103)	(261)
Interest income	—	—	3	8	282	68	100
Other income (expense), net	4	(4)	(26)	146	(377)	(101)	92
Net loss from continuing operations	(167)	(1,595)	(7,298)	(16,530)	(21,118)	(9,570)	(8,666)
Loss on discontinued operations	—	—	—	—	(1,981)	(174)	—
Net loss	(167)	(1,595)	(7,298)	(16,530)	(23,099)	(9,744)	(8,666)
Preferred stock dividends	—	—	—	—	(121)	—	(242)
Net loss available to common stockholders	<u>\$ (167)</u>	<u>\$ (1,595)</u>	<u>\$ (7,298)</u>	<u>\$ (16,530)</u>	<u>\$ (23,220)</u>	<u>\$ (9,744)</u>	<u>\$ (8,908)</u>
Net loss per common share: basic and diluted <sup>(2)</sup>							
Continuing operations	(0.04)	(0.40)	(1.87)	(4.22)	(5.12)	(2.34)	(2.11)
Discontinued operations	—	—	—	—	(0.48)	(0.04)	—
	<u>\$ (0.04)</u>	<u>\$ (0.40)</u>	<u>\$ (1.87)</u>	<u>\$ (4.22)</u>	<u>\$ (5.60)</u>	<u>\$ (2.38)</u>	<u>\$ (2.11)</u>
Weighted average number of shares used in per common share calculations: basic and diluted	3,795	3,827	3,911	3,914	4,150	4,086	4,221
Pro forma net loss per common share: basic and diluted					\$ (2.16)		\$ (0.79)
Pro forma weighted average number of shares used in per common share calculations: basic and diluted					10,759		11,283

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(1) Includes the following stock-based compensation charges:

	Year Ended March 31,					Six Months Ended	
	2002	2003	2004	2005	2006	2005	2006
	(unaudited)					(unaudited)	
	(In thousands)						
Cost of revenues							
Product	\$ —	\$ —	\$ —	\$ 2	\$ 2	\$ 1	\$ —
Service	—	55	10	3	1	—	1
Operating expenses							
Research and development	—	—	56	5	52	12	40
Selling, general and administrative	—	186	358	2,339	542	253	229

(2) See Note 1 to our consolidated financial statements for a description of the method used to compute basic and diluted net loss per share and number of shares used in computing historical basic and diluted net loss per share.

	As of March 31,					As of
	2002	2003	2004	2005	2006	September 30,
	(unaudited)					2006
	(In thousands)					
<b>Consolidated Balance Sheet Data:</b>						
Cash and cash equivalents	\$ 764	\$ 177	\$ 869	\$ 3,287	\$ 7,448	\$ 2,269
Working capital	889	(145)	(1,186)	663	5,127	(797)
Total assets	1,687	961	2,992	6,940	12,689	10,056
Total liabilities	747	1,040	3,374	4,738	5,351	9,082
Total stockholders' equity (deficit)	940	(79)	(382)	2,202	7,338	974



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements based upon current expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors," "Information Regarding Forward-looking Statements" and elsewhere in this prospectus.*

### Overview

We have developed and manufacture and market a family of products intended to help prevent and treat infections in chronic and acute wounds. Infection is a serious potential complication in both chronic and acute wounds, and controlling infection is a critical step in wound healing. Our platform technology, called Microcyn, is a non-toxic, super-oxidized water-based solution that is designed to treat a wide range of pathogens, including 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. We do not have the necessary regulatory approvals to market Microcyn in the United States as a drug. However, in clinical testing and studies, our products were effective against a wide range of pathogens and were found to be non-toxic, easy to use and complementary to most existing treatment methods in wound care. Our experience and clinical data indicate that the use of Microcyn may shorten hospital stays, lower aggregate patient care costs and, in certain cases, reduce the need for systemic antibiotics. Microcyn also has potential applications in several other large markets, including respiratory, dermatology, dental and veterinary markets.

We believe that Microcyn may be the first topical product that is effective against a broad range of bacteria and other infectious microbes without causing toxic side effects on, or irritation of, healthy tissue. Unlike most antibiotics, including antibiotic resistant strains, such as MRSA and VRE, we believe Microcyn does not target specific strains of bacteria, a practice which has been shown to promote the development of resistant bacteria. In addition, our products are shelf stable, require no special preparation and are easy to use.

We currently sell Microcyn in the United States through a small commercial team and through one national and five regional distributors. In Europe, we have a small direct sales force and exclusive distribution agreements with four distributors, all of which are experienced suppliers to the wound care market, with an aggregate combined sales force of over 25 full-time equivalent salespeople. In Mexico, we sell through a dedicated contract sales force, including salespeople, nurses and clinical support staff, and a network of distributors to both the public and private sector. The MOH, which approves product selection and procurement for government hospitals and healthcare institutions, has approved reimbursement for Microcyn. In India we sell through a national distributor, and in Canada, we have entered into a distribution agreement under which distribution will commence upon required regulatory approvals. We plan to expand our direct sales force in the United States, Europe and Mexico to support our distribution network.

Our products have received CE Mark approval for wound cleaning and reduction of microbial loads, three U.S. FDA 510(k) clearances as a medical device in wound debridement, lubricating, moistening and dressing, approvals for use as an antiseptic, disinfectant and sterilant in Mexico, approval for use in cleaning and debriding in wound management in India, and approval for moistening, irrigating, cleansing and debriding skin lesions in Canada. Physicians in several countries have conducted studies in which Microcyn was used to treat infection in a variety of wounds, including hard-to-treat wounds such as diabetic ulcers and burns, and, in some cases, reduced the need for systemic antibiotics. In July 2006, we completed a controlled clinical trial for pre-operative skin preparation. After completion of this trial, the FDA advised us that it is considering adopting new heightened performance requirements for evaluating efficacy of products designed to be used in pre-operative skin preparation such as ours. In discussions with the FDA, the FDA has not provided us with the definitive timing for, or parameters of, any such new requirements, and has informally stated that it is uncertain during what time frame it will be able to do so. We plan to continue our discussions with the FDA regarding the possible timing and parameters of any new guidelines for evaluating efficacy for pre-operative skin preparations. Depending on the ultimate position of the FDA regarding the performance criteria for pre-

operative skin preparations, we may reassess our priorities, clinical timelines and schedules for pursuing a pre-operative skin preparation indication or may decide not to pursue this indication.

We intend to conduct a pilot study in early 2007 to evaluate the effectiveness of Microcyn in patients with open wounds. Following completion of the pilot study, we intend to establish a protocol for a Phase IIb clinical trial in a similar patient population, which we intend to begin in mid to late 2007. We anticipate this trial to last approximately 12 months. The Phase IIb clinical trial is expected to cost approximately \$4.0 million and will be funded through proceeds from this offering. We anticipate this clinical trial to be completed in late 2008.

In the event we choose to pursue a partnering arrangement to commercialize products, we would expect a larger portion of our revenues would be derived from licensing as opposed to direct sales.

We also have a non-Microcyn based compound in the research and development phase. This compound has potential applications in oncology. We anticipate spending approximately \$500,000 on further clinical studies on this compound, funded by proceeds from this offering. We expect these studies to be completed in 2008.

We have incurred significant net losses since our inception and had an accumulated deficit of \$59.3 million as of September 30, 2006. We expect to incur significant expenses in the foreseeable future as we seek to commercialize our products, and we cannot be sure that we will achieve profitability.

## **Financial Operations Overview**

### *Revenues*

We derive our revenues from product sales and service arrangements. Product revenues are generated from the sale of Microcyn to hospitals, medical centers, doctors, pharmacies, distributors and strategic partners, and are generally recorded upon shipment following receipt of a purchase order or upon obtaining proof of sell-through by a distributor. Product sales are made either through direct sales personnel or distributors. Historically, a significant majority of our product sales have been in Mexico.

Service revenues are derived from consulting and testing contracts. Service revenues are generally recorded upon performance under the service contract. Revenues generated from testing contracts are recorded upon completion of the test and when the final report is sent to the customer. We have refocused our business efforts away from consulting and testing services toward the commercialization of Microcyn. As a result, we expect service revenues to continue to significantly decline in future periods.

### *Cost of Revenues*

Cost of product revenues represents the costs associated with the manufacturing of our products, including expenses for our various facilities which are fixed, and related personnel cost and the cost of materials used to produce our products. Cost of service revenues consists primarily of personnel related expenses and supplies.

### *Research and Development Expense*

Research and development expense consists of costs related to the research and development of Microcyn and our manufacturing process, the development of new products and new delivery systems for our products and to carry out preclinical studies and clinical trials to obtain various regulatory approvals. Research and development expense is charged as incurred.

### *Selling, General and Administrative Expense*

Selling, general and administrative expense consists of personnel related costs, including salaries and sales commissions, and education and promotional expenses associated with Microcyn and costs related to administrative personnel and senior management. These expenses also include the costs of educating physicians and other healthcare professionals regarding our products and participating in industry conferences

and seminars. Selling, general and administrative expense also includes travel costs, outside consulting services, legal and accounting fees and other professional and administrative costs.

*Stock-Based Compensation Expense*

Prior to April 1, 2006, we accounted for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, or APB No. 25, "Accounting for Stock Issued to Employees," and its interpretations and applied the disclosure requirements of SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123." We used the minimum value method to measure the fair value of awards issued prior to April 1, 2006 with respect to its application requirements under SFAS No. 123.

Effective April 1, 2006, we adopted SFAS No. 123(R) "Share Based Payment," or SFAS 123(R). This statement is a revision of SFAS Statement No. 123, "Accounting for Stock-Based Compensation" and supersedes APB Opinion No. 25, and its related implementation guidance. SFAS 123(R) addresses all forms of share-based payment, or SBP, awards including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. Under SFAS 123(R), SBP awards result in a cost that will be measured at fair value on the awards' grant date, based on the estimated number of awards that are expected to vest and will result in a charge to operations.

Under SFAS 123(R), nonpublic entities, including those that become public entities after June 15, 2005, that used the minimum value method of measuring equity share options and similar instruments for either recognition or pro forma disclosure purposes under Statement 123 are required to apply SFAS 123(R) prospectively to new awards and to awards modified, repurchased or cancelled after the date of adoption. In addition, SFAS 123(R) requires such entities to continue accounting for any portion of awards outstanding at the date of initial application using the accounting principles originally applied to those awards. Accordingly, we record stock-based compensation expense relating to awards granted prior to April 1, 2006 that are expected to vest in periods ending after April 1, 2006 in accordance with the provisions of APB No. 25 and related interpretive guidance.

We have adopted the prospective method with respect to accounting for our transition to SFAS 123(R). Accordingly, we recognized in salaries and related expense \$104,000 of stock-based compensation expense in the six months ended September 30, 2006, which represents the intrinsic value of options granted prior to April 1, 2006 that we continue to account for using the recognition and measurement principles prescribed under APB No. 25.

*Discontinued Operations*

On June 16, 2005, we entered into a series of agreements with Quimica Pasteur, or QP, a Mexico-based distributor of pharmaceutical products to hospitals and health care entities owned and/or operated by the Mexican Ministry of Health, or MOH. These agreements provided, among other things, for QP to act as our exclusive distributor of Microcyn to the MOH for a period of three years.

In connection with these agreements, we were granted an option to acquire all except a minority share of the equity of QP directly from its principals in exchange for 150,000 shares of common stock, contingent upon QP's attainment of certain financial milestones. Two of our employees were appointed as officers of QP, which resulted in the establishment of financial control of QP by our company under applicable accounting literature. In addition, due to its liquidity circumstances, QP was unable to sustain operations without our financial and management support. Accordingly, QP was deemed to be a variable interest entity in accordance with FIN 46R and the results of QP were therefore consolidated with our financial statements for the period from June 16, 2005 through March 26, 2006, the effective termination date of the distribution and related agreements.

In connection with an audit of QP's financial statements in late 2005, we were made aware of a number of facts that suggested that QP or its principals may have engaged in some form of fraudulent tax avoidance practice prior to the execution of the agreements between our company and QP. We did not discover these facts prior to our execution of these agreements or for several months thereafter. Our prior independent

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auditors informed us that we did not have effective anti-fraud programs designed to detect the activities in which QP's principals engaged or the personnel to effectively evaluate and determine the accounting for non-routine or complex accounting transactions. Our audit committee engaged an outside law firm to conduct an investigation whose findings implicated QP's principals in a systemic tax avoidance practice prior to June 16, 2005. Based on the results of this investigation, we terminated our agreements with QP on March 26, 2006. We estimate that QP's liability for taxes, interest and penalties related to these practices could amount to \$7 million or more. QP had a well-established relationship with the MOH. Although we lost the benefit of this relationship when we terminated our agreements with QP, we continue to sell to the MOH through our dedicated direct sales force and through other distributors. As of September 30, 2006, our sales to the MOH were not negatively affected by the termination of our relationship with QP and we do not expect that it will have a significant effect on sales to the MOH in the future.

In accordance with SFAS 144, we have reported QP's results for the period of June 16, 2005 through March 26, 2006 as discontinued operations because the operations and cash flows of QP have been eliminated from our ongoing operations as a result of the termination of these agreements. We no longer have any continuing involvement with QP as of the date on which the agreements were terminated. Amounts associated with the loss upon the termination of the agreements with QP, which consisted of funds we advanced to QP to provide it with working capital, are presented separately from QP's operating results.

### **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 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, depreciation, amortization, recoverability of long-lived assets, income taxes, equity transactions (compensatory and financing) and contingencies. We have also adopted certain policies with respect to our recognition of revenue that we believe are consistent with the guidance provided under Securities and Exchange Commission Staff Accounting Bulletin No. 104.

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

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

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

#### *Revenue Recognition and Accounts Receivable*

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

We apply the revenue recognition principles set forth in Securities and Exchange Commission Staff Accounting Bulletin, or SAB, 104 "Revenue Recognition," with respect to all of our revenues. Accordingly, we

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

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

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

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

We market a substantial portion of our goods through distributors. In Europe, we defer recognition of distributor-generated revenues until the time we confirm that distributors have sold these goods. Although our terms provide for no right of return, our products have a finite shelf life and we may, at our discretion, accommodate distributors by accepting returns to avoid the distribution of expired goods.

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

### *Inventory and Cost of Revenues*

We state our inventory at the lower of cost, determined using the first-in, first-out method, or market, based on standard costs. Establishing standard manufacturing costs requires us to make estimates and assumptions as to the quantities and costs of materials, labor and overhead that are required to produce a finished good. Cost of service revenues is expensed when incurred.

### *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, as a result of 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.

### *Equity Transactions*

Under generally accepted accounting principles, we have the ability to choose between two alternative methods of accounting for employee stock based compensation: the intrinsic value method or the fair value method. Although we have adopted the intrinsic value method, the results we could derive under the fair value method could differ significantly. In addition, since our stock is not publicly traded, we must estimate its fair value. We have used outside valuation specialists that have relied upon information provided by management to determine value of our stock and have also made valuation estimates based on concurrent sales of equity securities for cash and other business related information.

*Deferred Stock-Based Compensation Expense*

Stock-based compensation expense, which is a non-cash charge, results from stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the fair value of the underlying common stock. We recognize stock-based compensation expense on a straight-line basis over the vesting period of the underlying option, which is generally five years. The amount of stock-based compensation expense expected to be amortized in future periods may decrease if unvested options for which deferred stock-based compensation expense has been recorded are subsequently cancelled or may increase if future option grants are made with exercise prices below the deemed fair value of the common stock on the date of measurement.

During the period from April 1, 2005 to March 31, 2006, we granted options to purchase a total of 787,000 shares of common stock with exercise prices ranging from \$4.40 to \$12.00 per share and at a weighted average exercise price of \$9.20 per share. We obtained a contemporaneous valuation from an independent valuation specialist in July 2005. This valuation was used by our board of directors to establish the fair market value of our common stock with respect to the majority of options granted in the year ended March 31, 2006. Our other options were granted at fair market value as determined by our board of directors. Given the absence of an active market for our common stock and resulting lack of liquidity in the year ended March 31, 2006, our board of directors determined the estimated fair value of our common stock on the date of grant based on several factors, including the offering prices and liquidation preferences of our preferred stock, progress and milestones achieved in our business, our financial condition, equity market conditions, trading ranges of comparable public companies and the likelihood of achieving a liquidity event such as an initial public offering or a sale of the company given prevailing market conditions.

After receipt of the independent valuation in July 2005, our board of directors reassessed the value of our common stock. In reassessing the value of our common stock, we used a straight-line approach because we determined no single event supported incremental movement in the underlying stock. Further, we believe this approach is consistent with valuation methodologies applied by similar companies pursuing an initial public offering. Based upon this process, we determined that the reassessed fair value of options granted from August 7, 2003 through April 1, 2005 ranged from \$3.28 to \$9.12 per share. Accordingly, we recorded deferred stock-based compensation of \$233,000, \$2.8 million and \$401,000 during the years ended March 31, 2004, 2005 and 2006, respectively, in accordance with Accounting Principles Board, or APB, Opinion 25. The deferred stock-based compensation is being amortized on a straight-line basis over the vesting period of the related awards, which is generally five years. For the years ended March 31, 2004, 2005 and 2006, we recorded employee stock-based compensation of \$30,000, \$2.3 million and \$279,000, respectively. Stock-based compensation expense recorded during the year ended March 31, 2005 includes \$1.7 million for the intrinsic value of options to purchase 1.2 million shares of common stock granted to our Chief Executive Officer.

The information regarding net loss as required by SFAS No. 123 presented in Note 13 to our consolidated financial statements, has been determined as if we had accounted for our employee stock options under the fair value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effect on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the impact of future years' vesting.

**Comparison of Six Months Ended September 30, 2006 and September 30, 2005**

*Revenues*

Revenues increased \$1.2 million, or 116%, to \$2.3 million for the six months ended September 30, 2006, from \$1.1 million for the six months ended September 30, 2005. Product revenues increased \$1.1 million, or 140%, to \$1.9 million for the six months ended September 30, 2006, from \$807,000 for the six months ended September 30, 2005. This increase was primarily due to \$580,000 in sales to a new customer, Alkem Laboratories Limited, in India, during the six months ended September 30, 2006. Additionally, Microcyn product revenues increased from the six months ended September 30, 2005 to the six months ended September 30, 2006 by \$403,000 and \$184,000 in Mexico and Europe, respectively.

Service revenues increased \$113,000, or 41%, to \$388,000 for the six months ended September 30, 2006, from \$275,000 for the six months ended September 30, 2005.

We expect that product revenues will continue to increase as we expand our sales and marketing efforts worldwide. As of September 30, 2006, sales of our product to the MOH were not negatively affected by the termination of our relationship with QP. We expect that our service revenues will significantly decline in future periods, as we continue to implement our strategy of focusing primarily on our Microcyn business.

*Cost of Revenues*

Cost of revenues decreased \$381,000, or 21%, to \$1.5 million for the six months ended September 30, 2006, from \$1.8 million for the six months ended September 30, 2005. Cost of revenues from product sales principally include fixed costs associated with plant and labor and to a lesser extent variable costs associated with packaging and other raw materials. During the six months ended September 30, 2006, revenues from product sales exceeded cost of revenues from product sales as our sales volumes were sufficient to cover our fixed and variable cost components.

Cost of revenues from product sales decreased \$307,000, or 23%, to \$1.0 million for the six months ended September 30, 2006, from \$1.4 million for the six months ended September 30, 2005. Cost of revenues from product sales in the U.S. decreased \$612,000 for the six months ended September 30, 2006, as compared to the six months ended September 30, 2005. Beginning in April 2006, we shifted the focus of our United States facility from manufacturing to activities related to the research and development of new Microcyn products. As a result, we began classifying the expense associated with our United States facility as a research and development expense, and therefore our fixed cost of product revenues decreased accordingly. Cost of revenues from product sales in Europe increased \$448,000 for the six months ended September 30, 2006 as compared to the six months ended September 30, 2005, as our European manufacturing center expanded production capacity and the associated fixed costs grew accordingly. Also during that time, cost of sales from product revenues in Mexico decreased by \$110,000 as we closed a manufacturing facility in Morelia, Mexico in September 2005, and opened a new, lower fixed cost facility in Guadalajara, Mexico the following quarter.

Cost of revenues from services decreased \$75,000, or 15%, to \$422,000 for the six months ended September 30, 2006, from \$497,000 for the six months ended September 30, 2005.

Gross margins increased \$1.6 million to a gross profit of \$865,000 for the six months ended September 30, 2006, from a gross loss of \$765,000 for the six months ended September 30, 2005. Primarily this increase was due to the \$1.1 million growth in product revenues, while the cost of product revenues decreased by \$306,000.

We experienced positive gross margins during the six months ended September 30, 2006, and expect to experience positive gross margins in future periods as well. If we fail to increase our sales volume to sufficient levels in the future, we may have to examine strategies to reduce our recurring fixed costs of manufacturing. We expect that cost of revenues will continue to increase in absolute dollars as product sales increase in future periods.

*Research and Development Expense*

Research and development expense increased \$631,000, or 65%, to \$1.6 million for the six months ended September 30, 2006, from \$965,000 for the six months ended September 30, 2005. This increase was primarily attributable to the U.S. manufacturing department shifting focus from product manufacturing to research and development in April 2006. As a result, we began classifying the expense associated with our U.S. facility as a research and development expense, and therefore our research and development expense increased accordingly. Additionally, \$205,000 of this increase was attributable to higher salary and related expenses in the clinical and regulatory department. The expansion of our clinical and regulatory team was due to our increased focus on medical education, clinical trials and the management of regulatory trials designed to obtain FDA drug approvals for our Microcyn products.

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We expect that research and development expense will continue to increase substantially in future years as we seek additional regulatory approvals of our Microcyn products. We expect to expand the scope of our new product development, which may also result in substantial increases in research and development expense.

### *Selling, General and Administrative Expense*

Selling, general and administrative expense increased \$216,000, or 3%, to \$7.9 million during the six months ended September 30, 2006, from \$7.7 million during the six months ended September 30, 2005. This increase in expense for the six months ended September 30, 2006 was primarily attributable to increases in personnel and professional service expenses.

We expect that selling, general and administrative expense will increase in the future as we increase sales and marketing personnel and expand our infrastructure to support the requirements of being a public company.

### *Interest Expense and Interest Income*

Interest expense increased \$157,000, or 152%, to \$261,000 for the six months ended September 30, 2006 from \$103,000 for the six months ended September 30, 2005. This increase was primarily the result of higher borrowings during the six months ended September 30, 2006. Interest income increased \$31,000 or 45%, to \$100,000 for the six months ended September 30, 2006, from \$68,000 for the six months ended September 30, 2005. This increase was primarily the result of higher balances of interest-bearing instruments during the six months ended September 30, 2006.

### *Other Income (Expense), Net*

Other income (expense), net was \$92,000 net income for the six months ended September 30, 2006, compared with \$101,000 net expense for the six months ended September 30, 2005. This change was primarily attributable to a \$119,000 gain on foreign exchange translation for the six months ended September 30, 2006, as compared to loss of \$102,000 for the six months ended September 30, 2005.

### *Discontinued Operations*

Loss on the disposal of discontinued business was \$174,000 for the six months ended September 30, 2005. This charge represents the net loss associated with the entity QP which were consolidated with our financial statements as required by FIN 46(R), and later deemed to be a discontinued operation. As no relationship existed with this entity following the year ended March 31, 2006, no charges were recognized during the six months ended September 30, 2006.

## **Comparison of Years Ended March 31, 2006 and March 31, 2005**

### *Revenues*

Revenues increased \$1.2 million, or 91%, to \$2.6 million for the year ended March 31, 2006, from \$1.4 million for the year ended March 31, 2005. Product revenues increased \$1.5 million, or 316%, to \$2.0 million for the year ended March 31, 2006, from \$473,000 for the year ended March 31, 2005. This increase was primarily due to a \$1.4 million increase in sales of Microcyn60 in Mexico following the expansion of our sales force in that country and the receipt of product reimbursement by the MOH.

The increase in product revenues was partially offset by a \$265,000 decrease in service revenues during the year ended March 31, 2006, as compared to the prior year. The decrease in service revenues was a result of a shift in our focus from services to the development of our Microcyn products in fiscal 2006.

### *Cost of Revenues*

Cost of revenues increased \$1.4 million, or 39%, to \$4.9 million for the year ended March 31, 2006, from \$3.5 million for the year ended March 31, 2005. Cost of revenues from product sales principally include fixed costs associated with plant and labor and to a lesser extent variable costs associated with packaging and other



raw materials. Cost of revenues from product sales increased \$1.7 million, or 76%, to \$3.9 million in the year ended March 31, 2006, from \$2.2 million in the year ended March 31, 2005. This increase was due primarily to European product manufacturing beginning in the middle of the year ended March 31, 2005 as compared to a full year of costs in the year ended March 31, 2006. As such, total cost of product revenues in Europe increased \$637,000 to \$1.0 million for the year ended March 31, 2006 from \$381,000 for the year ended March 31, 2005. Additionally, we incurred charges we believe to be non-recurring. We wrote off \$1.0 million of inventory due to product labeling issues and expiring shelf life of products as a result of a one-time build-up of excess product inventory. We also relocated our manufacturing facility in Mexico and incurred approximately \$200,000 of labor and severance charges related to the move. These increases were partially offset by a \$308,000, or 23%, decrease in costs related to service revenues to \$1.0 million in the year ended March 31, 2006, from \$1.3 million in the year ended March 31, 2005. The lower cost of service revenues was related to our shift in focus to product development and the sale of our Microcyn products during fiscal 2006.

We experienced a gross loss of \$2.3 million during the year ended March 31, 2006. This gross loss was primarily due to relatively high fixed costs associated with manufacturing our products and a sales volume that was not sufficient to cover these costs. Additionally, there were several charges that we believe to be non-recurring that were incurred during the year ended March 31, 2006 that increased our gross loss for the period. The most significant of these charges was the write off of inventory and the costs associated with the relocation of our Mexican manufacturing facility as described above.

#### *Research and Development Expense*

Research and development expense increased \$946,000, or 57%, to \$2.6 million in the year ended March 31, 2006, from \$1.7 million in the year ended March 31, 2005. This increase was primarily attributable to the expansion of our regulatory team, which focused on EPA, FDA and KEMA approvals for Microcyn products during the period. Additionally, in September 2005, we commenced our pre-operative skin preparation pilot studies to support our application for an FDA drug clearance indicating microbial load reduction. Total spending on regulatory trials, other clinical studies, and related expenses increased \$1.2 million, or 164%, to \$1.9 million for the year ended March 31, 2006, from \$735,000 during the year ended March 31, 2005. This increase was partially offset by a \$418,000 decrease in spending on new product development to \$497,000 in the year ended March 31, 2006, from \$915,000 in the year ended March 31, 2005.

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

Selling, general and administrative expense increased \$3.4 million, or 28%, to \$15.9 million during the year ended March 31, 2006, from \$12.5 million during the year ended March 31, 2005. This increase was partially due to a \$1.8 million increase in United States selling, general and administrative expense primarily as a result of higher outside consulting and service fees during the year ended March 31, 2006. Specifically, outside accounting fees increased by \$653,000 due to the preparation and completion of an audit of our last four fiscal years, legal fees increased by \$507,000 due to expanded intellectual property and general legal support, and outside consulting and service fees increased by \$294,000 due to consulting expenses related to the marketing of our products in Asia.

In addition, sales and marketing expense in Europe increased \$429,000 due to the hiring of additional sales and marketing personnel during the year ended March 31, 2006.

Selling, general and administrative expense in Mexico increased \$3.3 million in the year ended March 31, 2006 compared to the prior year primarily due to expanded sales and marketing efforts in Mexico, as well as non-recurring charges associated with the relocation of our Mexican subsidiary's facility. During the year ended March 31, 2006, we began utilizing 75 full-time, direct sales personnel in the major districts of Mexico, dedicated to the sale of Microcyn60 in the hospital and pharmacy markets in Mexico. As a result, sales and marketing expense in Mexico increased \$2.7 million during the year ended March 31, 2006, compared to the prior year.

The increase in selling, general and administrative expense was offset by a \$1.8 million decrease in non-cash stock compensation expense in the year ended March 31, 2006 compared to the prior year. Approximately

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\$1.7 million of non-cash stock-based compensation expense incurred in the year ended March 31, 2005 was related to the grant of an option to purchase 1.2 million shares of common stock to our Chief Executive Officer.

### *Interest Expense and Interest Income*

Interest expense decreased \$200,000, or 54%, to \$172,000 in the year ended March 31, 2006, from \$372,000 in the year ended March 31, 2005. This decrease was primarily the result of lower borrowings during the year. Interest income increased \$274,000, to \$282,000 in the year ended March 31, 2006, from \$8,000 in the year ended March 31, 2005. This increase was primarily the result of higher balances of interest-bearing instruments during the year ended March 31, 2006.

### *Other Income (Expense), Net*

Other income (expense), net was \$377,000 net expense in the year ended March 31, 2006, compared with \$146,000 net income in the year ended March 31, 2005. This change was primarily attributable to a \$283,000 loss on foreign exchange translation in the year ended March 31, 2006, as compared to a gain of \$134,000 in the year ended March 31, 2005.

### *Discontinued Operations*

Loss on discontinued operations was \$2.0 million in the year ended March 31, 2006. This loss consisted of \$818,000 classified as a loss from operations of discontinued business and \$1.2 million of loss on the disposal of discontinued business. The loss from operations of discontinued business represents the net operating loss of QP, which was consolidated with our financial results as required by FIN 46(R). The relationship was terminated in the fourth quarter of the fiscal year ended March 31, 2006 and the loss was classified as a discontinued operation on our statements of operations. In addition, \$1.2 million of net assets associated with this entity were written off and classified as a loss on disposal of discontinued business. As no relationship existed with this entity prior to the year ended March 31, 2006, no charges were recognized in prior years.

## **Comparison of Years Ended March 31, 2005 and March 31, 2004**

### *Revenues*

Revenues increased \$454,000, or 50%, to \$1.4 million for the year ended March 31, 2005, from \$902,000 for the year ended March 31, 2004. Product revenues increased \$378,000 to \$473,000 for the year ended March 31, 2005, as compared to \$95,000 in the prior year. This increase was primarily attributable to the hiring of new sales and marketing personnel in Mexico and an increased demand for Microcyn60 in the Mexican private hospital market.

Service revenues increased \$76,000, or 9%, to \$883,000 for the year ended March 31, 2005, as compared to \$807,000 for the prior year. This increase was primarily the result of increased demand for our laboratory testing services.

### *Cost of Revenues*

Cost of revenues increased \$854,000, or 32%, to \$3.5 million for the year ended March 31, 2005, from \$2.7 million for the year ended March 31, 2004. Cost of product revenues increased \$808,000 primarily due to the expansion of our manufacturing capacity in the United States and Europe and related costs, including operating expenses for new facilities and an increase in personnel.

Cost of service revenues was \$1.3 million for both the years ended March 31, 2005 and 2004.

We experienced gross losses during the years ended March 31, 2005 and March 31, 2004 of \$2.2 million and \$1.8 million, respectively. These gross losses were primarily due to the relatively high fixed costs associated with manufacturing our products and a sales volume that was not sufficient to cover these costs.

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During these years we developed our manufacturing sites in the United States, Europe and Mexico, prior to significant sales in those countries.

### *Research and Development Expense*

Research and development expense increased \$241,000, or 17%, to \$1.7 million for the year ended March 31, 2005, from \$1.4 million for the year ended March 31, 2004. This increase was primarily related to a \$194,000 increase in salary expense related to the expansion of our research and development and regulatory teams and a \$102,000 increase in consulting services in the year ended March 31, 2005, as compared to the prior year.

### *Selling, General and Administrative Expense*

Selling, general and administrative expense increased \$8.6 million, or 219%, to \$12.5 million for the year ended March 31, 2005, from \$3.9 million for the year ended March 31, 2004. This increase was due in part to a \$4.1 million increase in general and administrative expense, primarily personnel costs associated with hiring additional senior management, sales and marketing, operations and administrative personnel. Additionally, selling, general and administrative expense was higher due to a \$2.0 million increase in non-cash stock compensation expense in the year ended March 31, 2005 compared to the prior year.

### *Interest Expense*

Interest expense increased \$194,000, or 109%, to \$372,000 in the year ended March 31, 2005, from \$178,000 in the year ended March 31, 2004. This increase was primarily due to an increase in non-cash interest expense charged on warrants issued in connection with debt financing transactions in the year ended March 31, 2005.

### *Other Income (Expense), net*

Other income (expense), net was net income of \$146,000 in the year ended March 31, 2005, compared to net expense of \$26,000 in the year ended March 31, 2004. The change was primarily attributable to a gain of \$134,000 on foreign exchange transactions in the year ended March 31, 2005, compared to a loss of \$4,000 in the prior year.

## **Liquidity and Capital Resources**

Since our inception, we have incurred significant losses and, as of September 30, 2006, we had an accumulated deficit of approximately \$59.2 million. We have not yet achieved profitability. We expect that our research and development and selling, general and administrative expenses will continue to increase and, as a result, we will need to generate significant product revenues to achieve profitability. We may never achieve profitability.

### *Sources of Liquidity*

Since our inception, substantially all of our operations have been financed through the sale of our common and preferred stock. Through September 30, 2006, we had received net proceeds of \$3.5 million from the sale of common stock, \$6.6 million from the sale of Series A convertible preferred stock, \$43.7 million from the sale of Series B convertible preferred stock and \$304,000 from the issuance of common stock to employees, consultants and directors in connection with the exercise of stock options. We have received additional funding through loans and capital equipment leases, as described below. We have also used our revenues to date as a source of additional liquidity. As of September 30, 2006, we had cash and cash equivalents of \$2.3 million and debt under our notes payable and equipment loans of \$4.5 million.

In June 2006, we entered into a loan and security agreement with a financial institution to borrow a maximum of \$5.0 million. The facility allows us to borrow a maximum of \$2.7 million in working capital, \$1.3 million in accounts receivable financing and \$1.0 million in equipment financing, subject to certain conditions.

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In conjunction with this agreement, we issued warrants to purchase up to 75,000 shares of our Series B preferred stock at an exercise price of \$18.00 per share. Warrants to purchase 53,750 shares were earned and exercisable at execution of the agreement, and warrants to purchase 21,250 shares will be earned on a pro rata basis upon our use of this facility. As of October 31, 2006, we had borrowed \$4.2 million against this facility at an interest rate of 8.5%. Draws under this facility bear interest at prime plus one-half percent.

On September 14, 2006, we sold 84,539 units, consisting of 84,539 shares of our Series C convertible preferred stock and warrants to purchase 16,907 shares of our common stock at an exercise price of \$18.00 per share, at a per unit price of \$18.00 for aggregate gross proceeds of \$1,521,702. In connection with this sale, we paid to Brookstreet, as placement agent, an aggregate of \$152,170 in commissions and issued to Brookstreet fully vested warrants to purchase an aggregate of 10,567 shares of our common stock at an exercise price of \$18.00 per share.

On October 20, 2006, we sold 108,486 units, consisting of 108,486 shares of our Series C convertible preferred stock and warrants to purchase 21,697 shares of our common stock at an exercise price of \$18.00 per share, at a per unit price of \$18.00 for aggregate gross proceeds of \$1,952,748. In connection with this sale, we paid to Brookstreet, as placement agent, an aggregate of \$195,274 in commissions and issued to Brookstreet fully vested warrants to purchase an aggregate of 13,560 shares of our common stock at an exercise price of \$18.00 per share.

On November 7, 2006, we signed a loan agreement with Robert Burlingame, under which Mr. Burlingame agreed to advance to us, \$4.0 million, which accrues interest at an annual rate of 7%. The principal and all accrued interest under the loan agreement will become due and payable in full on the earlier of November 10, 2007 or five days after the completion of an initial public offering of our common stock resulting in gross proceeds to us of at least \$30.0 million. The loan is secured by all of our assets, other than our intellectual property, but is subordinate to the security interest held by our secured lender. At the time the principal is advanced to us, Brookstreet will be paid a fee in the amount of \$50,000 and will be granted a warrant to purchase 25,000 shares of our common stock at an exercise price of \$18.00 per share.

### *Cash Flows*

As of September 30, 2006, we had cash and cash equivalents of \$2.3 million, compared to \$7.4 million at March 31, 2006 and \$3.3 million at March 31, 2005.

Net cash used in operating activities was \$5.6 million, \$13.5 million and \$19.7 million in the years ended March 31, 2004, 2005 and 2006, respectively, and \$8.7 million for the six months ended September 30, 2006. Net cash used in each of these periods primarily reflects net loss for these periods, offset in part by non-cash charges in operating assets and liabilities, non-cash stock-based compensation and depreciation.

Net cash used in investing activities was \$1.0 million, \$1.1 million and \$897,000 for the years ended March 31, 2004, 2005 and 2006, respectively, and \$1.5 million for the six months ended September 30, 2006. Cash was used primarily to invest in fixed assets and other capital expenditures to support increased personnel and manufacturing facility expansion in Europe and Mexico during the years ended March 31, 2004 and 2005. We expect to continue to make significant investments in the purchase of property and equipment to support our expanding operations.

Net cash provided by financing activities for the years ended March 31, 2004, 2005 and 2006 was \$7.3 million, \$17.2 million and \$26.6 million, respectively, and \$5.2 million for the six months ended September 30, 2006. The net cash provided by financing activities for the year end periods was primarily attributable to the sale of convertible preferred stock, which generated \$6.6 million, \$16.7 million and \$27.0 million for the years ended March 31, 2004, 2005 and 2006, respectively. In addition, net proceeds from debt financing added \$574,000, \$1.2 million and \$257,000 for the years ended March 31, 2004, 2005 and 2006, respectively, and \$4.4 million for the six months ended September 30, 2006. Debt financing consisted primarily of notes payable to individuals and secured notes issued to finance the purchase of capital equipment, corporate insurance premiums and general operations.

*Contractual Obligations*

As of March 31, 2006, we had contractual obligations as follows (long-term debt and capital lease amounts include principal payments only):

	Payments Due by Period				
	Total	Less than 1 year	1-3 years (in thousands)	4-5 years	After 5 years
Long-term debt	\$ 714	\$ 504	\$ 93	\$ 117	\$ —
Capital leases	69	21	42	6	—
Operating leases	878	341	340	197	—
Total	\$ 1,661	\$ 866	\$ 475	\$ 320	\$ —

We have leases covering approximately 40,000 square feet of office and manufacturing space in Petaluma, California, expiring in 2007, and our monthly rent is \$23,493. We also have leases covering approximately 19,000 square feet of office and manufacturing space in Sittard, The Netherlands expiring in 2009, and approximately 12,000 square feet of office and manufacturing space and 5,000 square feet of warehouse space in Zapopan, Mexico, expiring in 2011 and 2007, respectively.

In June 2006, we entered into a loan and security agreement with a financial institution to borrow a maximum of \$5.0 million. The facility allows us to borrow a maximum of \$2.7 million in working capital, \$1.3 million in accounts receivable financing and \$1.0 million in equipment financing, subject to certain conditions. As a result of our borrowings of \$4.2 million under such agreement, as of September 30, 2006, our total debt has increased to \$4.6 million as of September 30, 2006.

We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

*Operating Capital and Capital Expenditure Requirements*

We expect to continue to incur substantial operating losses in the future and to make capital expenditures to support the expansion of our research and development programs and to expand our commercial operations. We anticipate using a portion of the proceeds from this offering to finance these activities. It may take several years to obtain the necessary regulatory approvals to commercialize Microcyn as a drug in the United States.

We expect to use the net proceeds from this offering to fund approximately \$14.3 million in expenses related to the expansion of our sales and marketing capabilities, including the expansion of our direct sales forces in the United States and Europe, approximately \$13.0 million in clinical trials and related research, the repayment of the principal and interest on our Bridge Loan and the remaining proceeds for general corporate purposes, including working capital. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products. The amount and timing of actual expenditures may vary significantly depending upon the rate of growth, if any, of our business, the amount of cash generated by our operations, status of our research and development efforts, competitive and technological developments and the amount of proceeds actually raised in this offering.

We currently anticipate that the net proceeds from this offering, the Series C Financing and the Bridge Loan, together with our future revenues, cash and cash equivalent balances and interest we earn on these balances will be sufficient to meet our anticipated cash requirements through at least the next 12 months.

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.

If we are unable to generate a sufficient amount of revenue to finance our operations, research and development and regulatory plans, we may seek to raise additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations or other means. We may seek to raise additional capital due to favorable market conditions or strategic considerations even if we have sufficient funds for planned operations. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that are not favorable to us. We do not know whether additional funding will be available on acceptable terms, or at all. A failure to secure additional funding when needed may require us to curtail certain operational activities, including regulatory trials, sales and marketing, and international operations and would have a material adverse effect on our future business and financial condition.

#### **Recent Accounting Pronouncements**

In Emerging Issues Task Force, or EITF, Issue No. 04-8, "The Effect of Contingently Convertible Instruments on Diluted Earnings per Share," the EITF reached a consensus that contingently convertible instruments, such as contingently convertible debt, contingently convertible preferred stock and other such securities should be included in diluted earnings per share (if dilutive) regardless of whether the market price trigger has been met. The consensus became effective for reporting periods ending after December 15, 2004. The adoption of this pronouncement did not have material effect on our financial statements.

In May 2005, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 154, "Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3", or SFAS 154. This Statement replaces APB Opinion No. 20, "Accounting Changes", and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements", and changes the requirements for the accounting for and reporting of a change in accounting principle. This Statement applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed.

APB Opinion No. 20 previously required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. This Statement requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, this Statement requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings (or other appropriate components of equity or net assets in the statement of financial position) for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, this Statement requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. This Statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not believe that the adoption of SFAS 154 will have a significant effect on our financial statements.

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On June 29, 2005, the EITF ratified Issue No. 05-2, "The Meaning of 'Conventional Convertible Debt Instrument' in EITF Issue No. 00-19, 'Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock.'" EITF Issue 05-2 provides guidance on determining whether a convertible debt instrument is "conventional" for the purpose of determining when an issuer is required to bifurcate a conversion option that is embedded in convertible debt in accordance with SFAS 133. Issue No. 05-2 is effective for new instruments entered into and instruments modified in reporting periods beginning after June 29, 2005. We do not believe that the adoption of this pronouncement will have a significant effect on our financial statements.

In September 2005, the EITF ratified Issue No. 05-4, "The Effect of a Liquidated Damages Clause on a Freestanding Financial Instrument Subject to EITF Issue No. 00-19, 'Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock.'" EITF 05-4 provides guidance to issuers as to how to account for registration rights agreements that require an issuer to use its "best efforts" to file a registration statement for the resale of equity instruments and have it declared effective by the end of a specified grace period and, if applicable, maintain the effectiveness of the registration statement for a period of time or pay a liquidated damage penalty to the investor. We are currently in the process of evaluating the effect that the adoption of this pronouncement may have on our financial statements.

In September 2005, the FASB ratified the EITF Issue No. 05-7, "Accounting for Modifications to Conversion Options Embedded in Debt Instruments and Related Issues," which addresses whether a modification to a conversion option that changes its fair value affects the recognition of interest expense for the associated debt instrument after the modification and whether a borrower should recognize a beneficial conversion feature, not a debt extinguishment if a debt modification increases the intrinsic value of the debt (for example, the modification reduces the conversion price of the debt). This issue is effective for future modifications of debt instruments beginning in the first interim or annual reporting period beginning after December 15, 2005. We do not believe that the adoption of this pronouncement will have a significant effect on our financial statements.

In September 2005, the FASB also ratified the EITF's Issue No. 05-8, "Income Tax Consequences of Issuing Convertible Debt with a Beneficial Conversion Feature," which discusses whether the issuance of convertible debt with a beneficial conversion feature results in a basis difference arising from the intrinsic value of the beneficial conversion feature on the commitment date, which is treated and recorded in the shareholder's equity for book purposes, but as a liability for income tax purposes, and, if so, whether that basis difference is a temporary difference under FASB Statement No. 109, "Accounting for Income Taxes." This Issue should be applied by retrospective application pursuant to Statement 154 to all instruments with a beneficial conversion feature accounted for under Issue 00-27 included in financial statements for reporting periods beginning after December 15, 2005. We do not believe that the adoption of this pronouncement will have a significant effect on our financial statements.

In February 2006, the FASB issued SFAS No. 155 "Accounting for Certain Hybrid Financial Instruments—an amendment of FASB Statements No. 133 and 140", or FAS 155. FAS 155 addresses the following: a) permits fair value re-measurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation; b) clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement 133; c) establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation; d) clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives; and e) amends Statement 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. FAS 155 is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. We are currently evaluating the requirements of FAS 155, but do not expect that the adoption of this pronouncement will have a material effect on our financial statements.

In March 2006, the FASB issued SFAS 156 "Accounting for Servicing of Financial Assets, an amendment of FASB Statement No. 140," or SFAS 156. SFAS 156 is effective for the first fiscal year beginning after

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September 15, 2006. SFAS 156 changes the way entities account for servicing assets and obligations associated with financial assets acquired or disposed of. We have not yet completed our evaluation of the impact of adopting SFAS 156 on our results of operations or financial position, but do not expect that the adoption of SFAS 156 will have a material impact.

In September 2006, the FASB issued SFAS No. 157, "Accounting for Fair Value Measurements", or SFAS 157. SFAS 157 defines fair value, and establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosure about fair value measurements. SFAS 157 is effective for financial statements issued subsequent to November 15, 2007. We do not expect the new standard to have any material impact on our financial position, results of operations or cash flows.

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

### **Income Taxes**

Since inception, we have incurred operating losses and, accordingly, have not recorded a provision for income taxes for any of the periods presented. As of March 31, 2006, we had net operating loss carryforwards for federal, state and foreign income tax purposes of approximately \$28.8 million, \$25.9 million and \$17.4 million, respectively. The carryforwards expire beginning 2020, 2010 and 2014, respectively. We also had, as of March 31, 2006, federal and state research credit carryforwards of approximately \$104,000 and \$108,000, respectively. The federal credits expire beginning 2026, and the state credits have no expiration.

We have experienced substantial ownership changes in connection with financing transactions completed through the year ended March 31, 2006. Accordingly, our utilization of net operating loss and tax credit carryforwards against taxable income in future periods, if any, is subject to substantial limitations under the Change in Ownership rules of Section 382 of the Internal Revenue Code. After considering all available evidence, we have fully reserved for these and other deferred tax assets since it is more likely than not such benefits will not be realized in future periods. We will continue to evaluate our 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 our deferred income tax assets satisfy the realization standard of SFAS No. 109, the valuation allowance will be reduced accordingly.

### **Quantitative and Qualitative Disclosures About Market Risk**

Market risk represents the risk of changes in the value of market risk sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices. Changes in these factors could cause fluctuations in our results of operations and cash flows.

Our exposure to interest rate risk is confined to our excess cash in highly liquid money market funds. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations.

We have operated primarily in the United States; however we do have two significant subsidiaries, one each in Europe and Mexico. In order to mitigate our exposure to foreign currency rate fluctuations, we maintain minimal cash balances in the foreign subsidiaries. However, if we are successful in our efforts to grow internationally, our exposure to foreign currency rate fluctuations, primarily the Euro and Mexican Peso, may increase. We are exposed to foreign currency risk related to the Euro denominated and Mexican Peso denominated intercompany receivables. Because our intercompany receivables are accounted for in Euros and Mexican Pesos, any appreciation or devaluation of the Euro or Mexican Peso will result in a gain or loss to the consolidated statements of operations.



## BUSINESS

### Overview

We have developed and manufacture and market, a family of products intended to help prevent and treat infections in chronic and acute wounds. Infection is a serious potential complication in both chronic and acute wounds, and controlling infection is a critical step in wound healing. Our platform technology, called Microcyn, is a non-toxic, super-oxidized water-based solution that is designed to treat a wide range of pathogens, including 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. We do not have the necessary regulatory approvals to market Microcyn in the United States as a drug. However, in clinical testing and studies, our products were effective against a wide range of pathogens and were found to be non-toxic, easy to use and complementary to most existing treatment methods in wound care. Microcyn-based products have also received three U.S. 510(k) regulatory clearances and approvals in Canada, Mexico and India. Our experience and clinical data indicate that the use of Microcyn has the potential to shorten hospital stays, lower aggregate patient care costs and, in certain cases, reduce the need for systemic antibiotics. Microcyn also has potential applications in several other large markets, including respiratory, dermatology, dental and veterinary markets.

In 2004, chronic and acute wound care represented an aggregate of \$9.6 billion in global product sales, of which \$3.3 billion was spent for the treatment of skin ulcers, \$1.6 billion to treat burns and \$4.7 billion for the treatment of surgical and trauma wounds, according to Kalorama Information, a life sciences market research firm. 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 not be effective in controlling infection in patients with disorders affecting circulation, such as diabetes, which are commonly associated with chronic wounds. As a result, no single treatment is used across all types of wounds and stages of healing.

We believe Microcyn provides significant advantages over current methods of care in the treatment of a wide range of chronic and acute wounds throughout all stages of treatment. These stages include debridement, cleaning, prevention and treatment of infections and wound moistening. We believe that Microcyn may be the first topical product that is effective against a broad range of bacteria and other infectious microbes including antibiotic resistant strains such as MRSA and VRE, without causing toxic side effects on healthy tissue. Unlike most antibiotics, we believe Microcyn does not target specific strains of bacteria, a practice which has been shown to promote the development of resistant bacteria. In addition, our products are shelf stable, require no special preparation, and are easy to use.

Our goal is to become a worldwide leader in wound care by establishing Microcyn as the standard of care for helping to prevent and treat infections in chronic and acute wounds. We currently have, and intend to seek additional regulatory clearances and approvals to market Microcyn worldwide. In July 2004, we began selling Microcyn in Mexico after receiving approval from the Mexican Ministry of Health, or MOH, for the use of Microcyn as an antiseptic, disinfectant and sterilant. Since then, physicians in the United States, Europe and Mexico have conducted twelve physician clinical studies assessing Microcyn's use in the treatment of infections in a variety of wounds, including hard-to-treat wounds such as diabetic ulcers and burns. We used the data generated from some of these studies to support our application for the CE Mark for wound cleaning and reduction of infection. We received the CE Mark in November 2004 and additional international approvals in Canada, Mexico and India. Microcyn has also received three FDA 510(k) clearances for use as a medical device in the debridement, lubricating, moistening and dressing of wounds, including traumatic wounds and acute and chronic dermal lesions.

In July 2006, we completed a controlled clinical trial for pre-operative skin preparation. After completion of this trial, the FDA advised us that it is considering adopting new heightened performance requirements for evaluating efficacy of products designed to be used in pre-operative skin preparation such as ours. In

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discussions with the FDA, the FDA has not provided us with the definitive timing for, or parameters of, any such new requirements, and has informally stated that it is uncertain during what time frame it will be able to do so. We plan to continue our discussions with the FDA regarding the possible timing and parameters of any new guidelines for evaluating efficacy for pre-operative skin preparations. Depending on the ultimate position of the FDA regarding performance criteria for pre-operative skin preparations, we may reassess our priorities, clinical timelines and schedules for pursuing a pre-operative skin preparation indication or may decide not to pursue this indication.

We intend to conduct a pilot study in early 2007 to evaluate the effectiveness of Microcyn in patients with infections in open wounds. Following completion of the pilot study, we intend to establish a protocol for a Phase IIb clinical trial in a similar patient population, which we hope to begin in mid to late 2007. We anticipate this trial to last approximately 12 months.

We currently sell Microcyn in the United States through one national and five regional distributors who are supported by our commercial team and clinical support staff. In October 2006, we initiated a focused U.S.-based sales effort to increase the awareness of Microcyn at selected wound treatment centers in a major metropolitan area, and, if this strategy is successful, we intend to target other metropolitan areas in 2007 and 2008. In Europe, we sell Microcyn through exclusive distribution agreements with distributors, all of which, we believe, are experienced suppliers to the wound care market, supported by our direct sales force. In Mexico, we sell Microcyn through a network of distributors and through a contract sales force, including salespeople, nurses and clinical support staff. We plan to continue to expand our sales and marketing force to support our distribution network. In India we sell through a national distributor and in Canada, we have entered into a distribution agreement under which distribution will commence upon required regulatory approvals.

Our goal is to achieve the following milestones through 2009:

### **2007**

- Initiate and complete pilot study for Microcyn in the treatment of infections in open wounds
- Initiate enrollment for Phase IIb clinical trial for Microcyn in the treatment of infections in open wounds
- Initiate several physician-sponsored studies in the United States, Europe and India
- Initiate 510(k) clearance process for next generation Microcyn product formulation
- Execute distribution agreements for Microcyn in select European, Asian and South American countries
- Expand U.S. sales force to cover additional major U.S. metropolitan areas

### **2008**

- Receive 510(k) marketing clearance for next generation Microcyn product formulation

### **2009**

- Data expected from Phase IIb clinical trial for Microcyn in the treatment of infections in open wounds
- Initiate strategic partner discussions for Microcyn in the treatment of infections in open wounds

## **Industry Background**

### *Wound Care Industry Overview*

According to Medtech Insight, a Division of Windhover Information, there were over 90 million incidents of wounds in the United States during 2004. Of these, over six million were chronic wounds, including arterial, diabetic, pressure and venous ulcers. The remaining 84 million were acute wounds, which follow the normal

process of healing and commonly include burns, traumatic wounds, and approximately 67 million surgical incisions.

Key trends in wound care include:

- large and increasing elderly, diabetic and obese populations, each of which is vulnerable to developing a variety of difficult-to-heal ulcers;
- increased emphasis on controlling the cost of patient care in hospitals, wound care centers and in private practice;
- technological innovation, which has expanded treatment options from traditional ointments and gauze to include advanced treatments, such as vacuum devices, silver dressings, ultrasound and skin grafts;
- increased focus on improving the patient experience, including reduction of pain and accelerated healing time; and
- adjunctive nature of the market where multiple treatment methods are employed, either simultaneously or sequentially, depending on the type and stage of the wound.

Wound care is complex, and controlling infection is a critical step in wound healing. Difficult-to-heal wounds can result from traumatic injury, diabetes, peripheral vascular disease, complications following surgery, rheumatoid arthritis, congestive heart failure, arterial or venous ulcers and many other conditions which compromise circulation. Without proper medical intervention and control of infection, these types of wounds typically remain open and chronically infected.

#### ***Chronic Wounds***

Chronic wounds are wounds that do not heal within a normally expected time frame under standard care. The most frequently occurring chronic wounds are venous, arterial, pressure and diabetic foot ulcers. According to Medtech Insight, in 2004, the incidence of chronic wounds in the United States was approximately 6.1 million, comprised of 2.0 million pressure ulcers, 1.7 million arterial ulcers, 1.6 million venous ulcers and 800,000 diabetic foot ulcers. In addition to being expensive to treat, chronic wounds are debilitating, painful and can result in amputations and other serious consequences. Clinical studies suggest that, depending on the severity of the wound, up to 43% of patients with diabetic foot ulcers undergo an amputation. Furthermore, the five year survival rate for patients undergoing amputations as a result of diabetic foot ulcers is 27%.

The increasing prevalence of chronic wounds is driven by the large and growing elderly, diabetic and obese populations.

*Aging.* People aged 65 and over are more susceptible to wounds that become chronic than the overall population. In 2006, there were more than 37 million people in the United States over 65, representing more than 12% of the population. By 2030, this group is expected to comprise more than 19% of the total population of the United States, according to U.S. Census Bureau projections. Additionally, according to Medtech Insight, 70% of pressure ulcers occur in people age 70 years or older and 25% of patients in nursing homes suffer from pressure ulcers.

*Diabetes.* Diabetics are particularly vulnerable to chronic wounds as a result of the debilitating effect of diabetes on the circulatory system. According to the Centers for Disease Control and Prevention, CDC, one out of three children born in 2000 in the United States will develop diabetes. There are currently approximately 14.7 million diabetic Americans, representing 5% of the total population, up from 2.7% in 1990. Furthermore, according to the CDC the incidence of diabetes is significantly higher in people over 65: in 2004, 16% of people over 65 were diabetic compared to 7.5% of the total population.

*Obesity.* Obesity is a leading cause of Type II, or “adult onset,” diabetes, making the obese population more likely to eventually sustain chronic wounds. Obesity in the United States is a growing problem. According to the National Institute of Diabetes and Digestive and Kidney Diseases in 2000, more than 30% of the United States adult population was obese, up from 13% in 1960.

### ***Acute Wounds***

Acute wounds are typically caused by traumatic injury or surgical incision and are broadly categorized as those that can be expected to heal within a definable timeframe. However, the healing process may be affected by complicating factors such as infection, leading to chronic wounds.

All acute wounds have the potential for infection and may require prophylactic treatment to prevent infection. According to Medtech Insight, in 2004, about 16.2 million traumatic wounds were treated, including 8.7 million open wounds. Also according to Medtech Insight, in 2004, approximately 67 million surgical wounds were reported in the United States, including 36 million completed under anesthesia. Despite modern infection control procedures, and technologies at hospitals and surgery centers, every time the skin is opened there is a risk of infection. We believe that there is a higher likelihood of infection in surgeries involving anesthesia because of the length of time the wound is open. In a clinical study on surgical infections, it was shown that infection rates vary with the time required to complete the surgery. For example, infection rates varied from about 3.6% for surgeries taking less than 30 minutes to about 16.4% for those longer than 5 hours.

### ***Critical Steps for Wound Treatment***

#### ***Infection Control***

According to the Committee to Reduce Infection Deaths, or RID, one out of every 20 patients contracts an infection while in the hospital. Certain infections are increasingly dangerous because they cannot be effectively controlled by commonly used antibiotics. According to the RID's industry estimates, infections add more than \$30 billion annually to health care costs in the United States. In addition, the RID estimates that each year in the United States, approximately two million patients contract infections while in hospitals and, of those, an estimated 100,000 die as a result. According to a recent study, patients with surgical site infections incur almost triple the average hospital costs of other patients. Surgical site infections account for approximately 500,000 hospital acquired infections in the United States each year, according to the CDC. Surgical site infections are estimated to cost hospitals more than \$1.0 billion each year in additional medical treatment.

*Staphylococcus aureus*, or *Staph*, is one of the most common hospital acquired infections. One of the deadliest forms of *Staph* infection is MRSA. According to data from the CDC, in 2003, 57% of the *Staph* infections reported were MRSA, up from 22% in 1995 and 2% in 1974. Patients who do survive MRSA often spend months in the hospital and endure repeated surgeries to remove infected tissue.

When infection is present in a wound, standard treatments can include cleansing, debridement and systemic antibiotics. Many cleansing agents can harm tissue, causing irritation and sensitization and impeding the wound healing process. Some forms of debridement may increase scar tissue and complicate skin grafting. Systemic antibiotics may be ineffective if the patient's metabolic state is compromised. Additionally, the effectiveness of oral or systemic antibiotics in diabetic foot ulcer patients may be diminished due to the patient's poor circulation, limiting delivery of the antibiotics to the wound site.

Because there is a risk of infection with many surgical procedures, clinicians perform several procedures before and after surgery designed to prevent infection. Pre-operative procedures generally involve preparing the surgical site with an anti-bacterial agent, such as Betadine. Post-operative procedures can include an anti-infective irrigation, a therapeutic body cavity cleansing and the use of systemic antibiotics.

#### ***Wound Healing and Closure***

Wound healing is a cascade process comprised of inflammation, proliferation and maturation. The first stage of the wound healing process is the inflammatory phase, which is associated with swelling, redness and heat, and involves the migration of healthy cells to the wound bed. Removing dead tissue or debris from the wound prepares the wound bed for regeneration of new tissue. The second phase is the proliferative phase, which involves collagen and blood vessel formation and tissue growth. The final phase, maturation, occurs as the wound begins to take on its permanent form as collagen is reconstituted, forming new skin. None of these phases, however, will progress normally in the presence of infection.

*Advanced Technologies*

Techniques and devices have been developed to treat complex and hard-to-treat wounds, ranging from specialized devices to antimicrobial dressings. Negative pressure wound therapy, high pressure oxygen chambers and localized devices, sophisticated water-based tissue removal devices, oxygenated mist devices and tissue engineered skin substitutes are some of the most advanced devices available to the wound care specialist. Although relatively effective, many of these treatments have limitations or drawbacks in that they cannot be used on certain types of wounds or are expensive and complex to use. Despite these advanced technologies, treatment of challenging wounds continues to be multi-pronged, with a number of associated therapies employed in an attempt to achieve wound closure.

*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:

- 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; and
- the increase in antibiotic resistant bacterial strains, such as MRSA and VRE, have compromised the effectiveness of some widely used topical antibiotics including Neosporin and Bacitracin.

**Our Solution**

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

- **Efficacy.** In both laboratory testing and physician clinical studies, our products were 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 where Microcyn was used both independent of and in conjunction with other wound care therapeutic products, data supported that patients generally experienced less pain, improved mobility and physical activity levels and better quality of life.
- **Safety.** Preclinical and clinical data shows that Microcyn is non-toxic. Throughout all our clinical trials and physician clinical studies to date and since commercialization in 2004, we have received no reports of serious adverse events related to the use of Microcyn products.
- **Ease of Use.** 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 and does not require any specific handling procedures. Unlike other super-oxidized water 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 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 help treat infection, accelerate healing time and, in certain cases, may help reduce the need for systemic antibiotics, thereby lowering overall patient cost.

## Our Strategy

Our goal is to become a worldwide leader in wound care by establishing Microcyn as the standard of care for helping to prevent and treat infections in chronic and acute wounds. We also intend to leverage our expertise in wound care into additional market opportunities. The key elements of our strategy include the following:

- ***Drive adoption of Microcyn as the standard of care in the wound care market to help prevent and treat infection***

We believe our products are well positioned to become the standard of care in helping to prevent and treat infection. We seek to drive adoption of Microcyn as the standard of care in the wound care market through data from physician clinical studies, our own clinical trials and key opinion leader programs. We intend to continue to maintain a marketing presence in key medical communities throughout the world through targeted direct marketing and sponsorships of physician presentations at medical conferences and seminars.

- ***Obtain additional regulatory approvals in the United States***

We intend to seek additional regulatory clearances and approvals, which we believe will allow us to accelerate adoption of our products by wound care specialists worldwide. Our current focus is on developing a well-defined, well-controlled clinical protocol for a Phase IIb trial. To increase our probability of success in the trial, we intend to conduct a pilot study in early 2007 to evaluate the effectiveness of Microcyn in subjects with infections in open wounds. Following completion of the pilot study, we intend to establish a Phase IIb clinical trial in a similar patient population.

- ***Expand our direct sales force and distribution networks***

We intend to expand our direct sales force and distribution networks in the United States, Europe and the rest of the world. In the United States, Europe and Mexico, we sell our products through distribution networks supported by our direct sales force. We also have distribution agreements for our products in India, Southeast Asia and the Middle East. We select distributors based on their demonstrated expertise in selling to wound care professionals and facilities. In the United States we are initiating a series of focused, intense product roll-outs in large metropolitan areas to increase the awareness of Dermacyn among healthcare providers. We will continue to expand the number of metropolitan areas included in this roll-out as we expand our U.S.-based sales force.

- ***Pursue opportunities to combine Microcyn with other treatments***

We believe our products are compatible with and may potentially enhance the efficacy of a variety of existing wound care treatment methods including negative pressure wound therapy, pulse and jet lavage and tissue engineered skin substitutes. Combining Microcyn with these therapies has been and continues to be evaluated in physician clinical studies. We believe combination therapies to treat open wounds are gaining acceptance by wound care professionals and may prove to be clinically and commercially attractive.

- ***Develop strategic collaborations in the wound care market***

We intend to pursue strategic relationships with respect to both product development and distribution. To accelerate adoption of our products, we may enter into strategic relationships with healthcare companies that have product lines or distribution channels that are complementary to ours. We believe collaborations allow us to leverage our resources and technology. These relationships may take the form of co-development, co-promotion or distribution agreements. In addition, we may expand our offerings of new products or technologies through acquisitions or licensing agreements.

- ***Leverage our Microcyn platform to address additional markets***

We believe our products have potential applications in several other large markets, including the respiratory, dermatology, dental and veterinary markets. We intend to pursue access to these markets through strategic partnerships.

## **Microcyn Platform Technology**

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

We believe Microcyn's ability to treat and help prevent infection and its sterilant properties are based on its uniquely engineered chemistry. As a result of our proprietary electrolysis process, Microcyn contains a wide array of oxidized chemical species that, among other things, interact and inactivate surface proteins on microorganisms and viruses. The function of these proteins are varied and play significant roles in receptor binding, molecular transport and other required functions for cell viability. Once Microcyn surrounds single cell microorganisms, it damages these proteins, causing cell membrane rupture, leading to cell death. This destruction of the cell appears to occur through a fundamentally different process than that which occurs as a result of contact with a hypochlorite-based solution because experiments have demonstrated that Microcyn kills hypochlorite-resistant bacteria. However, the solution remains non-toxic to animals and human tissues because human cells are interlocked and prevent Microcyn from targeting and surrounding single cells topically on the body.

In laboratory tests, Microcyn has been shown to eliminate certain biofilms. A biofilm is a complex aggregation of microorganisms or bacteria marked by the formation of a protective and adhesive matrix, 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. In our laboratory studies, Microcyn was shown to destroy two common biofilms after five minutes of exposure.

It is widely accepted that reducing inflammation surrounding an injury or wound is beneficial to wound healing. Our laboratory research indicates that Microcyn may inhibit histamine production and cytokine release from mast cells, a validated model for evaluating inflammatory responses in vitro. These factors are critical components of the body's natural inflammatory response to injury or wounds, as well as other conditions, such as rhinosinusitis. Inhibition of cytokine release blocks the initial stages of the inflammation process, in which cells, including mast cells, involved in triggering the inflammatory response, are prevented from releasing the inflammation signal to the rest of the body. Our laboratory research suggests that Microcyn's interference with these cells is selective to only the inflammation response and does not interfere with other functions of these cells. Additionally, physician clinical studies suggest that Microcyn only inhibits this function in tissue that is directly exposed to the solution.

Microcyn 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 Microcyn by a variety of certified independent testing laboratories. Some of the pathogens against which Microcyn has demonstrated antimicrobial activity are listed below:

**Pathogen**

**Antibiotic-Resistant Bacteria**

*Enterococcus faecalis* Vancomycin Resistant (VRE)  
Methicillin resistant *Staphylococcus aureus* (MRSA)

**Other Bacteria**

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

**Viruses**

Human Coronavirus  
Human Immunodeficiency Virus Type 1 — HIV  
Influenza A  
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, which was co-authored by our Director of Medical Affairs, Andres Gutiérrez, M.D., Ph.D., that showed that Microcyn exerts a wide range of antimicrobial activity (Landa-Solis, González-Espinosa D, Guzman B, Snyder M, Reyes-Terán G, Torres K and Gutiérrez AA. Microcyn: a novel super-oxidized water with neutral pH and disinfectant activity. J Hosp Infect (UK) 61: 291-299).

**Current Regulatory Approvals and Clearances**

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

<b>Region</b>	<b>Approval or Clearance Type</b>	<b>Year of Approval or Clearance</b>	<b>Summary Indication</b>
United States	510(k)	2005	Moistening and lubricating absorbent wound dressings for traumatic wounds.
	510(k)	2005	Moistening and debriding acute and chronic dermal lesions.
	510(k)	2006	Moistening absorbent wound dressings and cleaning minor cuts.



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<u>Region</u>	<u>Approval or Clearance Type</u>	<u>Year of Approval or Clearance</u>	<u>Summary Indication</u>
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	2004	Antiseptic treatment of wounds and infected areas.
	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.
Canada	Class II Medical Device	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.

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

### ***Clinical Trials***

In July 2006, we completed a controlled clinical trial for the use of Microcyn as a pre-operative skin preparation. Microcyn demonstrated a bacterial load reduction comparable to Hibiclens in intact skin. In this study, the application of Microcyn, chlorhexidine gluconate solution 4% (Hibiclens), or 0.9% saline chloride for irrigation, USP (sterile saline) was randomized so that each subject had two of the three alternatives on a possible four sites per person. The amount of bacteria per square centimeter was measured initially to determine the baseline level. Subsequently, the amount of bacteria on the groin and abdominal sites were measured after 30 seconds, 10 minutes and six hours. The trial was conducted by a third party laboratory that has completed numerous similar studies with other pre-operative skin preparation products. The trial was completed in July 2006.

The results of this trial showed that Microcyn produced an average log<sub>10</sub> reduction from baseline population of 3.19 and 2.04 at 10 minutes post-application for the groin and abdominal test sites, respectively. In addition, the microorganism populations from the six hour post-application samples for both test sites did not return to baseline. The results from this trial showed that Hibiclens produced an average log<sub>10</sub> reduction from baseline population of 3.07 and 2.15 at 10 minutes post-application for the groin and abdominal test sites, respectively. The microorganism populations from the six hour post-application samples for both test sites did not return to baseline. Sterile saline only produced an average log<sub>10</sub> reduction from baseline population of 2.36 and 1.28 at 10 minutes post-application for the groin and abdominal test sites, respectively.

After completion of this trial, the FDA advised us that it is considering adopting new heightened performance requirements for evaluating efficacy of products designed to be used in pre-operative skin preparation such as ours. In discussions with the FDA, the FDA has not provided us with the definitive timing for, or parameters of, any such new requirements, and has informally stated that it is uncertain during what time frame it will be able to do so. We plan to continue our discussions with the FDA regarding the possible timing and parameters of any new guidelines for evaluating efficacy for pre-operative skin preparations. Depending on the ultimate position of the FDA regarding the performance criteria for pre-operative skin preparations, we may reassess our priorities, clinical timelines and schedules for pursuing a pre-operative skin preparation indication or may decide not to pursue this indication.

We intend to develop Microcyn as a topical antimicrobial to treat infected wounds and to obtain the necessary clearances and/or approvals to commercialize this product. We intend to conduct a pilot study in early 2007 to evaluate the effectiveness of Microcyn in patients with infections in open wounds. Following completion of the pilot study, we intend to establish a protocol for a Phase IIb clinical trial in a similar patient

population, which we intend to begin in mid to late 2007. We expect to have data available from the trial by 2009. Assuming the results of the Phase IIb trial supports further development of our product for treatment of open wounds, the results of this Phase IIb trial will be used to determine the design and sample sizes for subsequent Phase III trials. These Phase IIb and Phase III clinical trials are intended to provide the clinical basis for submission to the FDA of an NDA for the treatment of open wounds.

**Physician Clinical Studies**

In addition to our clinical trials, several physicians have conducted twelve clinical studies of Microcyn generating data supporting that Microcyn is safe, reduces microbial load, shortens treatment time and may have the potential to reduce costs to healthcare providers and patients. We have sponsored the majority of physicians performing these studies by supplying Microcyn, unrestricted research grants and paying expenses and honoraria. In some cases, the physicians who performed these studies are also shareholders in our company. The studies were performed in the United States, Mexico and Italy, and used various endpoints, methods and controls (for example, some of these studies used 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 an NDA submission to the FDA in that they did not 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 a selection of articles and publications from physicians who have completed studies on the use of Microcyn for wound care and wound irrigation.

<u>Physician</u>	<u>Country</u>	<u>Number of Patients</u>	<u>Publication</u>
David E. Allie, M.D.(1)	U.S.	40	Allie D. Super-Oxidized Dermacyn in Lower-Extremity Wounds. <i>Wounds</i> , 2006, Jan (Suppl), 3-6
Tom Wolvos, M.D.(2)	U.S.	26	Wolvos TA. Advanced Wound Care with Stable, Super-Oxidized Water. A look at how combination therapy can optimize wound healing. <i>Wounds</i> , 2006, Jan (Suppl), 11-13
Cheryl Bongiovanni, Ph.D.(3)	U.S.	8	Bongiovanni CM. Superoxidized Water Improves Wound Care Outcomes in Diabetic Patients. <i>Diabetic Microvascular Complications Today</i> , 2006, May-Jun: 11-14
Luca Dalla Paola, M.D.(4)	Italy	218	Dalla Paola L, Brocco E, Senesi, A, Merico M, De Vido D, Assaloni R, DaRos R. Super-Oxidized Solution (SOS) Therapy for Infected Diabetic Foot Ulcers. <i>Wounds</i> , 2006, vol. 18: 262-270 Dalla Paola, L. Treating diabetic foot ulcers with super-oxidized water. <i>Wounds</i> , 2006, Jan (Suppl), 14-16

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<u>Physician</u>	<u>Country</u>	<u>Number of Patients</u>	<u>Publication</u>
Ariel Miranda, M.D.(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, Jan (Suppl), 17-19
Fermin Martínez de Jesus, M.D.	Mexico	45	Martínez de Jesús, F. Sterilant for human wounds is changing patient's lives. <i>Infection Control Today</i> , 2004, Vol. 8, No. 11.

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### Notes

- (1) indicates that the physician is a member of our Medical and Business Advisory Board, a paid consultant, an investor and received research grants, expense payments, honorarium and Microcyn to complete the study
- (2) indicates that the physician is a paid consultant and a warrant holder
- (3) indicates that the doctor received Microcyn to complete the study
- (4) indicates that the physician is 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

In addition to the above articles and publications, several additional journal articles have been submitted for peer review and publication. There are also several ongoing and planned physician clinical studies in the United States, Europe and India to assess Microcyn's effectiveness in helping to prevent and treat infections in wounds. For example, we are supporting a study by Dr. David Armstrong of the Scholl College of Podiatric Medicine in Chicago, Illinois and Dr. Andrew Boulton, Head of the Manchester Diabetes Center at the Manchester Royal Infirmary in the United Kingdom. This is a study of diabetic foot ulcers using the VersaJet, and aggressive debridement system, in two groups of 20 patients each, one utilizing Microcyn and the other utilizing saline. The endpoints are microbial load reduction and time to complete wound healing.

Dr. Dalla Paola is conducting a study involving 100 patients comparing Microcyn to another antimicrobial agent in the treatment of diabetic foot necrobiosis, with time to wound healing the primary endpoint. We have given Dr. Tom Wolvos, a board certified surgeon who is the Medical Director at the Scottsdale Healthcare Wound Management Center in Arizona, an unrestricted research grant to conduct a 40-patient study comparing Microcyn to saline solution with the VAC, a negative pressure wound therapy system, in the treatment of a variety of wounds. Lastly, Cheryl Bongiovanni, Ph.D., Director of the Lake Wound Clinics in Lakeview, Oregon, is conducting two patient studies, one focusing on the potential cost savings from the use of Microcyn in treating a variety of wounds, and one 20-patient study comparing Microcyn with saline solution in the treatment of leg ulcers. We provided each of these doctors with Microcyn and may pay their expenses, including travel, hotels and meals, to attend medical conferences to present their findings. We have also paid consulting fees and expenses to Dr. Wolvos in connection with corporate development and licensing evaluations.

### Sales and Marketing

We are developing distribution and sales networks to market our products domestically and in a number of countries outside the United States. We expect to expand our existing sales force in the United States, Europe and Mexico as we obtain additional regulatory claims. Our products are purchased by hospitals, physicians, nurses and other healthcare practitioners who are the primary caregivers to patients being treated for acute or chronic wounds, as well as those patients undergoing surgical procedures.

Our strategy is to enter into agreements with established regional distributors, provide ongoing sales support and utilize clinical studies and key opinion leader programs to accelerate product adoption. Implementation of our strategy includes the development of relationships with wound care specialists through

targeted direct marketing and communications programs and through sponsorship of physician presentations at medical conferences and seminars.

In the United States, we currently distribute our products through one national and five regional distributors who are supported by our commercial team and clinical support staff. In addition to our distributors, we employ medical and clinical professionals, with marketing contacts in leading wound care clinics, hospitals and health care agencies that provide wound care services. Our U.S. commercial team is initiating a focused sales strategy that will allow us to increase the awareness of Microcyn to healthcare providers. This strategy involves sampling and customer education efforts in a major metropolitan area. Based on the success of this initial roll-out, we intend to target other metropolitan areas in 2007 and 2008. We intend to hire additional salespeople in the United States in the event we receive FDA approval of our product for additional indications.

In Europe, we have arrangements with distributors in Germany, Italy, Sweden and the Czech Republic who are supported by our sales team. We are actively pursuing additional distribution arrangements in other European countries. We currently have a small direct sales force in our European regional sales office in The Netherlands, and intend to hire additional direct sales people to support our distributors.

In Mexico, we market our products through our established distribution network and direct sales organization. We have a dedicated contract sales force, including salespeople, nurses and clinical support staff responsible for selling Microcyn to private and public hospitals and to retail independent pharmacies.

We have established distribution channels for our disinfectant and wound care products in India, Bangladesh, Pakistan, Singapore, United Arab Emirates and Saudi Arabia. In December 2005, we entered into an agreement with Alkem Laboratories, a large pharmaceutical company in India, which employs more than 800 salespeople servicing the Indian healthcare market. We commenced sales to Alkem Laboratories in April 2006.

#### **Other Market Opportunities**

We believe our products have potential applications in several other large markets and intend to pursue access to these markets through strategic partnerships. We have entered into distribution or license agreements in some of these markets; however, we have not generated meaningful revenue from any of these agreements. In addition, we plan to develop new applications of our products in the respiratory, dermatology and oral care market through strategic partnerships. Some of these market opportunities include:

##### ***Respiratory***

Our nasal product candidate is an anti-microbial solution designed to be self-administered into a patient's nasal cavity for the treatment of chronic rhinosinusitis, or inflammation of the nasal sinuses. In animal studies, Microcyn has been shown to kill the bacteria that causes rhinosinusitis. We are currently conducting pre-clinical animal studies seeking to support the efficacy and safety of this product candidate.

Rhinosinusitis affects an estimated 35 million people in the United States. There is no FDA-approved therapy for chronic rhinosinusitis. Most treatment methods have focused on the symptoms of the disease and include the use of antibiotics, antihistamines, corticosteroids and sinus surgery.

##### ***Dermatology***

We believe that our Microcyn technology can be used to develop products to treat various fungal and bacterial skin infections, such as: acne vulgaris, psoriasis, vaginal candidiasis and onychomycosis. Laboratory

and clinical test data support that our technology may be effective in treating these bacterial and fungal infections.

#### ***Dental and Oral Care***

Based on data from the Freedonia Group, the United States market for mouthwash and dental rinse products was \$600 million in 2003. We believe that our Microcyn technology may be used to develop oral healthcare products. As an example, Microcyn has been tested in physician studies, and these early study data support its safe use in oral surgery.

#### ***Veterinary Medicine***

Our animal wound care product based on Microcyn technology, Vetericyn, was launched in late 2004 and is currently available for purchase by veterinarians through MWI Veterinary Supply, Inc., a distributor of animal health products. Vetericyn has uses in a variety of applications, including, the treatment of hard-to-heal equine wounds. We believe a non-toxic wound spray that is safe for use in animals has wide application for use in companion animals. According to the American Veterinary Medical Association, as of December 31, 2005, there were more than 54,000 veterinarians in private practice in more than 27,000 veterinary practices nationwide.

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

The main goals of our research and product development program are to design, develop and produce products to treat acute and chronic wounds, and to identify new applications for our technology. Our research and product development efforts with our Microcyn-based products are divided into three areas: science, new product development and engineering.

Our scientists work to continually improve our product performance by evaluating variations of the formulations and chemical structures of our products. For example, we are evaluating alterations to Microcyn to increase the speed at which it kills certain bacteria and viruses.

The focus of our current development efforts is new formulations, applications and delivery systems for Microcyn, including the following:

- an intravenous bag and spikeable bottle for use with compatible wound care systems, such as negative wound pressure therapy, jet lavage and oxygenated mist devices;
- various formulations and delivery systems that extend the stability of the product;
- a surgical irrigant to control infections during and after surgery; and
- a fine mist to treat chronic rhinosinusitis.

Our engineers seek to optimize our manufacturing process by reducing costs and increasing yield. For example, we have significantly decreased the waste product resulting from our manufacturing process, and we continue to experiment to find ways of decreasing it further.

Our technology may have application in other non-medical markets. We intend to pursue opportunities in these markets with third parties. Our director of research and development coordinates all research and product development activities. We plan to increase our research and product development staff in the future to address market demands identified in our market research and commercial practice.

#### **Manufacturing**

We manufacture Microcyn through a proprietary electrolysis process within a multi-chamber system. We are able to control the passage of ions through proprietary membranes, yielding electrolyzed water with only trace amounts of chlorine. This process is fundamentally different from the processes for manufacturing hydrogen peroxide and bleach and is the basis for our technology's efficacy 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 in Petaluma, California, Sittard, The Netherlands and Zapopan, Mexico. We have developed an automated manufacturing process and conduct quality assurance testing on each production batch in accordance with current U.S. Good Manufacturing Practices, or cGMP. Our facilities are required to meet and maintain regulatory standards applicable to the manufacture pharmaceutical and medical device products. Our United States and Netherlands facilities are certified and comply with cGMP medical device Quality Systems Regulation or QSR, and International Organization for Standardization, or ISO, guidelines. Our Mexico facility has been approved by the MOH.

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

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

#### **Intellectual Property**

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

As of October 30, 2006, we own one issued U.S. patent, 12 pending U.S. patent applications and 18 foreign pending patent applications generally relating to super-oxidized water. These applications include three U.S. provisional applications for which the one-year period to file a non-provisional application has not yet expired as well as three international PCT applications that have not yet reached the deadline to file counterpart phase applications. We filed the provisional U.S. patent applications as a way of deferring the payment of U.S. and foreign patent office fees while we decide whether the invention merits a full examination based on the development of the market for the product. In addition, a provisional patent application gives us the opportunity to continue to develop the inventive concepts further before filing further U.S. and foreign patent applications that are subject to examination. Our portfolio of pending applications can be divided into two groups. The first group includes one U.S. issued patent and three pending U.S. patent applications and seven foreign patent applications that relate to early generation super-oxidized water product, methods of using super-oxidized water, and aspects of the method and apparatus for manufacturing super-oxidized water. The second group includes nine pending U.S. patent applications, including three provisional applications, and 11 foreign patent applications that relate to Microcyn, the method and apparatus for manufacturing Microcyn, and its uses.

In March 2003, we obtained an exclusive license to six issued Japanese patents and five Japanese published pending patent applications owned by Coherent Technologies, or Coherent. The issued Japanese patents and pending Japanese patent applications relate to an early generation of unstable, super-oxidized water product and aspects of the method and apparatus for producing super-oxidized water and will expire between 2011 and 2014. In June 2006, we received written notice via email from Coherent advising us that the patent license was terminated, citing various reasons with which we disagree. Although we do not believe Coherent has grounds to terminate the license, we may have to take legal action to preserve our rights under the license and to enjoin Coherent from breaching its terms. We do not know whether we would prevail in any such action, which would be costly and time consuming, and we could lose our rights under the license, which could have a material adverse impact on our business opportunities in Japan. In addition, we may have to defend ourselves against infringement claims from Coherent in Japan based on their position on termination of the license. We do not believe the Japanese patents disclose or cover certain innovations in our products, which we developed independently and are the subject of our own patent applications. Neither party has sought legal

remedy to this issue. In fact, we maintain an ongoing dialogue with Coherent. To date, we have not commercialized any products or generated any revenue in Japan.

Although we work to protect our technology, we cannot assure you that any patent will issue from 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 develop similar products, duplicate any of our products or design around our patents.

We have also filed for trademark protection for marks used with our Microcyn products in each of the United States, Europe, certain countries in Central and South America, including Mexico and Brazil, Latin America, certain countries in Asia, including Japan, China and the Republic of Korea, 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 who 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. For more information, please see “Risk Factors,” “Our competitive position depends on our ability to protect our intellectual property and our proprietary technologies.”

### **Competition**

We believe the principal competitive factors in our target market include improved patient outcomes, such as time in the hospital, healing time, adverse events, safety of products, ease of use, stability, spore killing and cost effectiveness. The medical device industry, and in particular the wound 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.

Our products compete with a variety of products used for wound cleaning, debriding and moistening, including sterile saline, and chlorhexadine-based products, and they also compete with a large number of prescription and over-the-counter products for the prevention and treatment of infections, including topical anti-infectives, such as Betadine, silver sulfadiazine, hydrogen peroxide, Dakin’s solution and hypochlorous acid, and topical antibiotics, such as Neosporine 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 also replace the use of sterile saline for debriding and moistening a dressing as well as for use as a complementary product with many advanced wound care technologies, such as the VAC from Kinetic Concepts Inc., skin substitute products from Smith & Nephew, Integra Life Sciences, Life Cell, Organogenesis and Ortec International, and ultrasound from Celleration. We believe that Microcyn 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 other product lines.

While many companies are able to produce oxidized water, their products, unlike ours, typically become unstable after 48 hours, and we believe they have a much higher chlorine content that may not be suitable for treatment of infections in wounds. One such company, PuriCore, sells electrolysis machines used to manufacture brine-based oxidized water primarily as a sterilant.

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 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 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***

New medical devices, such as Microcyn, are subject to FDA approval and extensive regulation under the Federal Food Drug and Cosmetic Act, or FDCA. Under the FDCA, 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.

Class I devices are those for which safety and effectiveness can be assured by adherence to a set of general controls. These general controls include compliance with the applicable portions of the FDA's Quality System Regulation, which sets forth good manufacturing practice requirements; facility registration, device listing and product reporting of adverse medical events; truthful and non-misleading labeling; and promotion of the device only for its cleared or approved intended uses. Class II devices are also subject to these general controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Review and clearance by the FDA for these devices is typically accomplished through the so-called 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 Class II device (for example, a device previously cleared through the 510(k) premarket notification process). 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 pre-market approval, or PMA.

Clinical trials are almost always required to support a PMA 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, or IDE. An IDE 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 IDE 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 PMA approval or for unsupported safety or effectiveness claims. Although the FDA does not regulate physicians' practice of medicine, the FDA does regulate manufacturer communications with respect to off-label use.

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

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

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

The FDA also administers certain controls over the export of medical devices from the United States, as international sales of medical devices that have not received FDA approval 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.

#### ***Pharmaceutical Product Regulation***

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

Under the United States regulatory scheme, the development process for new pharmaceutical products can be divided into three distinct phases:

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

Each of these three phases is discussed further below.

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

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

- *Phase I.* Phase I human clinical trials are conducted in a limited number of healthy individuals to determine the drug's safety and tolerability and include biological analyses to determine the availability and metabolization of the active ingredient following administration. The total number of subjects and patients included in Phase I clinical trials varies, but is generally in the range of 20 to 80 people.
- *Phase II.* Phase II clinical trials involve administering the drug to individuals who suffer from the target disease or condition to determine the drug's potential efficacy and ideal dose. These clinical trials

are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. These trials require scale up for manufacture of increasingly larger batches of bulk chemical. These batches require validation analysis to confirm the consistent composition of the product.

- *Phase III.* Phase III clinical trials are performed after preliminary evidence suggesting effectiveness of a drug has been obtained and safety (toxicity), tolerability, and an ideal dosing regimen have been established. Phase III clinical trials are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to complete the information needed to provide adequate instructions for the use of the drug. Phase III trials usually include from several hundred to several thousand subjects.

Throughout the clinical phase, samples of the product made in different batches are tested for stability to establish shelf life constraints. In addition, large-scale production protocols and written standard operating procedures for each aspect of commercial manufacture and testing must be developed.

Phase I, II, and III testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. Clinical investigators, or IRBs, and companies may be subject to pre-approval, routine, or "for cause" inspections by the FDA for compliance with Good Clinical Practices, or GCPs, and FDA regulations governing clinical investigations. The FDA may suspend or terminate clinical trials, or a clinical investigator's participation in a clinical trial, at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, institutional review boards, which are independent entities constituted to protect human subjects in the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

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

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

In addition, following FDA approval of a product, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer, or holder of an approved marketing application, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or effectiveness

data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, the FDA may require post-market testing and surveillance to monitor the product's safety or efficacy, including additional clinical studies, known as Phase IV trials, to evaluate long-term effects.

#### ***Regulation of Disinfectants***

In the United States, the EPA regulates disinfectants as antimicrobial pesticides under the Federal Insecticide, Fungicide and Rodenticide Act, or FIFRA, and the implementing regulations that the EPA has adopted under FIFRA. Before marketing a disinfectant in the United States, we must satisfy the EPA's pesticide registration requirements. That registration process requires us to demonstrate the disinfectant's efficacy and to determine the potential human and ecological risks associated with use of the disinfectant. The testing and registration process could be lengthy and could be expensive. There is no assurance, however, that we will be able to satisfy all of the pesticide registration requirements for a particular proposed new disinfectant product. Once we satisfy the FIFRA registration requirements for an individual disinfectant, additional FIFRA regulations will apply to our various business activities, including marketing, related to that EPA-registered product.

Failure to comply with FIFRA's requirements could expose us to various enforcement actions. FIFRA empowers the EPA to seek administrative or judicial sanctions against those who violate FIFRA. Among the potential FIFRA penalties are civil administrative penalties, stop sale orders, cancellation of our registration, seizures, injunctions and criminal sanctions. If EPA were to initiate a FIFRA enforcement action against us, it could have a material adverse effect on us.

#### ***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 Claim Act and comparable state laws. These laws regulate the activities of entities involved in the healthcare industry, such as us, by limiting the kinds of financial arrangements such entities may have with healthcare providers who use or recommend the use of medical products (including for example, sales and marketing programs, advisory boards and research and educational grants). In addition, in order to ensure that healthcare entities comply with healthcare laws, the Office of Inspector General, or OIG, 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 OIG has issued model Compliance Program Guidance, or CPG, 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 CPG materials is voluntary, a recent California law requires pharmaceutical and devices manufacturers to initiate compliance programs that incorporate the CPG 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 OIG 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 OIG. 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, and those who bring such suits. Individuals may file suit on behalf of the government 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, the federal government created financial incentives for states to enact false claims laws consistent with the federal False Claims Act. As more states enact such laws, we expect the number of qui tam lawsuits to increase. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claims action, pay fines or be excluded from Medicare, Medicaid or other federal or state government healthcare programs as a result of investigations arising out of such actions.

*HIPAA.* Two federal crimes were created under the Health Insurance Portability and Accountability Act of 1996, or HIPAA: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing

or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

*Health Information Privacy and Security*

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

***Foreign Regulation***

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

*European Union Regulation*

*Medical Device Regulation.* Our Microcyn 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, or MDD, and its national implementations, including affixing CE Marks on our products. In order to comply with the MDD, 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. We executed the conformity assessment for production quality assurance for Class IIb products for Dermacyn Wound Care. Compliance with production quality assurance is audited every year by a private entity certified by government regulators. 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 MDD.

We received our CE certificate for Dermacyn Wound Care as a Class IIb medical device in February 2005. There can be no assurance that we will be able to maintain the requirements established for CE Marks for any or all of our products or that we will be able to produce these products in a timely and profitable manner while complying with the requirements of the MDD and other regulatory requirements.

*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. NDA to the relevant authority. In contrast to the United States, where the FDA is the only authority that administers and approves NDAs, 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 our Microcyn based drugs will be reviewed by the Committee for Medicinal Products for Human Use, or CHMP, on behalf of the European Medicines Agency, or EMEA. Based upon the review of the CHMP, the EMEA 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 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 NDAs 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 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 GMP.* In the European Union, the manufacture of pharmaceutical products and clinical trial supplies is subject to good manufacturing practice, or GMP, as set forth in the relevant laws and guidelines. Compliance with GMP 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.

#### *Mexico*

The MOH 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 MOH. The MOH acts by virtue of the Federal Commission for the Protection against Sanitary Risks, or COFEPRIS, a decentralized entity of the MOH whose mission is to protect the population against sanitary risks, by means of centralized sanitary regulations, controls and by raising public awareness.

The MOH 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, preparation, manufacturing, maintenance, mixture, conditioning, packaging, handling, transport, distribution, storage and supply 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 manufacture 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 is considered a business that manufactures medical devices and therefore is not subject to a Sanitary Authorization, but rather only an Operating Notice.

In addition to its Operating Notice, our Mexico subsidiary has obtained a "Good Processing Practices Certificate" issued by COFEPRIS, 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 MOH.

The MOH classifies the medical devices in three classes:

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

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

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

#### **Employees**

As of September 30, 2006, we had 76 full-time employees, including 19 in manufacturing, eight in research and development, five in regulatory and clinical, 17 in sales and marketing and 13 in executive or administrative functions in the U.S., four in administrative functions in Europe, eight in administrative functions in Mexico, and two in information technology function. In early 2007, we plan to add additional sales and marketing personnel to support our various markets and opportunities. We also plan to hire additional clinical support personnel to work with key opinion leaders, and to provide educational services and technical support our distribution channels. None of our employees is covered by collective bargaining arrangements, and we consider our relationship with our employees to be good.

#### **Properties**

We currently lease approximately 12,000 square feet of office, research and manufacturing space in Petaluma, California, which serves as our principal executive offices. We also lease approximately 28,000 square feet of office space in an adjacent building for manufacturing and research and development. Both leases expire in September 2007.



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We lease approximately 4,000 square feet of office space and approximately 14,000 square feet of manufacturing and warehouse space in Zapopan, Mexico, under a lease that expires in April 2011. We lease approximately 5,000 square feet of office space and approximately 14,000 square feet of manufacturing and warehouse space in Sittard, The Netherlands, under leases that expire in January 2009. As we expand, we may need to establish manufacturing facilities in other countries.

We believe our properties are adequate to meet our needs through September 2007.

**Legal Proceedings**

In March 2006, we filed suit in the U.S. District Court for the Northern District of California against Nofil Corporation and Naoshi Kono, its Chief Executive Officer, for breach of contract, misappropriation of trade secrets and trademark infringement. We believe that Nofil Corporation violated key terms of both an exclusive purchase agreement and non-disclosure agreement by contacting and working with a potential competitor in Mexico. In the complaint, we seek damages of \$3.5 million and immediate injunctive relief. No trial date has been set.

In September 2005, a complaint was filed against us in Mexico claiming trademark infringement with respect to our Microcyn60 mark. To settle this claim we have agreed to cease marketing our product in Mexico under the name Microcyn60 in Mexico by September 2007. A second unrelated claim was filed against us in Mexico in May 2006, claiming trademark infringement with respect to our Microcyn60 mark in Mexico. We are in discussions with the claimant to settle the matter.

In September 2006, a consulting firm in Mexico City contacted us threatening legal action in Mexico, alleging breach of contract and claiming damages of \$225,000. A formal complaint has not been served and no trial date has been set. We are currently in settlement negotiations with the plaintiff. If these negotiations are not successful, we intend to vigorously defend this action. If the claims are litigated, we may incur considerable litigation costs.

In April 2005, a former director and Chief Operating Officer of our company filed an action in the Superior Court of the State of California, Sonoma County, alleging breach of employment contract. In the complaint, the plaintiff claims \$300,000 and the right to purchase approximately 150,000 shares of our common stock at \$3.00 per share. We entered into a settlement agreement with the plaintiff in November 2006 which provides for the payment of \$250,000 and the issuance of a warrant to purchase 50,000 shares of our common stock exercisable at \$3.00 per share. The issuance of warrants is subject to our obtaining appropriate waivers from our preferred stockholders and the cash payment is subject to the closing of an equity financing resulting in gross proceeds to us of \$10 million or more on the completion of our initial public offering. Under the terms of the agreement, the plaintiff has agreed to dismiss his claim and waived any other previous claims against us. If the claims are litigated, we may incur considerable litigation costs. We expect our insurance carrier to cover a portion of the claim.

Except for the foregoing, we are not a party to any material legal proceedings, and, except as set forth above, management is not aware of any threatened legal proceedings that it believes could cause a material adverse impact on our business, financial condition or results of operations. From time to time, we may be party to lawsuits in the ordinary course of business.

**GLOSSARY OF TECHNICAL, MEDICAL AND INDUSTRY TERMS**

The following technical, medical, and industry-specific terms used in this prospectus have the following meanings:

<i>Anti-infective</i>	Capable of killing infectious agents or of preventing them from spreading and causing infection.
<i>Antimicrobial</i>	Capable of destroying or inhibiting the growth of micro-organisms.
<i>Antiseptic</i>	A germicide used on skin or living tissue for the purpose of inhibiting or destroying microorganisms (for example, alcohol, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol PCMX, quaternary ammonium compounds, and triclosan).
<i>Debridement</i>	Removal of dead tissue or foreign material from a wound.
<i>Disinfection</i>	Destruction of pathogenic and other kinds of microorganisms by physical or chemical means. Disinfection is less lethal than sterilization, because it destroys the majority of recognized pathogenic microorganisms, but not necessarily all microbial forms (for example, bacterial spores). Disinfection does not ensure the degree of safety associated with sterilization processes.
<i>Germicide</i>	An agent that destroys microorganisms, especially pathogenic organisms. Terms with the same suffix (e.g., virucide, fungicide, bactericide, tuberculocide, and sporicide) indicate agents that destroy the specific microorganism identified by the prefix. Germicides can be used to inactivate microorganisms in or on living tissue (antiseptics), or on environmental surfaces (disinfectants).
<i>Log reduction</i>	Log reduction refers to the killing of microorganisms in a standardized test. A single log reduction describes the reduction of microorganisms by a factor of 10, or the reduction from 1,000 microorganisms to 100.
<i>Microbial load</i>	Number of viable organisms in or on an object or surface or organic material on a surface or object before decontamination or sterilization.
<i>P-value</i>	Indicates the probability that the result obtained in a statistical test is due to chance rather than a true relationship between measures. A small p-value, generally less than 0.05, or $p < 0.05$ , indicates that it is very unlikely that the results are due to chance.
<i>Pathogen</i>	A specific causative agent of disease, such as a bacteria, virus or fungus.
<i>Spore</i>	A small, usually single-celled reproductive body that is highly resistant to desiccation and heat and is capable of growing into a new organism, produced especially by certain bacteria, fungi, algae, and nonflowering plants. A dormant nonreproductive body formed by certain bacteria in response to adverse environmental conditions.
<i>Wound debridement</i>	Surgical removal of dead, devitalized or contaminated tissue and removal of foreign matter from a wound.

## MANAGEMENT

## Executive Officers, Key Employees and Directors

The following table shows information about our executive officers, key employees and directors as of October 31, 2006:

Name	Age	Position(s)
Hojabr Alimi	46	Chief Executive Officer, President and Chairman of the Board
Michael Wokasch	55	Chief Operating Officer
Robert Miller	64	Chief Financial Officer
James Schutz	43	Vice President of Corporate Development, General Counsel, Corporate Secretary and Director
Theresa Mitchell <sup>(1)</sup>	56	Vice President of Regulatory, Clinical Affairs, Quality Assurance and Research and Development
Bruce Thornton	42	Vice President of International Operations and Sales
Robert Northey, Ph.D.	49	Director of Research and Development
Andres Gutiérrez, M.D., Ph.D.	45	Director of Medical Affairs
Gerard de Nies	42	Director of Marketing and Sales-Europe, Middle East and Africa of Oculus Innovative Sciences Netherlands
Sergio Caletti	41	Commercial Director of Oculus Technologies of Mexico
Akihisa Akao	52	Director
Edward Brown <sup>(4)</sup>	42	Director
Richard Conley <sup>(2)(3)(4)</sup>	55	Director
Gregory French <sup>(2)(3)(4)</sup>	45	Director
Robert Burlingame	72	Director

(1) Resignation tendered effective January 2, 2007, at which time we anticipate that Ms. Mitchell will transition to a consulting role with us, the terms of which are yet to be determined.

(2) Member of the audit committee

(3) Member of the compensation committee

(4) Member of the nominating and corporate governance committee

*Hojabr Alimi*, one of our founders, has served as our Chief Executive Officer, President and director since 1999 and was appointed as Chairman of the board of directors in June 2006. Prior to co-founding our company with his spouse in 1999, Mr. Alimi was a Corporate Microbiologist for Arterial Vascular Engineering. Mr. Alimi received a B.A. in biology from Sonoma State University.

*Michael Wokasch* has served as our Chief Operating Officer since June 2006. From July 2004 to May 2006, Mr. Wokasch served as Senior Vice President Global Commercial Operations for the Biopharmaceuticals division of Chiron Corporation, a biotechnology company. He served as Chief Operating Officer of Impax Laboratories, a pharmaceutical company, from January 2003 to June 2004. Prior to Impax, Mr. Wokasch served as President of PanVera Corporation and then Aurora Biosciences Corporation, both drug discovery subsidiary companies of Vertex Pharmaceuticals, from July 2001 to December 2002, and as Chief Executive Officer of Gala Design, a biotechnology company, from June 2000 to July 2001. Prior to this, Mr. Wokasch also served as a President and Corporate Senior Vice President at Covance from 1997 to 1999, a contract research organization. In this capacity, Mr. Wokasch managed the global Early Development operations at Covance responsible for providing drug development services including preclinical toxicology, bioanalytical chemistry, regulatory, and Phase I clinical services to pharmaceutical and biotechnology companies. Prior to

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this, he held sales and marketing positions at Abbott Laboratories, Merck & Co., and Miles Inc. Mr. Wokasch received a B.S. from the University of Minnesota, College of Pharmacy.

*Robert Miller* has served as our Chief Financial Officer since June 2004 and was a consultant to us from March 2003 to May 2004. Mr. Miller has served as a director of Scanis, Inc. since 1998 and served as acting Chief Financial Officer from 1998 to June 2006. He was a Chief Financial Officer consultant to Evit Labs from June 2003 to December 2004, Wildlife International Network from October 2002 to December 2005, Endoscopic Technologies from November 2002 to March 2004, Biolog from January 2000 to December 2002 and Webware from August 2000 to August 2002. Prior to this, Mr. Miller was the Chief Financial Officer for GAF Corporation, Penwest Ltd. and Bugle Boy and Treasurer of Mead Corporation. He received a B.A. in economics from Stanford University and an M.B.A. in finance from Columbia University.

*James Schutz* has served as our Vice President of Corporate Development and General Counsel since August 2003, as a director since May 2004 and Corporate Secretary since June 2006. From August 2001 to August 2003, Mr. Schutz served as General Counsel at Jomed (formerly EndoSonic Corp.), an international medical device company. From 1999 to July 2001, Mr. Schutz served as in-house counsel at Urban Media Communications Corporation, an Internet/telecom company based in Palo Alto, California. Mr. Schutz received a B.A. in economics from the University of California, San Diego and a J.D. from the University of San Francisco School of Law.

*Theresa Mitchell* has served as our Vice President of Regulatory, Clinical Affairs, Quality Assurance and Research and Development since March 2005. Ms. Mitchell has tendered her resignation effective January 2, 2007, at which time we anticipate that she will transition to a consulting role with us on terms that are not yet determined. Prior to joining us, Ms. Mitchell took a sabbatical following her service as Vice President, Regulatory and Clinical Affairs and Quality Assurance at Oratec Interventions, Inc., a medical device company, from December 1998 to December 2003. She has held senior regulatory and clinical positions at Target Therapeutics, Fidus Medical, General Surgical Innovations and Advanced Cardiovascular Systems. Ms. Mitchell received a B.A. in experimental psychology/biostatistics and an M.A. in liberal arts from California State University, San Francisco.

*Bruce Thornton* has served as our Vice President of International Operations and Sales since June 2005. Mr. Thornton served as our General Manager for U.S. Operations from March 2004 to July 2005. He served as Vice President of Operations for Jomed (formerly EndoSonic Corp.) from January 1999 to September 2003, and as Vice President of Manufacturing for Volcano Therapeutics, an international medical device company, following its acquisition of Jomed, until March 2004. Mr. Thornton received a B.S. in aeronautical science from Embry-Riddle Aeronautical University and an M.B.A. from National University.

*Robert Northey, Ph.D.* has served as our Director of Research and Development since July 2005. Dr. Northey served as a consultant to us from May 2001 to June 2005. From August 1998 until June 2005, he was an Assistant Professor in the Paper Science and Engineering Department at the University of Washington. Dr. Northey received a B.S. in wood and fiber science and a Ph.D. in wood chemistry, each from the University of Washington.

*Andres Gutiérrez, M.D., Ph.D.* has served as our Director of Medical Affairs since August 2005. Dr. Gutiérrez served as a consultant to us from April 2003 to July 2005. He served as the Head of the Cell Therapy Unit at the National Institute of Rehabilitation in Mexico City from September 2000 to July 2005 and as a consulting physician with the Department of Medicine at Hospital Angeles del Pedregal in Mexico City from 1996 to July 2005. He received an M.D. with a specialty in internal medicine, and a Ph.D. in biomedical sciences, each from the National University of Mexico in Mexico City.

*Gerard de Nies* has served as Director of Marketing and Sales - Europe, Middle East and Africa of our Netherlands subsidiary, since August 2005. Mr. de Nies held a similar position in Kimberly-Clark for the Scientific & Industrial division, where he was responsible for sales and marketing in Europe from July 1999 through August 2005. He was the Sales Manager in the Ethicon Endo-Surgery division of Johnson & Johnson from June 1993 to July 1999. Mr. de Nies received a Bachelor of nursing and of healthcare management, each from the University of Amsterdam, The Netherlands.

*Sergio Caleti* has served as Commercial Director for our Mexican subsidiary since February 2005. Mr. Caleti served as the Mexico National Sales Manager of Darier Laboratories, a dermatological laboratory, from July 2003 to January 2005. He served as the Regional Sales Manager, Hospital Products Division for the central region for Abbott Laboratories from 1999 until June 2003. Mr. Caleti received an engineering degree from the Engineering School of Universidad Iberoamericana, Mexico.

*Akihisa Akao* has served as a director since 1999 and as a consultant since October 2005. Mr. Akao has served as President for White Moon Medical, Inc., a consulting company that provides advice to early-stage companies seeking to enter the Japanese medical products market. He served as the general manager in Japan at PowerMedical Interventions Inc., a medical device company, from January 2001 to September 2005. He also served as President of E-Med Japan, an application service provider for medical professionals and consumers, from 1999 to July 2000. Mr. Akao received a B.A. in electronic engineering from Doshisha University, Kyoto, Japan.

*Edward Brown* has served as a director since September 2005. Mr. Brown is co-founder of Healthcare Investment Partners, or HIP, a private equity buyout fund focused exclusively on healthcare, and has served as a Managing Director of HIP since June 2004. Before joining HIP, Mr. Brown was a Managing Director in the Healthcare Group of Credit Suisse First Boston, where he led the firm's West Coast healthcare effort and was one of the senior partners responsible for the firm's global life sciences practice, from August 2000 to June 2004. Mr. Brown serves on the board of directors of Angiotech Pharmaceuticals, Inc. Mr. Brown received an A.B. in English from Middlebury College.

*Richard Conley* has served as a director since 1999, and served as our Secretary from July 2002 to June 2006. Since April 2001, Mr. Conley has served as Executive Vice President and Chief Operating Officer at Don Sebastiani & Sons International Wine Negotiants, a branded wine marketing company. From 1994 to March 2001, he served as Senior Vice President and Chief Operating Officer at Sebastiani Vineyards, a California wine producer, where he was originally hired as Chief Financial Officer in 1994. Mr. Conley received a B.S. in finance and accounting from Western Carolina University and an M.B.A. from St. Mary's University.

*Gregory French* has served as a director since 2000. Mr. French is owner and Chairman of the Board of G&C Enterprises LLC, a real estate and investment company, which he founded in 1999. He held various engineering and senior management positions at several medical device companies, including Advanced Cardiovascular Systems, Peripheral Systems Group and Arterial Vascular Engineering. Mr. French received a B.S.I.E. from the California State Polytechnic University, San Luis Obispo.

*Robert Burlingame* has served as a director since November 2006. Mr. Burlingame is the Chief Executive Officer and Chairman of the Board of Burlingame Industries, Inc., a manufacturer of automated equipment specializing in the concrete roof tile industry, which he founded in 1969. He has held various senior management positions at several roof tile companies, including California Tile and Lifetile Corporation. Mr. Burlingame received a B.S. in business from Michigan State University and was a pilot in the U.S. Navy.

#### **Board of Directors**

Our board of directors currently consists of seven members. We are actively seeking two additional independent board members, in order to achieve a majority of independent directors on our board of directors. All directors are elected to hold office until their successors have been elected and qualified or until the earlier of death, resignation or removal. The authorized number of directors may be changed by resolution duly adopted by the board of directors. Vacancies on the board can be filled by resolution of the board of directors. Each of Messrs. Brown, Conley and French are independent directors as defined by Rule 4200(a)(15) of the National Association of Securities Dealers listing standards.

#### **Board Committees**

Our board of directors currently has an audit committee, compensation committee and nominating and corporate governance committee, which have the composition and responsibilities described below. As of the

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completion of this offering, we expect that all of the members of our committees will be independent directors under the rules of the SEC and the Nasdaq Stock Market.

*Audit Committee.* The audit committee provides assistance to the board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by:

- appointing, retaining, determining compensation and overseeing our independent accountants;
- ensuring that our accountants are independent from management;
- approving the services performed by our independent accountants;
- reviewing our independent accountants' reports regarding our accounting policies and systems of internal controls;
- reviewing compliance with legal and regulatory requirements; and
- ensuring the integrity of our financial statements.

Our audit committee presently consists of Messrs. Conley and French. Following this offering, we expect that our audit committee will consist of Messrs. Conley and French and one additional independent director, with Mr. Conley serving as Chairman of the Committee. Each member of the audit committee is able to read and understand fundamental financial statements, including our balance sheet, income statement and cash flow statements. Our board of directors has determined that Mr. Conley is an audit committee financial expert as currently defined under the rules of the SEC. We believe that the composition of our audit committee meets the criteria for independence under, and the functioning of our audit committee complies with the requirements of, the Sarbanes Oxley Act of 2002, the rules of the Nasdaq Stock Market and SEC rules and regulations. Our board of directors has approved and adopted a written charter for the audit committee.

*Compensation Committee.* The compensation committee performs the following functions, among others, as set forth in its committee charter:

- determining our general compensation policies and the compensation of our directors and officers;
- reviewing and approving bonuses for our officers and other employees;
- reviewing and determining equity based compensation for our directors, officers, employees and consultants;
- administering our stock option plans and employee stock purchase plans;
- reviewing corporate goals and objectives relative to executive compensation; and
- evaluating our chief executive officer's performance and setting our chief executive officer's compensation.

The compensation committee historically has established our chief executive officer compensation. Our compensation committee presently consists of Messrs. Conley and French. Following this offering, we expect that our compensation committee will be comprised of Messrs. Conley and French and one additional independent director, with Mr. French serving as Chairman of the Committee. Each member is and will be an outside director as currently defined in Section 162(m) of the Internal Revenue Code of 1986 and a non-employee director within the current meaning of Rule 16b-3 as promulgated under the Securities Exchange Act of 1934. We believe that the composition of our compensation committee meets the criteria for independence under, and the functioning of our compensation committee complies with the applicable requirements of, the Nasdaq Stock Market.

*Nominating and Corporate Governance Committee.* The nominating and corporate governance committee performs the following functions, among others, as set forth in its committee charter:

- evaluating and recommending to the full board of directors candidates for directorship and the size and composition of the board;

- recommending members of the board of directors to serve on the various committees of the board of directors;
- overseeing our corporate governance guidelines;
- developing plans for chief executive officer succession; and
- reporting and making recommendations to the board concerning corporate governance matters and recommending a code of conduct for our directors, officers and employees.

Our nominating and corporate governance committee consists of Messrs. Brown, Conley and French, with Mr. Brown serving as Chairman of the Committee. We believe that the composition of our nominating and corporate governance committee meets the criteria for independence under the rules of the Nasdaq Stock Market and SEC rules and regulations.

#### **Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee is presently nor at any time has been one of our executive officers or employees. Mr. Conley served as our Secretary from July 2002 until June 2006 but he was not compensated for such service, other than as a member of our board of directors. No interlocking relationship exists, or has existed in the past, between our board or compensation committee and the board or compensation committee of any other company.

#### **Director Compensation**

We have agreements with each of our directors, including our employee directors, which provide for the grant of stock options as compensation for service on our board of directors. Pursuant to our agreements with each of Messrs. Alimi, Akao, Conley and French, we granted to each of these directors an option to purchase 19,570 shares of our common stock, which represented 0.5% of the then outstanding shares of our common stock, and granted Mr. Schutz an option to purchase 6,250 shares of our common stock, each with an exercise price of \$3.00 per share. We granted an option to purchase 50,000 shares of our common stock to Mr. Brown pursuant to his agreement with an exercise price of \$10.16 per share. All unvested shares underlying the options mentioned above will vest in full upon completion of this offering. We also granted Messrs. Alimi and Schutz options to purchase 12,500 shares and 6,250 shares, respectively, of our common stock with an exercise price of \$10.16 per share. The director options granted to Messrs. Alimi and Schutz vest as to 20% of the shares on each of the first five anniversaries of the grant date. In addition, we reimburse our non-employee directors for reasonable out-of-pocket expenses incurred on our behalf. Mr. Brown's option vests as to 20% of the shares on the first anniversary of the grant date and as to  $\frac{1}{60}$  each month thereafter until fully vested. We also granted an option to purchase 75,000 shares of our common stock to Mr. Burlingame, with an exercise price of \$13.00 per share, which was fully vested upon grant.

**Executive Compensation**

The following table summarizes all compensation paid to our chief executive officer and to our four other most highly compensated executive officers whose total annual salary and bonus exceeded \$100,000 for all services rendered in all capacities to us during the fiscal year ended March 31, 2006. We refer to these individuals as our named executive officers. The compensation described in this table does not include medical, group life insurance or other benefits which are generally available to all of our salaried employees.

**Summary Compensation Table**

Name and Position(s)	Annual Compensation		Long-Term Compensation	All Other Compensation (\$)
	Salary (\$)	Bonus (\$)	Shares Underlying Options (#)	
Hojabr Alimi President and Chief Executive Officer	\$262,885	\$ 26,250	12,500	\$ 4,517 <sup>(1)</sup>
Robert Miller Chief Financial Officer	183,038	1,250	6,250	—
James Schutz Vice President of Corporate Development, General Counsel and Corporate Secretary	185,961	1,250	6,250	6,246 <sup>(2)</sup>
Theresa Mitchell Vice President of Regulatory, Clinical Affairs, Quality Assurance and Research and Development	170,077	6,250	100,624	—
Bruce Thornton Vice President of International Operations and Sales	171,851	1,250	90,624	5,042 <sup>(3)</sup>

(1) Consists of \$350 for IRA contributions and \$4,167 for life insurance premiums.

(2) Consists of \$5,486 for IRA contributions and \$760 for life insurance premiums.

(3) Consists of IRA contributions.

(4) Resignation tendered effective January 2, 2007, at which time it is anticipated that Ms. Mitchell will transition to a consulting role with us on terms which are not yet determined.



**Options/SAR Grants Table**

The following table set forth certain information for the year ended March 31, 2006 with respect to stock options granted to our named executive officers. The percentage of total options granted is based on an aggregate of 629,498 options granted to employees in the year ended March 31, 2006.

Name	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(4)	
	Number of Shares Underlying Options Granted(1)	% of Total Options Granted to Employees in 2006	Exercise Price Per Share(2)	Expiration Date(3)	5% (\$)	10% (\$)
Hojabr Alimi	12,500	2.0%	\$ 10.16	10/1/2015	\$131,437	\$ 275,236
Robert Miller	6,250	1.0	10.16	10/1/2015	65,719	137,618
James Schutz	6,250	1.0	10.16	10/1/2015	65,719	137,618
Theresa Mitchell	50,000	7.9	4.40	4/1/2015	788,768	1,313,867
	50,624	8.0	10.16	10/1/2015	532,310	1,114,683
Bruce Thornton	20,000	3.2	4.40	5/6/2015	317,399	531,180
	70,624	11.2	10.16	10/1/2015	742,609	1,555,061

- (1) The options become exercisable as to 20% of the shares on each of the first five anniversaries of the grant date.
- (2) The exercise price is the fair market value of our common stock on the date of grant, as determined by our board of directors.
- (3) The options have a term of ten years, subject to earlier termination upon the occurrence of certain events related to termination of service or employment. Vesting of the options is subject to acceleration under certain circumstances described under "Director Compensation" and "Employment, Severance and Change of Control Arrangements."
- (4) The 5% and 10% assumed rates of appreciation are required by the rules of the SEC and do not represent our estimate or projection of the future common stock price. There can be no assurance that any of the values reflected in the table will be achieved.

**Aggregated Option/SAR Exercises in Last Fiscal Year and Fiscal Year-End Option/SAR Values**

The following table shows information concerning the number and value of unexercised options held by each of the named executive officers at March 31, 2006. There was no public trading market for our common stock as of March 31, 2006. Accordingly, as permitted by the rules of the Commission, we have calculated the value of unexercised in-the-money options at fiscal year-end assuming that the fair market value of our common stock as of March 31, 2006 was equal to the initial public offering price of \$13.00, which is the midpoint of the range set forth on the cover of the prospectus, less the aggregate exercise price.

Name	Shares Acquired on Exercise	Value Realized	Number of Securities Underlying Unexercised Options at		Value of Unexercised In-the-Money Options/SARs at Fiscal Year-End (\$)	
			Fiscal Year-End (#)		Exercisable	Unexercisable
			Exercisable	Unexercisable		
Hojabr Alimi	—	—	414,828	27,242	\$ 5,287,230	\$ 182,920
Robert Miller	60,000	—	73,814	6,250	738,140	17,750
James Schutz	—	—	48,750	101,250	487,500	967,750
Theresa Mitchell	—	—	10,000	90,624	86,000	487,772
Bruce Thornton	—	—	4,000	96,624	40,000	432,572

**Employment, Severance and Change of Control Arrangements**

We have entered into employment agreements with each of Hojabr Alimi, Michael Wokasch, Robert Miller, James Schutz, Theresa Mitchell and Bruce Thornton. In the event Mr. Alimi, Mr. Wokasch, Mr. Miller or Mr. Schutz is terminated without cause or resigns for good reason, upon satisfaction of certain requirements, including executing a general release of claims against us, the officer is entitled to accrued but unpaid salary (including vacation pay), reimbursement of any outstanding business expenses, a lump severance payment equal to 12 times in the case of Mr. Wokasch, 18 times in the case of Mr. Miller and Mr. Schutz, or 24 times in the case of Mr. Alimi, the average monthly base salary paid to the officer over the preceding 12 months (or for the term of the officer's employment if less than 12 months), automatic vesting of all unvested options and other equity awards, the extension of exercisability of all options and other equity awards to at least 12 months following the date the officer terminates employment or, if earlier, until the option expires, up to one year reimbursement for health care premiums and a full gross up of any excise taxes payable by the officer under Section 4999 of the Internal Revenue Code because of the foregoing payments and acceleration (including the reimbursement of any additional federal, state and local taxes payable as a result of the gross up). If any officer terminates his or her employment for any reason, he or she must give us at least 30 days', or in the case of Mr. Alimi, at least 60 days' prior written notice.

*Hojabr Alimi.* Our agreement with Mr. Alimi, dated January 1, 2004, provides for an annual salary of \$225,000, which amount may be increased by our board of directors. Separately, we granted Mr. Alimi an option to purchase 19,570 shares of our common stock for service as a director at an exercise price of \$3.00 per share, which vests at a rate of 20% per year from the date of grant with accelerated vesting in full upon completion of this offering.

*Michael Wokasch.* Our agreement with Mr. Wokasch, dated June 10, 2006, provides for an annual salary of \$200,000. In connection with Mr. Wokasch's agreement, we granted him an option to purchase 125,000 shares of our common stock on July 27, 2006, at an exercise price of \$12.00 per share, which will vest over five years from the date of grant. We will also grant Mr. Wokasch an annual bonus of \$100,000 upon meeting certain milestones. Separate from this agreement, we paid Mr. Wokasch a one-time signing bonus of \$25,000.

*Robert Miller.* Our agreement with Mr. Miller, dated June 1, 2004, provides for an annual salary of \$165,000. In connection with this agreement, we granted Mr. Miller an option to purchase 94,633 shares of our common stock, which vested immediately based on Mr. Miller's prior consultant work for us, and an option to purchase an additional 39,181 shares of our common stock, which vests based on Mr. Miller's hours

of service. Upon completion of this offering, we will grant Mr. Miller an additional fully-vested option to purchase 60,000 shares of our common stock. All of these options have, or will have, an exercise price of \$3.00 per share.

*James Schutz.* Our agreement with Mr. Schutz, dated January 1, 2004, provides for an annual salary of \$165,000, which amount may be increased by our board of directors, and an option to purchase 37,500 shares of our common stock at an exercise price of \$3.00 per share, which vests in five equal annual installments from the date of grant. Separately, we granted Mr. Schutz an option to purchase 6,250 shares of our common stock for service as a director, at an exercise price of \$3.00 per share, which vests at a rate of 20% per year from the date of grant with accelerated vesting in full upon completion of this offering.

*Theresa Mitchell.* Our agreement with Ms. Mitchell, dated March 23, 2005, provides for a salary of \$165,000, which amount may be increased by our board of directors. In connection with Ms. Mitchell's agreement, we also granted her an option to purchase 50,000 shares of our common stock, at an exercise price of \$4.40 per share, which vests in five equal annual installments from the date of grant. We must provide her with 12 months' notice if she is terminated without cause. During this 12-month period, we may provide Ms. Mitchell with continued salary payments as severance. In the event of a change of control of Oculus, if Ms. Mitchell is terminated, she is entitled to a lump sum severance payment equal to 12 months of her then base salary and all unvested options and other equity awards will immediately vest in full and remain exercisable for at least 12 months following her termination or, if earlier, the date the option or other equity award expires. Ms. Mitchell's agreement also provides her a full gross up of any excise taxes payable by Ms. Mitchell under Section 4999 of the Internal Revenue Code because of the foregoing payments and acceleration (including the reimbursement of any additional federal, state and local taxes payable as a result of the gross up). Ms. Mitchell has tendered her resignation effective January 2, 2007, at which time we anticipate she will assume a consulting role with us on terms not yet determined.

*Bruce Thornton.* Our agreement with Mr. Thornton, entered in June 2005, provides an annual salary of \$160,000, which amount may be increased by our board of directors. In connection with his agreement, we also granted him an option to purchase 20,000 shares of our common stock, at an exercise price of \$4.40 per share, which vests ratably over five years from the date of grant. We must provide him with six months' notice if he is terminated without cause. During this six-month period, we may provide Mr. Thornton with continued salary payments as severance. In the event of a change of control of Oculus, if Mr. Thornton is terminated, he is entitled to a lump sum severance payment equal to 12 months of his then base salary, and all unvested options and other equity awards will immediately vest in full and remain exercisable for at least 12 months following his termination or, if earlier, the date the option or other equity award expires. Mr. Thornton's agreement also provides him a full gross up of any excise taxes payable by Mr. Thornton under Section 4999 of the Internal Revenue Code because of the foregoing payments and acceleration (including the reimbursement of any additional federal, state and local taxes payable as a result of the gross up).

## **Equity Compensation Plans**

### ***1999 Stock Plan***

*General.* Our 1999 stock plan was adopted by our board of directors and approved by our shareholders in May 1999.

*Administration.* The compensation committee of our board of directors administers the 1999 stock plan. The 1999 stock plan provides for the granting of incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, or Section 422, to employees, officers and employee directors and the granting of nonstatutory stock options and stock purchase rights to employees, officers, directors (including non-employee directors) and consultants. The administrator determines to whom to grant options or stock purchase rights, the number of shares under the options or stock purchase rights, the exercise or purchase price, the fair market value of our common stock, the term of options, which is prohibited from exceeding 10 years (five years in the case of an incentive stock option granted to a shareholder holding more than 10% of the voting shares of our company, or 10% holders) and other terms and conditions. Under our 1999 stock plan, incentive stock options must be granted with an exercise price of at least 100% of the fair market value of our common stock on the date of grant, and

nonstatutory options must be granted with an exercise price of at least 85% of the fair market value of our common stock on the date of grant. Incentive stock options and nonstatutory stock options granted to 10% holders must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. To the extent an optionee would have the right in any calendar year to exercise for the first time one or more incentive stock options for shares having an aggregate fair market value in excess of \$100,000, any such excess options would be treated as nonstatutory stock options.

*Authorized Shares.* Under our 1999 Plan, we reserved 1,151,250 shares of our common stock for issuance. As of September 30, 2006, 473,650 shares of common stock remained available for future issuance under our 1999 stock plan. As of September 30, 2006, options to purchase a total of 418,500 shares of common stock were outstanding under the 1999 stock plan at a weighted average exercise price of \$0.44 per share. In June 2006, our board determined that no additional grants would be made under our 1999 stock plan.

*Plan Features.* Options granted under the 1999 stock plan generally vest at the rate of 20% of the total number of shares subject to the options on each anniversary of the vesting commencement date. No option may be transferred by the optionee other than by will or the laws of descent or distribution. Each option may be exercised during the lifetime of the optionee only by such optionee. Generally, options granted under the 1999 stock plan remain exercisable for 12 months following the termination of service of an optionee by reason of death or disability and remain exercisable for 3 months upon a termination of service for any other reason. The 1999 stock plan provides that in the event of a recapitalization, stock split or similar capital transaction, we will make appropriate adjustments in order to preserve the benefits of options outstanding under the plan. If we are involved in a merger or consolidation, options granted under the 1999 stock plan will fully vest immediately prior to the effective date of such transaction, unless the surviving or acquiring company assumes or substitutes an equivalent option or right for them.

#### **2000 Stock Plan**

*General.* Our 2000 stock plan was adopted by our board of directors in March 2000 and was subsequently approved by our shareholders in June 2000.

*Administration.* The compensation committee of our board of directors administers the 2000 stock plan. The 2000 stock plan provides for the granting of incentive stock options within the meaning of Section 422 to employees, officers and employee directors and the granting of nonstatutory stock options and stock purchase rights to employees, officers, directors (including non-employee directors) and consultants. The administrator determines to whom to grant options or stock purchase rights, the number of shares under the options or stock purchase rights, the exercise or purchase price, the fair market value of our common stock, the term of options, which is prohibited from exceeding 10 years (five years in the case of an incentive stock option granted to 10% holders) and other terms and conditions. Under our 2000 stock plan, incentive stock options must be granted with an exercise price of at least 100% of the fair market value of our common stock on the date of grant, and nonstatutory options must be granted with an exercise price of at least 85% of the fair market value of our common stock on the date of grant. Incentive stock options and nonstatutory stock options granted to 10% holders must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. To the extent an optionee would have the right in any calendar year to exercise for the first time one or more incentive stock options for shares having an aggregate fair market value in excess of \$100,000, any such excess options would be treated as nonstatutory stock options.

*Authorized Shares.* Under our 2000 stock plan, we reserved 348,750 shares of our common stock for issuance. As of September 30, 2006, 305,950 shares of common stock remained available for future issuance under our 2000 stock plan. As of September 30, 2006, options to purchase a total of 39,500 shares of common stock were outstanding under the 2000 stock plan at a weighted average exercise price of \$2.50 per share. In June 2006, our board determined that no additional grants would be made under our 2000 stock plan.

*Plan Features.* Options granted under the 2000 stock plan generally vest at the rate of 20% of the total number of shares subject to the options on each anniversary of the vesting commencement date. No option may be transferred by the optionee other than by will or the laws of descent or distribution. Each option may be exercised during the lifetime of the optionee only by such optionee. Generally, options granted under the

2000 stock plan remain exercisable for 12 months following the termination of service of an optionee by reason of death or disability and remain exercisable for 3 months upon a termination of service for any other reason. The 2000 stock plan provides that in the event of a recapitalization, stock split or similar capital transaction, we will make appropriate adjustments in order to preserve the benefits of options outstanding under the plan. If we are involved in a merger or consolidation, options granted under the 2000 stock plan will fully vest immediately prior to the effective date of such transaction, unless the surviving or acquiring company assumes or substitutes an equivalent option or right for them.

#### **2003 Stock Plan**

*General.* Our 2003 stock plan was adopted by our board of directors and approved by our shareholders in July 2003.

*Administration.* The compensation committee of our board of directors administers the 2003 stock plan. The 2003 stock plan provides for the granting of incentive stock options within the meaning of Section 422 to employees, officers and employee directors and the granting of nonstatutory stock options and stock purchase rights to employees, officers, directors (including non-employee directors) and consultants. The administrator determines to whom to grant options or stock purchase rights, the number of shares under the options or stock purchase rights, the exercise or purchase price, the fair market value of our common stock, the term of options, which is prohibited from exceeding 10 years (five years in the case of an incentive stock option granted to 10% holders) and other terms and conditions. Under our 2003 stock plan, incentive stock options must be granted with an exercise price of at least 100% of the fair market value of our common stock on the date of grant, and nonstatutory options must be granted with an exercise price of at least 85% of the fair market value of our common stock on the date of grant. Incentive stock options and nonstatutory stock options granted to 10% holders must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. To the extent an optionee would have the right in any calendar year to exercise for the first time one or more incentive stock options for shares having an aggregate fair market value in excess of \$100,000, any such excess options would be treated as nonstatutory stock options.

*Authorized Shares.* Under our 2003 stock plan, we have reserved 1,000,000 shares of our common stock for issuance. As of September 30, 2006, 656,720 shares of common stock remained available for future issuance under our 2003 stock plan. As of September 30, 2006, options to purchase a total of 321,452 shares of common stock were outstanding under the 2003 stock plan at a weighted average exercise price of \$3.00 per share. In June 2006, our board determined that no additional grants would be made under our 2003 stock plan.

*Plan Features.* Options granted under the 2003 stock plan generally vest at the rate of 20% of the total number of shares subject to the options on each anniversary of the vesting commencement date. No option may be transferred by the optionee other than by will or the laws of descent or distribution. Each option may be exercised during the lifetime of the optionee only by such optionee. Generally, options granted under the 2003 stock plan remain exercisable for 12 months following the termination of service of an optionee by reason of death or disability and remain exercisable for 3 months upon a termination of service for any other reason. The 2003 stock plan provides that in the event of a recapitalization, stock split or similar capital transaction, we will make appropriate adjustments in order to preserve the benefits of options outstanding under the plan. If we are involved in a merger or consolidation, options granted under the 2003 stock plan will fully vest immediately prior to the effective date of such transaction, unless the surviving or acquiring company assumes or substitutes an equivalent option or right for them.

#### **2004 Stock Plan**

*General.* Our 2004 stock plan was adopted by our board of directors and approved by our shareholders in July 2004.

*Administration.* The compensation committee of our board of directors administers the 2004 stock plan. The 2004 stock plan provides for the granting of incentive stock options within the meaning of Section 422 to employees, officers and employee directors and the granting of nonstatutory stock options to employees, officers, directors (including non-employee directors) and consultants. The administrator determines to whom

to grant options, the number of shares under the options, the fair market value of our common stock, the term of options, which is prohibited from exceeding 10 years (five years in the case of an incentive stock option granted to 10% holders) and other terms and conditions. Under our 2004 stock plan, incentive stock options must be granted with an exercise price of at least 100% of the fair market value of our common stock on the date of grant, and nonstatutory options must be granted with an exercise price of at least 85% of the fair market value of our common stock on the date of grant. Incentive stock options and nonstatutory stock options granted to 10% holders must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. No incentive stock option can be granted to an employee if as a result of the grant, the employee would have the right in any calendar year to exercise for the first time one or more incentive stock options for shares having an aggregate fair market value in excess of \$100,000.

*Authorized Shares.* Under our 2004 stock plan, we reserved 1,500,000 shares of our common stock for issuance. As of September 30, 2006, 394,189 shares of common stock remained available for future issuance under our 2004 stock plan. As of September 30, 2006, options to purchase a total of 1,045,811 shares of common stock were outstanding under the 2004 stock plan at a weighted average exercise price of \$8.54 per share. Our board determined that no additional grants under the 2004 stock plan will be made following the completion of this offering.

*Plan Features.* Options granted under the 2004 stock plan generally vest at the rate of 20% of the total number of shares subject to the options on each anniversary of the vesting commencement date. No option may be transferred by the optionee other than by will or the laws of descent or distribution. Each option may be exercised during the lifetime of the optionee only by such optionee. Generally, options granted under the 2004 stock plan remain exercisable for 6 months following the termination of service of an optionee by reason of death or disability and remain exercisable for between 30 days and 3 months upon a termination of service for any other reason. The exercise period for nonstatutory stock options may be extended for 6 months. An optionee must execute a shareholders agreement with us prior to the receipt of shares pursuant to the exercise of options granted under our 2004 stock plan. The 2004 stock plan provides that in the event of a recapitalization, stock split or similar capital transaction, we will make appropriate adjustments in order to preserve the benefits of options outstanding under the plan. If we are involved in a merger or consolidation, options granted under the 2004 stock plan will fully vest immediately prior to the effective date of such transaction, unless the surviving or acquiring company assumes or substitutes an equivalent option for them.

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

*General.* Our 2006 stock incentive plan was adopted by our board of directors in August 2006, subject to stockholder approval, and will become effective upon the completion of this offering.

The 2006 stock plan provides for the granting of incentive stock options within the meaning of Section 422 to employees and the granting of nonstatutory stock options to employees, non-employee directors, advisors, and consultants. The 2006 stock incentive plan also provides for grants of restricted stock, stock appreciation rights and stock units awards to employees, non-employee directors, advisors and consultants.

- *Stock Options.* The compensation committee, a plan administrator, determines to whom to grant awards, the number of shares under the awards, the fair market value of our common stock, the term of options, which is prohibited from exceeding 10 years (five years in the case of an incentive stock option granted to 10% holders) and other terms and conditions. Under our 2006 stock plan, incentive stock options must be granted with an exercise price of at least 100% of the fair market value of our common stock on the date of grant, and nonstatutory options must be granted with an exercise price of at least 85% of the fair market value of our common stock on the date of grant. Incentive stock options and nonstatutory stock options granted 10% holders must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. No incentive stock option can be granted to an employee if as a result of the grant, the employee would have the right in any calendar year to exercise for the first time one or more incentive stock options for shares having an aggregate fair market value in excess of \$100,000. The exercise price for the shares of common stock subject to option grants made under our 2006 stock plan may be paid in cash or in shares of our common stock held by the optionee. The option may be exercised through a same-day sale program without any cash outlay by the optionee. In addition, the administrator may provide

financial assistance to an optionee, provided such optionee is not an executive officer or board member, in the exercise of the optionee's outstanding options by allowing such individual to deliver a full-recourse, interest-bearing promissory note in payment of the exercise price and any associated withholding taxes incurred in connection with such exercise.

- *Restricted Stock.* Participants who are granted restricted stock awards generally have all of the rights of a stockholder with respect to such stock. Restricted stock may generally be subject to a repurchase right by us in the event the recipient ceases to be employed. Restricted stock may be issued for consideration determined by the compensation committee, including cash, promissory notes and past or future services. Restricted stock may be subject to vesting over time or upon achievement of milestones.
- *Stock Units.* Stock units are denominated in unit equivalent of shares of our common stock. They are typically awarded to participants without payment of consideration, but are subject to vesting conditions based upon a vesting schedule or performance criteria established by the plan administrator. Unlike restricted stock, the stock underlying stock units will not be issued until the stock units have vested, and recipients of stock units generally will have no voting or dividend rights prior to the time the vesting conditions are satisfied.
- *Stock Appreciation Rights.* Stock appreciation rights may be granted independently or in consideration of a reduction in the recipient's compensation. Stock appreciation rights typically will provide for payments to the holder based upon increases in the price of our common stock over the exercise price of the related option. The exercise price of a stock appreciation right will be determined by the committee and may vary in accordance with a predetermined formula while the stock appreciation right is outstanding. The plan administrator may elect to pay stock appreciation rights in cash or in common stock or in a combination of cash and common stock.

*Administration.* The compensation committee of our board of directors will administer the 2006 stock plan. Our board of directors may appoint one or more separate committees of our board of directors, each consisting of one or more members of our board of directors, to administer our 2006 stock plan with respect to participants other than employees who are subject to Section 16 of the Exchange Act. Our board of directors may also authorize one or more officers to designate employees, other than employees who are subject to Section 16 of the Exchange Act, to receive awards under our 2006 stock plan and/or to determine the number of such awards to be received by such employees subject to limits specified by our board of directors.

*Authorized Shares.* Under our 2006 stock plan, 1,250,000 shares of our common stock have been authorized for issuance. Shares subject to awards that expire unexercised or are forfeited or terminated will again become available for issuance under the 2006 stock plan. No participant in the 2006 stock plan can receive option grants, restricted shares, stock appreciation rights or stock units for more than 750,000 shares in the aggregate in any calendar year.

*Plan Features.* Under the 2006 stock plan:

- Generally, if we merge with or into another corporation, we may accelerate the vesting or exercisability of outstanding options and terminate any unexercised options unless they are assumed or substituted for by any surviving entity or a parent or subsidiary of the surviving entity.
- The administrator may permit or require a participant to have cash otherwise payable to a participant on exercise of a stock appreciation right or settlement of stock units credited to a deferred compensation account, have shares that would otherwise be deliverable to a participant on exercise of an option or stock appreciation right converted into an equal number of stock units or have shares otherwise deliverable upon exercise of an option or stock appreciation right or settlement of stock units converted into amounts credited to a deferred compensation account.
- Awards under our 2006 stock plan may provide that the number of shares of our common stock or other benefits granted, issued, retained or vested under the award are subject to the attainment of performance criteria including cash flow, earnings per share, earnings before interest, taxes and amortization, return on equity, total stockholder return, share price performance, return on capital, return on assets or net assets, revenue, income or net income, operating income or net operating income, operating profit or net operating profit, operating margin or profit shares. The administrator

may structure such awards to be qualified performance-based compensation under Section 162(m) of the Code.

- The 2006 stock plan terminates ten years after its initial adoption, unless terminated earlier by the board. The board of directors may amend or terminate the plan at any time, subject to stockholder approval where required by applicable law. Any amendment or termination may not impair the rights of holders of outstanding awards without their consent.

***SIMPLE IRA Plan***

We sponsor a SIMPLE IRA plan under which employees may choose to make salary reduction contributions, and we make matching contributions up to 3% of the employee's compensation for the year. All contributions are made directly to an individual retirement account established for each employee.

**Indemnification Agreements**

We intend to enter into agreements to indemnify our directors and executive officers following our reincorporation in Delaware. We believe that these agreements are necessary to attract and retain qualified persons as directors and executive officers. Our certificate of incorporation and our bylaws contain provisions that limit the liability of our directors and executive officers to the fullest extent permitted by Delaware law. A description of these provisions is contained under the heading "Description of Common Stock — Limitation of Liability and Indemnification Matters."

We have an insurance policy covering our directors and officers with respect to specified liabilities, including liabilities arising under the Securities Act, or otherwise. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to cover directors, officers and persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**Advisory Boards**

We have two advisory boards: Medical and Business Advisory Board and Clinical Investigational Board. We rely extensively on our physician advisors to advise on marketing and research and development efforts and provide information and data on the clinical use of our products. At least once per year we meet with each advisory board and each member is available to us as needed.

Our Medical and Business Advisory Board assists us in the following:

- prioritizing medical markets in terms of where our product can be the most effective, the speed with which they can be introduced and the scope of the problem in the market;
- prioritizing physician clinical studies;
- identifying clinical studies to be pursued;
- providing introductions to wound care specialists in the United States and Europe;
- advising regarding the success of our products in various market segments;
- reviewing and commenting on the specific protocols being considered;
- providing guidance on how best to educate and encourage the medical community to adopt our product as the standard of care in wound management;
- providing input to potential collaborators on the application and effectiveness of our products; and
- participating in physician clinical studies and presenting the results to other physicians.



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Our Medical and Business Advisory Board is currently comprised of the following individuals:

<u>Name</u>	<u>Specialty</u>	<u>Position</u>
Don C. Wukasz, M.D.	Cardiovascular Surgery	Fellow, American College of Surgeons and American College of Cardiology
Barnett L. Cline, M.D. M.P.H., Ph.D.	Tropical Medicine	Tulane University Professor of Tropical Medicine, Emeritus; member, Armed Forces Epidemiological Board
Paul L. Schnur, M.D.	Plastic and Reconstructive Surgery	Consultant, Plastic Surgery Division, Mayo Clinic Scottsdale; Associate Professor, University of Arizona, College of Medicine
Bruce C. Wilson, M.D., F.A.C.C.	Cardiology	Fellow, American College of Cardiology; Chairman, Heart Hospital of Milwaukee; Assistant Professor of Medicine, Medical College of Wisconsin
Gerald L. Woolam, M.D.	General Surgery	Professor of Surgery, Texas Tech University
Philip J. Kearney	Legal	Assistant United States Attorney
David E. Allie, M.D.	Cardiothoracic and Endovascular Surgery	Chief of Cardiothoracic and Endovascular Surgery, Cardiovascular Institute of the South Lafayette; Director, Vascular Surgery and Noninvasive Vascular Labs Houma
Luca Dalla Paola, M.D.	Endocrinologist and Surgery	Chief of the Diabetic Foot Unit of Presidio Ospedaliero Abano Terme Hospital; Professor, Bologna University School of Medicine

Our Clinical Investigational Board assists us by introducing us to practicing physicians and key opinion leaders in our target markets and reviewing physician clinical studies. The Clinical Investigational Board is currently comprised of the following individuals:

<u>Name</u>	<u>Specialty</u>	<u>Position</u>
Gerald Keusch, M.D.	Infectious Disease	Associate Dean of Global Health, Professor of Medicine, Boston University
Richard Marks, M.D.	Foot and Ankle Surgery	Associate Professor of Orthopedic Surgery, Medical College of Wisconsin
Akito Ohmura, M.D., Ph.D.	Anesthesiology	Head of Medical ISO Committee Japan; Dean, Teikyo University School of Medicine

All of our physician advisors serve one or five-year terms. All of our physician advisors are employed by employers other than us and may have commitments or consulting arrangements with other companies, including our competitors, that may limit their availability to consult for us. Although these advisors may contribute significantly to our affairs, we generally do not expect them to devote more than a small portion of their time to us.

**Advisory Board Compensation**

In consideration of the services provided, we pay each of the members on the Medical and Business Advisory Board a quarterly stipend, except for Dr. Allie and Mr. Kearney. Drs. Cline, Schnur, Woolam, Dalla Paola and Wilson each receive \$3,000 per quarter and Dr. Wukasz receives \$6,000 per quarter. We also have a consulting agreement with Dr. Wilson and pay him an additional \$12,000 per quarter pursuant to this agreement. Although Dr. Allie does not receive a quarterly stipend, we paid Dr. Allie \$10,000 and issued him 12,500 shares of our common stock as payment for our participation in the 2005 New Cardiovascular Horizons Conference, of which Dr. Allie served as conference co-chairman. In addition, we granted each of our

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physician advisors, except for Dr. Dalla Paola, warrants to purchase shares of our common stock with a conversion price of \$18.00 per share. Dr. Allie has a warrant to purchase 2,500 shares, Drs. Cline, Schnur, Wilson and Woolam each have a warrant to purchase 3,750 shares, and Dr. Wukasch has a warrant to purchase 6,250 shares. We also compensate our Medical Advisory Board members for physician clinical studies they conduct for us.

We do not provide cash compensation to members of our Clinical Investigation Board. However, we granted Drs. Keusch and Marks each a warrant to purchase 2,500 shares with a conversion price of \$18.00 per share. We also granted Dr. Ohmura an option to purchase 2,500 shares of our common stock with an exercise price of \$3.00 per share. This option will not vest fully until October 2008.

## RELATED PARTY TRANSACTIONS

We issued promissory notes to Akihisa Akao, one of our directors, in May 1999, December 1999 and February 2003 in the amount of \$15,000 bearing interest at a rate of 8% per annum, \$200,000 bearing interest at a rate of 8% per annum, and \$40,000 bearing interest at a rate of 10% per annum, respectively. These obligations were repaid in October 2004.

We entered into a consulting agreement with White Moon Medical, a company formed under the laws of Japan, in October 2005, which was renewed for an additional one-year term expiring in October 2007. Mr. Akihisa Akao is the sole stockholder of White Moon Medical. Under the terms of the agreement, White Moon Medical provides us with merger and acquisition strategy and technology support in Asia, particularly in Japan. We have agreed to pay White Moon Medical an annual consulting fee of \$146,000, and White Moon Medical is also eligible for additional bonuses. This agreement may be terminated by either party upon 30 days' written notice. Payments to White Moon Medical through September 30, 2006 amounted to \$146,000.

We entered into a consulting agreement with Mr. Robert Burlingame, one of our directors, in November 2006. Under the terms of the agreement, Mr. Burlingame provides us with consulting services relating to global planning and implementation of key performance indicators to track progress of company-wide projects. In return for his services, we have issued to Mr. Burlingame a warrant to purchase 75,000 shares of our common stock at an exercise price of \$13.00 per share.

We issued a promissory note to Richard Conley, one of our directors, in February 2003 in the amount of \$40,000 bearing interest at a rate of 10% per annum. This note was convertible at any time by Mr. Conley into 10,000 shares of either our common stock or Series A preferred stock. On June 30, 2005, Mr. Conley converted this note into an aggregate of 10,000 shares of our Series A preferred stock at a conversion price of \$4.00 per share.

We issued a promissory note to Mr. Burlingame, one of our directors, in November 2006 in the amount of \$4.0 million, bearing interest at a rate of 7% per annum. This obligation matures on the earlier of November 10, 2007 or five days after the consummation of our initial public offering resulting in gross proceeds to us of at least \$30.0 million. The loan is secured by all of our assets, other than our intellectual property, but is subordinate to the security interest held by our secured lender.

In accordance with the terms of the underlying option agreements, the vesting of options to purchase 85,062 shares of our common stock granted to our directors will be accelerated upon completion of this offering. Please see "Management — Director Compensation" for information on options granted to our directors.

In connection with the termination of Robert Miller's prior consulting agreement, we have agreed to grant him a fully-vested option to purchase 60,000 shares of our common stock at \$3.00 per share upon completion of this offering. Assuming an initial public offering price of \$13.00, we would recognize approximately \$600,000 of stock-based compensation expense related to this option grant.

Brookstreet also acted as managing dealer in the sale of our Series A convertible preferred stock and our Series B convertible preferred stock. In connection with the Series A convertible preferred stock offering, we paid Brookstreet \$1,123,746 in commissions and issued Brookstreet and its affiliates warrants to purchase an aggregate of 433,774 shares of our common stock, at an exercise price of \$3.00 per share. In connection with the Series B convertible preferred stock offering, we paid Brookstreet \$3,413,818 in commissions and issued Brookstreet and its affiliates warrants to purchase an aggregate of 329,471 shares of our common stock at an exercise price of \$18.00 per share.

We entered into a managing dealer agreement, as amended, with Brookstreet, a holder of more than 5% of our voting securities in May 2006, pursuant to which Brookstreet acted as managing dealer, on a best-efforts basis, for the sale of units of our securities. Each unit consisted of one share of our Series C convertible preferred stock, and a warrant to purchase that number of shares of our common stock equal to one-fifth of the number of Series C shares underlying the unit, at an exercise price of \$18.00 per share. In connection with

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the Series C Financing, we paid to Brookstreet \$347,444 in commissions and issued to Brookstreet fully vested warrants to purchase an aggregate of 24,127 shares of our common stock, at an exercise price of \$18.00 per share. In addition, we paid Brookstreet \$10,000 upon the execution of a term sheet regarding the terms of this offering, and an additional \$10,000 on May 31, 2006, to defray the costs associated with the solicitation of stockholder approval.

Brookstreet also acted as a finder in connection with the Bridge Loan, which we entered into in November 2006. At the time the principal is advanced to us, Brookstreet will be paid a fee in the amount of \$50,000 and will be granted a warrant to purchase 25,000 shares of our common stock at an exercise price of \$18.00 per share.

Please see “Management — Executive Compensation” for additional information on compensation of our executive officers and “Management — Employment, Severance and Change of Control Arrangements” for additional information regarding employment arrangements with our executive officers.

Our certificate of incorporation that will be in effect upon completion of this offering and our reincorporation in Delaware provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we intend to enter into indemnification agreements with our directors and executive officers in connection with our reincorporation in Delaware. Please see “Description of Common Stock — Limitations of Liability and Indemnification Matters” for further details.

**PRINCIPAL STOCKHOLDERS**

The following table sets forth information as of October 31, 2006 regarding the number of shares and the percentage of common stock beneficially owned before and after the completion of this offering by:

- each of our directors and named executive officers listed above in the summary compensation table; and
- all of our directors and executive officers as a group.

We are not aware of any owners of more than 5% of our common stock other than Messrs. Alimi and Akao and Brookstreet Securities Corporation. We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

For purposes of the table below, we have assumed that 8,399,209 shares of common stock are issued and outstanding prior to the completion of this offering and 11,476,132 shares of common stock issued and outstanding upon completion of this offering. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to all derivative securities held by that person that are currently exercisable or exercisable within 60 days of October 31, 2006 and shares of common stock subject to options that vest upon completion of this offering. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Name of Beneficial Owner(1)	Number of Shares Beneficially Owned	Percentage of Shares Outstanding	
		Before the Offering	After the Offering
<b>5% Stockholders:</b>			
Brookstreet Securities Corporation and related parties(2)	763,245	9.1%	6.7%
<b>Executive Officers and Directors:</b>			
Hojabr Alimi(3)	1,439,236	17.1%	12.5%
Robert Miller(4)	195,272	2.3%	1.7%
James Schutz(5)	82,708	*	
Theresa Mitchell(6)	21,813	*	
Bruce Thornton(7)	26,811	*	
Akihisa Akao(8)	541,236	6.4%	4.7%
Edward Brown(9)	50,000	*	
Richard Conley(10)	188,736	2.2%	1.6%
Gregory French(11)	74,445	*	
All directors and executive officers as a group (9 persons)(12)	2,620,257	31.2%	22.8%

\* Represents beneficial ownership of less than 1%.

- (1) Unless otherwise noted, the address of each beneficial owner listed in the table is: c/o Oculus Innovative Sciences, Inc., 1129 N. McDowell Boulevard, Petaluma, California 94954.
- (2) Principal address is 2361 Campus Drive, Suite 210, Irvine, California 92612. Consists of shares issuable under warrants that are immediately exercisable. Stan Brooks, trustee of the Brooks Family Trust, has voting or investment power for the shares held by Brookstreet Securities Corporation.
- (3) Includes 422,658 shares issuable upon exercise of options that are exercisable within 60 days of October 31, 2006 and 7,828 shares issuable upon exercise of options that will become exercisable upon completion of this offering.

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- (4) Includes 75,272 shares issuable upon exercise of options that are exercisable within 60 days of October 31, 2006, 60,000 shares issuable upon exercise of options to be granted upon completion of this offering and 50,000 shares held by The Miller 2005 Grandchildren's Trust, for which Mr. Miller is a trustee.
- (5) Includes 78,958 shares issuable upon exercise of options that are exercisable within 60 days of October 31, 2006 and 3,750 shares issuable upon exercise of options that will become exercisable upon completion of this offering.
- (6) Consists of 21,813 shares issuable upon exercise of options that are exercisable within 60 days of October 31, 2006.
- (7) Consists of 26,811 shares issuable upon exercise of options that are exercisable within 60 days of October 31, 2006.
- (8) Includes 10,994 shares issuable upon exercise of options that are exercisable within 60 days of October 31, 2006 and 7,828 shares issuable upon exercise of options that will become exercisable upon completion of this offering.
- (9) Consists of 50,000 shares issued upon exercise of options that will become exercisable upon completion of this offering.
- (10) Includes 140,908 shares issuable upon exercise of options that are exercisable within 60 days of October 31, 2006 and 7,828 shares issuable upon exercise of options that will become exercisable upon completion of this offering.
- (11) Includes 30,953 shares issuable upon exercise of options that are exercisable within 60 days of October 31, 2006 and 7,828 shares issuable upon exercise of options that will become exercisable upon completion of this offering.
- (12) Includes 808,367 shares issuable upon exercise of options that are exercisable within 60 days of October 31, 2006 and 145,062 shares issuable upon exercise of options that will become exercisable upon completion of this offering.

## DESCRIPTION OF CAPITAL STOCK

### General

The following describes our common stock and preferred stock and certain provisions of our certificate of incorporation and our bylaws as will be in effect upon the completion of this offering and assumes our reincorporation in Delaware. This description is only a summary. You should also refer to the certificate of incorporation and bylaws, which have been filed as exhibits to our registration statement, of which this prospectus forms a part. Upon completion of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, \$0.0001 par value per share, and 5,000,000 shares of preferred stock, \$0.0001 par value per share.

### *Common Stock*

As of October 31, 2006, there were 8,399,209 shares of common stock outstanding held by approximately 623 stockholders of record, assuming the automatic conversion of each outstanding share of preferred stock upon the closing of this offering.

Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our certificate of incorporation. This means that the holders of a majority of the shares voted can elect all of the directors then standing for election. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of assets legally available at the times and in the amounts that our board of directors may determine from time to time.

Holders of common stock have no preemptive subscription, redemption or conversion rights or other subscription rights. Upon our liquidation, dissolution or winding-up, the holders of common stock are entitled to share in all assets remaining after payment of all liabilities and the liquidation preferences of any outstanding preferred stock. Each outstanding share of common stock is, and all shares of common stock to be issued in this offering, when they are paid for will be, fully paid and nonassessable.

### *Preferred Stock*

Immediately prior to the closing of this offering, each share of our preferred stock issued and outstanding will convert into one shares of our common stock, for an aggregate of 4,176,478 shares of common stock. As a result, upon the closing of this offering, there will be no shares of preferred stock outstanding.

Upon completion of this offering, our certificate of incorporation will be amended to delete all reference to the prior series of preferred stock and our board of directors will be authorized, subject to limitations imposed by Delaware law, to issue up to a total of 5,000,000 shares of preferred stock in one or more series, without stockholder approval. Our board is authorized to establish from time to time the number of shares to be included in each series, and to fix the rights, preferences and privileges of the shares of each wholly unissued series and any of its qualifications, limitations or restrictions. Our board can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by the stockholders.

The board may authorize the issuance of preferred stock with voting or conversion rights that could harm the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and might harm the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

**Registration Rights**

In accordance with the terms of the Amended and Restated Investors Rights Agreement, or the Investors Rights Agreement, effective as of September 14, 2006, among us and certain stockholders referred to in the Investors Rights Agreement, upon completion of this offering, the holders of 4,176,478 shares of common stock issued upon conversion of the preferred stock will be entitled to contractual rights to require us to register those shares under the Securities Act. If we propose to register any of our securities under the Securities Act for our own account or the account of a security holder, other than on a Form S-8, holders of those shares are entitled to include their shares in our registration, provided, among other conditions, that the underwriters of any such offering have the right to limit the number of shares included in the registration. Six months after the effective date of the registration statement of which this prospectus is a part, and subject to limitations and conditions specified in the investor rights agreement with the holders, holders of a majority of the shares of common stock issued upon conversion of the preferred stock may require us to prepare and file a registration statement under the Securities Act at our expense covering those shares. We are not obligated to effect more than one of these stockholder-initiated registrations.

In accordance with the terms of our Investors Rights Agreement to which we and each of the holders of preferred stock are a party, upon completion of this offering, the holders of 88,200 shares of common stock issued upon conversion of the preferred stock issued pursuant to the exercise of warrants will be entitled to contractual rights to require us to register those shares under the Securities Act. If we propose to register any of our securities under the Securities Act for our own account or the account of a security holder, other than on a Form S-8, on a form in which the common stock issued upon conversion of the preferred stock may be included, holders of those shares are entitled to include their shares in our registration, provided, among other conditions, that the underwriters of any such offering have the right to limit the number of shares included in the registration. Six months after the effective date of the registration statement of which this prospectus is a part, and subject to limitations and conditions specified in the investor rights agreement or managing dealer warrant agreement with the holders, holders of a majority of the shares of common stock issued upon conversion of the preferred stock issued pursuant to the exercise of warrants may require us to prepare and file a registration statement under the Securities Act at our expense covering those shares. We are not obligated to effect more than one of these stockholder-initiated registrations.

In accordance with the terms of the Investors Rights Agreement, upon completion of this offering, the holders of 227,525 shares of common stock issued upon the exercise of warrants will be entitled to contractual rights to require us to register those shares under the Securities Act. If we propose to register any of our securities under the Securities Act for our own account, holders of those shares are entitled to include their shares in our registration, provided, among other conditions, that the underwriters of any such offering have the right to limit the number of shares included in the registration.

**Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws**

Certain provisions of Delaware law, our certificate of incorporation and our bylaws described below may have the effect of delaying, deferring or discouraging another party from acquiring control of us.

**Delaware Law**

We will be subject to the provisions of Section 203 of the Delaware General Corporation Law, or Delaware law, regulating corporate takeovers. In general, these provisions prohibit a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

- either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder is approved by our board of directors before the date the interested stockholder attained that status;



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- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after that date, the business combination is approved by our board of directors and authorized at a meeting of stockholders, and not by written consent, by at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

A Delaware corporation may opt out of this provision either with an express provision in its original certificate of incorporation or in an amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us.

### ***Charter and Bylaws***

Following the completion of this offering, our certificate of incorporation and bylaws will provide that:

- no action can be taken by stockholders except at an annual or special meeting of the stockholders called in accordance with our bylaws, and stockholders may not act by written consent;
- our board of directors will be expressly authorized to make, alter or repeal our bylaws;
- other than as otherwise required by law, stockholders may not call special meetings of the stockholders or fill vacancies on the board and may only be called by the Chairman of the Board, the Chief Executive Officer or by majority of the board of directors;
- stockholders will need to comply with advanced notice procedures to make nominations of candidates for election as directors or to bring matters before an annual stockholder meeting;
- our board of directors will be authorized to issue preferred stock without stockholder approval; and
- we will indemnify officers and directors against losses that they may incur in investigations and legal proceedings resulting from their services to us, which may include services in connection with takeover defense measures.

In addition, so long as a single or related group of stockholders continue to own at least one-third of our outstanding common stock, a transaction between us and any person or entity in which such stockholder or

stockholders have a material interest, if required under applicable federal and state law or Nasdaq rules to be approved by our stockholders, will require approval of a majority of the outstanding shares not held by such interested stockholders present in person or by proxy at the meeting of stockholders held with respect to such transaction.

#### **Limitation of Liability and Indemnification Matters**

We intend to adopt provisions in our certificate of incorporation and bylaws that limit the liability of our directors for monetary damages for breach of their fiduciary duty as directors, except for liability that cannot be eliminated under Delaware law. Under Delaware law, our directors have a fiduciary duty to us which will not be eliminated by this provision in our certificate of incorporation. In addition, each of our directors will continue to be subject to liability under Delaware law for breach of the director's duty of loyalty to us for acts or omissions which are found by a court of competent jurisdiction to be not in good faith or which involve intentional misconduct or knowing violations of law for actions leading to improper personal benefit to the director and for payment of dividends or approval of stock repurchases or redemptions that are prohibited by Delaware law. This provision does not affect the directors' responsibilities under any other laws, such as the Federal securities laws.

Delaware law permits a corporation to not hold its directors personally liable for monetary damages for breach of their fiduciary duty as directors, except for liability for the following:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- voting for or assenting to unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal or state securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission. Any amendment or repeal of these provisions requires the approval of the holders of shares representing at least two-thirds of our shares entitled to vote in the election of directors, voting as one class.

Delaware law provides that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under our bylaws, any agreement, and a vote of stockholders or otherwise. Our certificate of incorporation and bylaws will eliminate the personal liability of directors to the maximum extent permitted by Delaware law. In addition, our certificate of incorporation and bylaws will provide that we may fully indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (whether civil, criminal, administrative or investigative) by reason of the fact that such person is or was one of our directors, officers, employees or other agents, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding.

We have entered into separate indemnification agreements with our directors and executive officers that could require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified. We believe that the limitation of liability provision in our certificate of incorporation and the indemnification agreements will facilitate our ability to continue to attract and retain qualified individuals to serve as directors and officers. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions, regardless of whether Delaware law would permit indemnification. We have purchased liability insurance for our officers and directors.

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At present, there is no pending litigation or proceeding involving any director, officer, employee or agent as to which indemnification will be required or permitted under our certificate of incorporation. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

**Nasdaq Symbol**

We have applied for quotation of our common stock on the Nasdaq Global Market under the symbol "OCLS."

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Mellon Investor Services LLC.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. We cannot predict the effect, if any, that market sales of shares or the availability of shares for sale will have on the market price prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after the restrictions lapse, or the perception that those sales may occur, could cause the prevailing market price to decrease or to be lower than it might be in the absence of those sales of perceptions and could impair our ability to obtain future capital.

### Sale of Restricted Shares

Upon completion of this offering, we will have outstanding 11,476,132 shares of common stock, assuming outstanding options or warrants are not exercised prior to the completion of this offering. Of these outstanding shares, all of the 3,076,923 shares of common stock being sold in this offering will be freely tradable, other than by any of our "affiliates" as defined in Rule 144(a) under the Securities Act, without restriction or registration under the Securities Act. All of the remaining shares were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or sold in accordance with Rule 144 or Rule 701 under the Securities Act. These remaining shares are "restricted shares" within the meaning of Rule 144 under the Securities Act and will also be subject to the 180-day lock-up period described below.

### Lock-Up Agreements

We expect that our directors and executive officers and certain of our other stockholders, option holders and warrant holders who collectively hold at least 90% of our outstanding common stock, in the aggregate and on a fully diluted basis, will agree that they will not sell, offer, contract or grant any option to sell, pledge, transfer, establish an open put equivalent position or otherwise dispose of, any shares of our common stock, securities convertible into or exercisable or exchangeable for shares of our common stock or any interest therein, or any capital stock of our subsidiaries owned by them without the prior written consent of Roth Capital Partners for a period of at least 180 days after the date of this prospectus. Roth Capital Partners may, in its sole discretion, at any time and without notice, release for sale in the public market all or any portion of the shares subject to the lock-up agreements. To the extent shares are released before the expiration of the lock-up period and these shares are sold into the market, the market price of our common stock could decline. As a result of the lock-up agreements described above and the provisions of Rules 144, 144(k) and 701, the restricted shares will be available for sale in the public market as follows:

- 229,025 shares will be eligible for sale immediately following the date of this prospectus;
- 7,976,604 shares will be eligible for sale upon the expiration of the lock-up agreements, described above, beginning 180 days after the date of this prospectus; and
- 193,580 shares will be eligible for sale upon the exercise of vested options, beginning 180 days after the date of this prospectus.

### Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the date of this prospectus, a person who beneficially owns shares for at least one year, unless Rule 144(k) is available as described below, would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the then outstanding shares of common stock, or approximately 80,101 shares immediately after this offering, assuming no exercise of the underwriters' over-allotment option; and
- the average weekly trading volume of the common stock on the Nasdaq Global Market during the four calendar weeks preceding the date on which notice of the sale on Form 144 is filed with the SEC.

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Sales under Rule 144, however, are subject to specific manner of sale provisions, notice requirements and the availability of current public information about our company. We cannot estimate the number of shares of common stock our existing stockholders will sell under Rule 144 as this will depend on the market price of our common stock, the personal circumstances of the stockholders and other factors.

**Rule 144(k)**

Under Rule 144(k), in general, a stockholder who has beneficially owned shares of our common stock for at least two years and who is not deemed to have been an affiliate of our company at any time during the immediately preceding 90 days may sell shares without complying with the manner of sale provisions, notice requirements, public information requirements or volume limitations of Rule 144.

**Rule 701**

Subject to various limitations on the aggregate offering price of a transaction and other conditions, Rule 701 may be relied upon with respect to the resale of securities originally purchased from us by our employees, directors, officers, consultants or advisers prior to the completion of this offering, pursuant to written compensatory benefit plans or written contracts relating to the compensation of such persons. In addition, the SEC has indicated that Rule 701 will apply to stock options granted by us before this offering, along with the shares acquired upon exercise of those options. Securities issued in reliance on Rule 701 are deemed to be restricted shares and, beginning 90 days after the date of this prospectus, unless subject to the contractual restrictions described above, shares may be sold by such persons other than affiliates, subject only to the manner of sale provisions of Rule 144; however, no shares may be sold by affiliates under Rule 144 without compliance with the one-year minimum holding period requirements.

**Stock Options**

We intend to file a registration statement on Form S-8 under the Securities Act covering approximately 1,250,000 shares of common stock reserved for issuance under our stock option plans. Accordingly, the shares of common stock registered under this registration statement will be available for sale in the open market upon exercise by the holders, unless those shares are subject to vesting restrictions with us or the contractual restrictions described above.

**Registration Rights**

In addition, in accordance with the terms of the Amended and Restated Investors Rights Agreement, upon completion of this offering, the holders of approximately 4,176,478 shares of common stock will be entitled to cause us to register the sale of those shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares, other than shares purchased by our affiliates, becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See "Description of Capital Stock — Registration Rights."

**UNDERWRITING**

Subject to the terms and conditions of the underwriting agreement among us and the underwriters, each underwriter has agreed to purchase from us the following respective number of shares of common stock at the offering price less the underwriting discount set forth on the cover page of this prospectus.

<u>Underwriter</u>	<u>Shares</u>
Roth Capital Partners	
Brookstreet Securities Corporation	
Maxim Group LLC	
Total	

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters will purchase all such shares of common stock if any of these shares are purchased. The underwriters are obligated to take and pay for all of the shares of common stock offered hereby, other than those covered by the over-allotment option described below, if any are taken.

The underwriters have advised us that they propose to offer the shares of common stock to the public at the offering price set forth on the cover page of this prospectus and to certain dealers at such price less a concession not in excess of \$ per share. The underwriters may allow, and such dealers may re-allow, a concession not in excess of \$ per share to certain other dealers. If all of the shares are not sold at the initial offering price, the underwriters may change the offering price and other selling terms.

Pursuant to the underwriting agreement, we have granted to the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to an aggregate of 461,539 additional shares of common stock from us, at the offering price, less the underwriting discount set forth on the cover page of this prospectus, solely to cover over-allotments.

To the extent that the underwriters exercise such option, the underwriters will become obligated, subject to certain conditions, to purchase approximately the same percentage of such additional shares as the number set forth next to the underwriter's name in the preceding table bears to the total number of shares in the table, and we will be obligated, pursuant to the option, to sell such shares to the underwriters.

The following table summarizes the discounts and commissions to be paid to the underwriters by us in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares of common stock.

	<u>Total</u>	
	<u>No Exercise</u>	<u>Full Exercise</u>
Per Share	\$	\$
Total	\$	\$

We expect to incur expenses, exclusive of the underwriting discount and commission, of approximately \$ million in connection with this offering. We have agreed to pay to Roth Capital Partners and Brookstreet Securities Corporation a non-accountable expense allowance equal to 1% of the gross proceeds to us in the offering. An electronic prospectus is available on the websites maintained by the underwriters and may also be made available on websites maintained by selected dealers and selling group members participating in this offering. No form of prospectus other than print and electronic forms, which will be printable, will be used in connection with this offering.

In connection with the offering, we have agreed to sell to the underwriters, for nominal consideration, underwriter warrants entitling the underwriters, or their assigns, to purchase up to an aggregate of 7% of the total number of shares sold in this offering at a price equal to 165% of the public offering price per share. The underwriter warrants will be exercisable for five years from the effective date of the offering and will contain cashless exercise provisions and customary anti-dilution provisions.

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The underwriter warrants are deemed compensation by the National Association of Securities Dealers, or NASD, and may not be sold, transferred, pledged, hypothecated or assigned for a period of 180-days following the effective date of the offering pursuant to Rule 2710(g)(1) of the NASD Conduct Rules. The underwriter warrants grant the underwriters, or their assigns, "piggyback" registration rights with respect to the common stock issuable upon exercise of the underwriter warrants for the five-year period during which the underwriter warrants are exercisable.

We, our directors and executive officers and certain of our other stockholders, option holders and warrant holders have agreed, or, we expect will agree, that during the 180-day period after the date of this prospectus, subject to limited exceptions, we and they will not, without prior written consent, directly or indirectly, issue, sell, offer, agree to sell, grant any option or contract for the sale of, pledge, make any short sale of, maintain any short position with respect to, establish or maintain a "put equivalent option" (within the meaning of Rule 16a-1(h) under the Exchange Act) with respect to, enter into any swap, derivative transaction or other arrangement (whether any such transaction is to be settled by delivery of common stock, other securities, cash or other consideration) that transfers to another, in whole or in part, any of the economic consequences of ownership, or otherwise dispose of, any shares of our common stock, or any securities convertible into, exercisable or exchangeable for, our common stock or any interest therein or any capital stock of our subsidiaries). These lock-up agreements will cover approximately 90% of our outstanding common stock in the aggregate and on a fully-diluted basis. The managing underwriter may, in its sole discretion, allow any of these parties to dispose of common stock or other securities prior to the expiration of the 180-day period; no agreements between the managing underwriter and the parties that would allow them to do so as of the date of this prospectus.

The 180-day restricted period described above is subject to extension such that, in the event that either (1) during the last 17 days of the 180-day period, we issue an earnings release or material news or a material event relating to us occurs or (2) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period, the "lock-up" restrictions described above will, subject to limited exceptions, continue to apply until the date that is 15 calendar days plus three business days after the date of issuance of the earnings release or the occurrence of the material news or material event.

Prior to the offering, there has been no public market for the common stock. The initial public offering price for the shares of common stock included in this offering will be determined by negotiation among us and Roth Capital Partners. Among the factors considered in determining the price will be:

- the history of and prospects for our business and the industry in which we operate;
- an assessment of our management;
- our past and present revenues and earnings;
- the prospects for growth of our revenues and earnings; and
- currently prevailing conditions in the securities markets, including current market valuations of publicly traded companies which are comparable to us.

Each of the underwriters has advised us that it does not intend to confirm sales to any account over which it exercises discretionary authority.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Until the distribution of the common stock is completed, rules of the Commission may limit the ability of the underwriters and certain selling group members to bid for and purchase the common stock. As an exception to these rules, the underwriters are permitted to engage in certain transactions that stabilize, maintain or otherwise affect the price of the common stock.

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934.

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment transactions involve sales by the underwriters of the shares of common stock in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares of common stock in the open market.
- Syndicate covering transactions involve purchases of the shares of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of the shares of common stock to close out the short position, the underwriters will consider, among other things, the price of shares of common stock available for purchase in the open market as compared to the price at which they may purchase shares of common stock through the over-allotment option. If the underwriters sell more shares of common stock than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares of common stock in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit representatives to reclaim a selling concession from a syndicate member when the shares of common stock originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of the shares of common stock or preventing or retarding a decline in the market price of the shares of common stock. As a result, the price of the shares of common stock may be higher than the price that might otherwise exist in the open market.

The underwriters will deliver a prospectus to all purchasers of shares of common stock in the short sales. The purchases of shares of common stock in short sales are entitled to the same remedies under the federal securities laws as any other purchaser of shares of common stock covered by this prospectus.

Passive market making may stabilize or maintain the market price of our common stock at a level above that which might otherwise prevail and, if commenced, may be discontinued at any time.

The underwriters are not obligated to engage in any of the transactions described above. If they do engage in any of these transactions, they may discontinue them at any time.

We have applied to list the common stock on the Nasdaq Global Market under the symbol "OCLS."

From time to time in the ordinary course of their respective businesses, the underwriters and their affiliates may in the future engage in commercial banking or investment banking transactions with our affiliates and us.

#### **Selling Restrictions**

The distribution of this document and the offering and sale of shares in certain non-US jurisdictions may be restricted by law and therefore persons into whose possession this document comes should inform themselves about and observe any such restrictions. Any failure to comply with these restrictions may constitute a violation of securities law of any such jurisdiction.

Purchasers of the shares offered by this prospectus may be required to pay stamp taxes and other charges in accordance with the laws and practices of the country of purchase in addition to the offering price on the cover page of this prospectus.



## LEGAL MATTERS

The validity of the shares of our common stock offered by this prospectus will be passed upon for us by Pillsbury Winthrop Shaw Pittman LLP, Palo Alto, California. Selected legal matters relating to the offering will be passed upon for the underwriter by Stradling Yocca Carlson & Rauth, a professional corporation, Newport Beach, California.

## EXPERTS

Our consolidated financial statements as of March 31, 2005 and 2006 and for each of the three years in the period ended March 31, 2006 included in this prospectus have been so included in reliance on the report of Marcum & Kliegman LLP, independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. Valuation Research Corporation issued our July 2005 and June 2006 valuation reports.

### CHANGE IN INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

On April 12, 2006, the Audit Committee of our board of directors approved the dismissal of PricewaterhouseCoopers LLP, or PWC, as our independent registered public accounting firm and subsequently appointed Marcum & Kliegman LLP, or M&K, effective April 12, 2006. We did not consult with M&K on any accounting or financial reporting matters prior to M&K's appointment.

We engaged PWC on June 14, 2005, to perform an audit of our financial statements for our fiscal years ended March 31, 2003, 2004 and 2005. PWC did not issue a report on our financial statements for the years ended March 31, 2004 or 2005, or through April 12, 2006. For the years ended March 31, 2003, 2004 and 2005, and through April 12, 2006, there were no disagreements with PWC on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to PWC's satisfaction, would have caused PWC to make reference thereto in their report on the financial statements for such years if they had delivered a report. In March 2006, and prior to its dismissal, PWC advised our Audit Committee orally of the following:

- the absence of financial accounting personnel with sufficient skills and experience to effectively evaluate and determine the appropriate accounting for non-routine and/or complex accounting transactions consistent with accounting principles generally accepted in the United States, which resulted in a number of material audit adjustments to the financial statements during the course of audit procedures;
- the failure to maintain effective controls to ensure the identification of accounting issues related to and the proper accounting for stock options with the right of rescission that were granted under certain stock option plans that required registration or qualification under federal and state securities laws primarily due to insufficient oversight and lack of personnel in the accounting and finance organization with the appropriate level of accounting knowledge, experience and training;
- the failure to maintain an effective anti-fraud program designed to detect and prevent fraudulent activities in QP;
- the need to expand significantly the scope of the audit of QP to assess the impact of identified fraudulent activities on our financial statements, in which regard PWC advised our audit committee that the results of the fraud investigation may cause PWC to be unwilling to be associated with our financial statements;
- the "tone at the top" set by our senior management does not appear to encourage an attitude within our company that controls are important and that established controls cannot be circumvented;
- we did not have the appropriate financial management and reporting infrastructure in place to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act of 2002, and that we will be unable to report our financial results accurately or in a timely manner; and
- significant control deficiencies, when considered in the aggregate, constituted a material weakness over financial reporting.

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We have authorized PWC to respond fully to the inquiries of M&K concerning the foregoing. We have taken the following steps designed to address PWC's concerns and to implement the recommendations made by our special counsel to our audit committee in connection with its investigation of QP:

- we have implemented a training program to continue to educate our finance personnel on accounting developments and the application of accounting principles to complex transactions, emerging and higher-risk areas and the application of significant accounting policies and judgments;
- we have implemented programs so that all employees in finance responsible for overseeing the consolidation of financial results of any subsidiary, foreign or domestic, have the requisite knowledge to understand the potential issues that are peculiarly important in dealing with our operations, including the potential for fraud;
- we will continue engaging outside consultants to provide accounting, tax and Sarbanes-Oxley advice to our finance personnel;
- with regard to any future material acquisition or partnership that does not involve a well-known entity, management will present a written report to our board of directors concerning the proposed transaction, including a vetting of the management team or practices of the third party;
- we are continuing our efforts to streamline our monthly closing and reporting processes and have implemented financial statement review procedures with the Audit Committee;
- we have adopted a code of ethics for all directors, employees and advisors in compliance with Nasdaq regulations;
- we have adopted a whistleblower policy and are implementing procedures that will allow for anonymous reporting of any potential violations of law; and
- we have hired an experienced Chief Operating Officer to oversee our day-to-day operations, further strengthening our commitment to ensure accurate financial reporting, as well as compliance with laws and regulations.

Under the oversight of our audit committee, we are continuing to review our processes and procedures to strengthen and improve our internal controls, with the goals of ensuring accurate financial reporting and complying with laws and regulations applicable to us.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the Commission a registration statement under the Securities Act with respect to the common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement, exhibits and schedules for further information with respect to the common stock offered by this prospectus. Statements contained in this prospectus regarding the contents of any contract or other documents are not necessarily complete. With respect to any contract or document filed as an exhibit to the registration statement, you should refer to the exhibit for a copy of the contract or document, and each statement in this prospectus regarding that contract or document is qualified by reference to the exhibit. A copy of the registration statement and its exhibits and schedules may be inspected without charge at the Commission's public reference room, located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-202-551-8090 for further information on the public reference room. Our Commission filings, including the registration statement, are also available to the public on the Commission's website at [www.sec.gov](http://www.sec.gov).

Upon completion of this offering, we will be subject to the information and reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the Commission. Such periodic reports, proxy statements and other information will be available for inspection at the public reference room and website of the Commission referred to above.

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OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES

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After the effectiveness of the reverse stock split and execution of the firm commitment described in the last paragraph of (Note 18) to the financial statements of Oculus Innovative Sciences, Inc., we expect to be in a position to render the following audit report.

/s/ Marcum & Kliegman llp

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
Oculus Innovative Sciences, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Oculus Innovative Sciences, Inc. and Subsidiaries (the "Company") as of March 31, 2005 and 2006, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended March 31, 2006. 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 audit 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 audit 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 financial position of Oculus Innovative Sciences, Inc. and Subsidiaries, as of March 31, 2005 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended March 31, 2006 in conformity with United States generally accepted accounting principles.

New York, New York  
June 21, 2006, except for  
Note 18, as to which the date is       ,2006

OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS  
(In thousands, except share amounts)

	March 31,		September 30,
	2005	2006	2006 (unaudited)
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 3,287	\$ 7,448	\$ 2,269
Accounts receivable, net	227	1,076	1,701
Inventories	868	317	355
Prepaid expenses and other current assets	499	1,386	1,108
<b>Total current assets</b>	<b>4,881</b>	<b>10,227</b>	<b>5,433</b>
Property and equipment, net	1,959	1,940	2,224
Notes receivable	55	—	—
Restricted cash	45	44	46
Deferred offering costs	—	478	1,405
Debt issue costs	—	—	948
<b>Total assets</b>	<b>\$ 6,940</b>	<b>\$ 12,689</b>	<b>\$ 10,056</b>
<b>LIABILITIES</b>			
Current liabilities:			
Accounts payable	\$ 906	\$ 2,774	\$ 2,286
Accrued expenses and other current liabilities	2,335	1,686	1,805
Dividend payable	—	121	363
Current portion of long-term debt	950	504	1,760
Current portion of capital lease obligations	27	15	16
<b>Total current liabilities</b>	<b>4,218</b>	<b>5,100</b>	<b>6,230</b>
Long-term debt, less current portion	460	210	2,818
Capital lease obligations, less current portion	60	41	34
<b>Total liabilities</b>	<b>4,738</b>	<b>5,351</b>	<b>9,082</b>
<b>Commitments, Contingencies and Other Matters</b>			
<b>Stockholders' Equity</b>			
Convertible preferred stock, no par value; 7,500,000 shares authorized,			
Series A 1,337,709 shares issued and outstanding at March 31, 2005 and 1,347,709 shares issued and outstanding at March 31, 2006 and September 30, 2006 (unaudited)	6,628	6,668	6,668
Series B 1,014,093 shares issued and outstanding at March 31, 2005 and 2,635,744 shares issued and outstanding at March 31, 2006 and September 30, 2006 (unaudited)	16,696	43,722	43,722
Series C 84,539 shares issued and outstanding at September 30, 2006 (unaudited)	—	—	1,370
Common stock, no par value; 25,000,000 shares authorized,			
3,914,653 and 4,218,981 and 4,222,731 shares issued and outstanding at March 31, 2005 and 2006 and September 30, 2006 (unaudited), respectively	3,101	3,399	3,399
Additional paid-in capital	3,674	4,644	5,163
Deferred compensation	(676)	(798)	—
Accumulated other comprehensive (loss) income	(141)	3	(140)
Accumulated deficit	(27,080)	(50,300)	(59,208)
<b>Total stockholders' equity</b>	<b>2,202</b>	<b>7,338</b>	<b>974</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 6,940</b>	<b>\$ 12,689</b>	<b>\$ 10,056</b>

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

OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended March 31,			Six Months Ended September 30,	
	2004	2005	2006	2005	2006
				(unaudited)	
Revenues					
Product	\$ 95	\$ 473	\$ 1,966	\$ 807	\$ 1,942
Service	807	883	618	275	388
Total revenues	902	1,356	2,584	1,082	2,330
Cost of revenues					
Product	1,403	2,211	3,899	1,350	1,043
Service	1,265	1,311	1,003	497	422
Total cost of revenues	2,668	3,522	4,902	1,847	1,465
Gross profit (loss)	(1,766)	(2,166)	(2,318)	(765)	865
Operating expenses					
Research and development	1,413	1,654	2,600	965	1,595
Selling, general and administrative	3,918	12,492	15,933	7,704	7,867
Total operating expenses	5,331	14,146	18,533	8,669	9,462
Loss from operations	(7,097)	(16,312)	(20,851)	(9,434)	(8,597)
Interest expense	(178)	(372)	(172)	(103)	(261)
Interest income	3	8	282	68	100
Other income (expense), net	(26)	146	(377)	(101)	92
Net loss from continuing operations	(7,298)	(16,530)	(21,118)	(9,570)	(8,666)
Discontinued operations					
Loss from operations of discontinued business	—	—	(818)	(174)	—
Loss on disposal of discontinued business	—	—	(1,163)	—	—
Loss on discontinued operations	—	—	(1,981)	(174)	—
Net loss	(7,298)	(16,530)	(23,099)	(9,744)	(8,666)
Preferred stock dividends	—	—	(121)	—	(242)
Net loss available to common stockholders	\$ (7,298)	\$ (16,530)	\$ (23,220)	\$ (9,744)	\$ (8,908)
Net loss per common share: basic and diluted					
Continuing operations	\$ (1.87)	\$ (4.22)	\$ (5.12)	\$ (2.34)	\$ (2.11)
Discontinued operations	—	—	(0.48)	(0.04)	—
	\$ (1.87)	\$ (4.22)	\$ (5.60)	\$ (2.38)	\$ (2.11)
Weighted-average number of shares used in per common share calculations:					
Basic and diluted	3,911	3,914	4,150	4,086	4,221
Other comprehensive loss, net of tax					
Net loss	\$ (7,298)	\$ (16,530)	\$ (23,099)	\$ (9,744)	\$ (8,965)
Foreign currency translation adjustments	(14)	(127)	144	22	(143)
Comprehensive loss	\$ (7,312)	\$ (16,657)	\$ (22,955)	\$ (9,722)	\$ (9,108)

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

**OCULUS INNOVATIVE SCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
(In thousands, except share amounts)

	Convertible Preferred Stock						Common Stock		Additional Paid in Capital	Deferred Stock- Based Compen- sation	Accumu- lated Other Compre- hensive Income	Accum- ulated Deficit	Total
	Series A		Series B		Series C		Shares	Amount					
	Shares	Amount	Shares	Amount	Shares	Amount							
Balance, April 1, 2003	—	—	—	—	—	—	3,858,778	\$ 2,892	\$ 286	\$ (5)	—	\$ (3,252)	\$ (79)
Issuance of common stock, net of offering costs	—	—	—	—	—	—	25,375	203	—	—	—	—	203
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	30,500	6	—	—	—	—	6
Deferred stock-based compensation	—	—	—	—	—	—	—	—	233	(233)	—	—	—
Amortization of stock-based compensation	—	—	—	—	—	—	—	—	—	30	—	—	30
Non-employee stock-based compensation	—	—	—	—	—	—	—	—	7	—	—	—	7
Issuance of common stock warrants in exchange for services	—	—	—	—	—	—	—	—	44	—	—	—	44
Reclassification of options subject to cash settlement	—	—	—	—	—	—	—	—	3	—	—	—	3
Issuance of common stock warrants in connection with debt financing	—	—	—	—	—	—	—	—	88	—	—	—	88
Issuance of Series A convertible preferred stock, net of offering costs	1,337,709	\$ 6,628	—	—	—	—	—	—	—	—	—	—	6,628
Translation adjustment	—	—	—	—	—	—	—	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(7,298)	(7,298)
Balance, March 31, 2004	1,337,709	6,628	—	—	—	—	3,914,653	3,101	661	(208)	(14)	(10,550)	(382)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	—
Deferred stock-based compensation	—	—	—	—	—	—	—	—	2,765	(2,765)	—	—	—
Amortization of stock-based compensation	—	—	—	—	—	—	—	—	—	2,297	—	—	2,297
Non-employee stock-based compensation	—	—	—	—	—	—	—	—	30	—	—	—	30

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	Convertible Preferred Stock						Common Stock		Additional Paid in Capital	Deferred Stock- Based Compen- sation	Accumu- lated Other Compre- hensive Income	Accum- ulated Deficit	Total
	Series A		Series B		Series C		Shares	Amount					
	Shares	Amount	Shares	Amount	Shares	Amount							
Reclassification of options subject to cash settlement	—	—	—	—	—	—	—	—	113	—	—	—	113
Issuance of common stock warrants in connection with debt financing	—	—	—	—	—	—	—	—	28	—	—	—	28
Issuance of Series A convertible preferred stock warrants in connection with debt financing	—	—	—	—	—	—	—	—	77	—	—	—	77



OCULUS INNOVATIVE SCIENCES, INC.  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
(In thousands, except share amounts)

	Convertible Preferred Stock						Common Stock		Additional Paid in Capital	Deferred Stock- Based Compen- sation	Accumu- lated Other Compre- hensive Income	Accum- ulated Deficit	Total
	Series A		Series B		Series C		Shares	Amount					
	Shares	Amount	Shares	Amount	Shares	Amount							
Issuance of Series B convertible preferred stock, net of offering costs	—	—	1,014,093	16,696	—	—	—	—	—	—	—	16,696	
Translation adjustment	—	—	—	—	—	—	—	—	—	(127)	—	(127)	
Net loss	—	—	—	—	—	—	—	—	—	—	(16,530)	(16,530)	
Balances, March 31, 2005	1,337,709	\$ 6,628	1,014,093	\$16,696	—	—	3,914,653	\$ 3,101	\$ 3,674	\$ (676)	\$ (141)	\$ (27,080)	\$ 2,202
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	291,828	298	—	—	—	—	298
Deferred stock-based compensation	—	—	—	—	—	—	—	—	401	(401)	—	—	—
Amortization of stock-based compensation	—	—	—	—	—	—	—	—	—	279	—	—	279
Non-employee stock-based compensation	—	—	—	—	—	—	—	—	32	—	—	—	32
Fair value adjustment related to common stock warrants with service conditions	—	—	—	—	—	—	—	—	153	—	—	—	153
Issuance of common stock in exchange for services	—	—	—	—	—	—	12,500	—	127	—	—	—	127
Reclassification of options subject to cash settlement	—	—	—	—	—	—	—	—	257	—	—	—	257
Issuance of Series B convertible preferred stock, net of offering costs	—	—	1,621,651	27,026	—	—	—	—	—	—	—	—	27,026

	Convertible Preferred Stock						Common Stock		Additional Paid in Capital	Deferred Stock- Based Compen- sation	Accumu- lated Other Compre- hensive Income	Accum- ulated Deficit	Total
	Series A		Series B		Series C		Shares	Amount					
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Issuance of Series A convertible preferred stock in connections with convertible debt	10,000	40	—	—	—	—	—	—	—	—	—	—	40
Dividend payable to Series A preferred stockholders	—	—	—	—	—	—	—	—	—	—	—	(121)	(121)
Translation adjustment	—	—	—	—	—	—	—	—	—	—	144	—	144
Net loss	—	—	—	—	—	—	—	—	—	—	—	(23,099)	(23,099)
Balance, March 31, 2006	1,347,709	\$ 6,668	2,635,744	\$43,722	—	—	4,218,981	\$ 3,399	\$ 4,644	\$ (798)	\$ 3	\$(50,300)	\$7,338

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

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
(In thousands, except share amounts)

	Convertible Preferred Stock						Common Stock		Additional Paid in Capital	Deferred Stock- Based Compen- sation	Accumu- lated Other Compre- hensive Income	Accum- ulated Deficit	Total
	Series A		Series B		Series C		Shares	Amount					
	Shares	Amount	Shares	Amount	Shares	Amount							
Balance, March 31, 2006	1,347,709	\$ 6,668	2,635,744	\$ 43,722	—	—	4,218,981	\$ 3,399	\$ 4,644	\$ (798)	\$ 3	\$(50,300)	\$ 7,338
Deferred stock-based compensation	—	—	—	—	—	—	—	—	(96)	96	—	—	—
Amortization of stock-based compensation	—	—	—	—	—	—	—	—	—	104	—	—	104
Non-employee stock-based compensation	—	—	—	—	—	—	—	—	11	—	—	—	11
Fair value related to common warrant adjustment with services conditions	—	—	—	—	—	—	—	—	70	—	—	—	70
Issuance of common stock in exchange for services	—	—	—	—	—	—	3,750	—	43	—	—	—	43
Issuance of common warrants in connection with line of credit	—	—	—	—	—	—	—	—	1,047	—	—	—	1,047
Issuance of Series C convertible preferred stock net of offering costs	—	—	—	—	84,539	\$ 1,370	—	—	—	—	—	—	1,370
Employee stock-based compensation expense recognized under SFAS No. 123R, net of forfeitures	—	—	—	—	—	—	—	—	42	—	—	—	42
Dividend payable to Series A preferred stockholders	—	—	—	—	—	—	—	—	—	—	—	(242)	(242)
Reclassification of deferred stock based compensation	—	—	—	—	—	—	—	—	(598)	598	—	—	—
Translation adjustment	—	—	—	—	—	—	—	—	—	—	(143)	—	(143)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(8,666)	(8,666)
Balance, September 30, 2006 (unaudited)	<u>1,347,709</u>	<u>\$ 6,668</u>	<u>2,635,744</u>	<u>\$ 43,722</u>	<u>84,539</u>	<u>\$ 1,370</u>	<u>4,222,731</u>	<u>\$ 3,399</u>	<u>\$ 5,163</u>	<u>\$ —</u>	<u>\$ (140)</u>	<u>\$(59,208)</u>	<u>\$ 974</u>

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

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended March 31,			Six Months Ended September 30,	
	2004	2005	2006	2005	2006
	(unaudited)				
<b>Cash flows from operating activities:</b>					
Net loss from continuing operations	\$ (7,298)	\$ (16,530)	\$ (21,118)	\$ (9,570)	\$ (8,666)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:					
Depreciation and amortization	163	434	651	307	328
Stock-based compensation	424	2,349	597	266	270
Non-cash interest expense	37	131	21	21	125
Loss on disposal of assets	10	2	113	—	—
Changes in operating assets and liabilities					
Accounts receivable, net of doubtful accounts	(195)	217	(849)	(119)	(617)
Inventory	(119)	(748)	551	(81)	(27)
Prepaid expenses and other current assets	(163)	(278)	(887)	(585)	262
Accounts payable	857	(165)	1,868	1,028	(494)
Accrued expenses and other current liabilities	726	1,055	(649)	(828)	106
Net cash used in operating activities	<u>(5,558)</u>	<u>(13,533)</u>	<u>(19,702)</u>	<u>(9,561)</u>	<u>(8,713)</u>
<b>Cash flows from investing activities:</b>					
Purchases of property and equipment	(982)	(1,042)	(475)	(166)	(585)
Issuance of note receivable	—	(55)	55	(2)	—
Changes in restricted cash	(25)	(21)	1	—	(2)
Net cash used in investing activities	<u>(1,007)</u>	<u>(1,118)</u>	<u>(419)</u>	<u>(168)</u>	<u>(587)</u>
<b>Cash flows from financing activities:</b>					
Proceeds from the issuance of common stock	203	—	—	—	—
Deferred offering costs	—	—	(478)	(342)	(926)
Issuance of common stock upon exercise of stock options	6	—	298	298	—
Proceeds from the issuance of preferred stock	6,628	16,696	27,026	25,744	1,370
Debt issue costs	—	—	—	—	(20)
Proceeds from issued debt	574	1,205	257	79	4,379
Principal payments on debt	(106)	(664)	(953)	(694)	(515)
Payments on capital leases	(34)	(41)	(31)	(9)	(7)
Net cash provided by financing activities	<u>7,271</u>	<u>17,196</u>	<u>26,119</u>	<u>25,076</u>	<u>4,281</u>
<b>Cash flows from discontinued operations</b>					
Operating cash flows	—	—	(818)	(174)	—
Investing cash flows	—	—	(1,163)	(970)	—
Net cash used in discontinued operations	<u>—</u>	<u>—</u>	<u>(1,981)</u>	<u>(1,144)</u>	<u>—</u>
Effect of exchange rates on cash and cash equivalents	(14)	(127)	144	22	(160)
Net increase (decrease) in cash and cash equivalents	692	2,418	4,161	14,225	(5,179)
Cash and equivalents, beginning of period	177	869	3,287	3,287	7,448
Cash and equivalents, end of period	<u>\$ 869</u>	<u>\$ 3,287</u>	<u>\$ 7,448</u>	<u>\$ 17,512</u>	<u>\$ 2,269</u>
<b>Supplemental disclosure of cash flow information:</b>					
Cash paid for interest	<u>\$ 134</u>	<u>\$ 221</u>	<u>\$ 125</u>	<u>\$ 78</u>	<u>\$ 136</u>
Equipment purchased under capital leases	<u>\$ 40</u>	<u>\$ 37</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
Conversion of note into Series A preferred stock	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 40</u>	<u>\$ 40</u>	<u>\$ —</u>
Fair value of warrants issued with line of credit	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,047</u>

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

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(INFORMATION AS OF SEPTEMBER 30, 2006 AND FOR THE SIX MONTHS ENDED**  
**SEPTEMBER 30, 2005 AND 2006 IS UNAUDITED)**

**NOTE 1 — The Company**

Oculus Innovative Sciences, Inc. (the "Company") was incorporated under the laws of the State of California in April 1999. The Company's principal office is located in Petaluma, California. The Company has developed and manufactures and markets a family of products intended to help prevent and treat infection in acute and chronic wounds. The Company's platform technology, Microcyn, is a non-toxic, super-oxidized water-based solution that is designed to treat a wide range of pathogens, including viruses, fungi, spores and antibiotic resistant strains of bacteria, such as MRSA and VRE, in wounds. The Company conducts its business world-wide, with its principal subsidiaries in Europe and Mexico.

As discussed in (Note 2), the Company's amended articles of incorporation were amended on August 28, 2006, authorizing it to issue up to 875,000 of Series C convertible preferred stock.

**Stock Split**

In November 2006, the board of directors of the Company approved a reverse split within a range of 1 for 2, 1 for 4, or 1 for 6 of the Company's outstanding shares. The reverse stock split will be effected by filing an amended and restated certificate of incorporation of the Company immediately prior to the Company's initial public offering. All shares and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect a 1 for 4 reverse stock split, or the midpoint of the range.

**NOTE 2 — Liquidity and Financial Condition**

The Company incurred net losses of \$7,298,000, \$16,530,000 and \$23,099,000 for the years ended March 31, 2004, 2005 and 2006, respectively, and \$8,666,000 for the six months ended September 30, 2006. At March 31, 2006 and September 30, 2006, the Company's accumulated deficit amounted to \$50,300,000 and \$59,208,000, respectively.

During the years ended March 31, 2004, 2005 and 2006, the Company raised, net of offering costs, an aggregate of \$6,837,000, \$16,696,000 and \$27,324,000, respectively in various equity financing transactions that, together with the proceeds of certain debt financing transactions, enabled it to sustain operations while attempting to execute its business plan. The Company had \$5,127,000 of working capital as of March 31, 2006 and a working capital deficiency of \$(797,000) as of September 30, 2006. In addition, in June 2006, the Company entered into a \$5,000,000 credit facility from which it drew \$4,182,000, to fund its operations, and invest in new equipment (Note 9). In addition, on November 7, 2006, the Company entered into a \$4.0 million loan agreement which will be repaid within twelve months or within 5 days after the close of the Company's initial public offering of its common stock,

The Company's ability to continue its operations is dependent upon its ability to raise additional capital and generate revenue and operating cash flow through the execution of its business plan. The Company is also in the process of effectuating an initial public offering ("IPO") of its equity securities. The Company's Board of Directors and stockholders also approved an amendment to the Articles of Incorporation (that became effective on August 28, 2006) to authorize the issuance of up to 875,000 shares of Series C convertible preferred stock. On September 14, 2006, the Company sold 84,539 units, consisting of 84,539 shares of Series C convertible preferred stock and warrants to purchase 16,907 shares of the Company's common stock, for gross proceeds of \$1,521,702 (\$1,369,532 net of offering costs). On October 20, 2006, the Company sold 108,486 units, consisting of 108,486 shares of Series C convertible preferred stock and warrants to purchase 21,697 shares of the Company's common stock, for gross proceeds of \$1,952,478 (\$1,757,230 net of offering costs). The Company cannot provide any assurance that it will successfully raise any additional capital under this offering as a result of the authorization to issue these shares.

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(INFORMATION AS OF SEPTEMBER 30, 2006 AND FOR THE SIX MONTHS ENDED**  
**SEPTEMBER 30, 2005 AND 2006 IS UNAUDITED)**

Management believes the Company's current level of working capital, the \$4.0 million raised in the note offering described in Note 18, as well as funds the Company expects to generate from operations and raise through an initial public offering, will sustain the business through September 30, 2007. However, the Company cannot provide any assurance that it will raise capital through this initial public offering or an alternative funding source. Without completion of this offering, or the raise of capital through an alternative funding source, the Company may curtail certain operational activities in order to reduce costs. These activities may include clinical and regulatory trials, sales and marketing activities, and international operations. In the event that the Company is required to raise additional capital, the Company cannot provide any assurance that it will secure any commitments for new financing on acceptable terms, if at all.

**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 C.V. ("OTM"), and Oculus Innovative Sciences B.V. ("OIS Europe"). All significant intercompany accounts and transactions have been eliminated in consolidation.

The consolidated financial statements are presented in United States Dollars in accordance with Statement of Financial Accounting Standard ("SFAS") No. 52, "Foreign Currency Translation." ("SFAS 52"). 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 are recorded directly to accumulated other comprehensive (loss) income.

The Company, in determining whether it is required to consolidate investee businesses, considers both the voting and variable interest models of consolidation as required under Financial Accounting Standards Board ("FASB") Interpretation No. 46(R) "Consolidation of Variable Interest Entities," ("FIN 46(R)"). Accordingly the Company consolidates investee entities when it owns less than 50% of the voting interests but, based on the risks and rewards of its participation, has established financial control. As described in Note 17, the Company's consolidated financial statements include the results of a variable interest entity that is being presented as a discontinued operation in accordance with SFAS No. 144 "Accounting for the Impairment and Disposal of Long Lived Assets."

***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. These estimates and assumptions include revenue recognition reserves and write-downs related to receivables and inventories, the recoverability of long-term assets, deferred taxes and related valuation allowances and valuation of equity instruments.

***Unaudited Interim Results***

The accompanying consolidated balance sheet as of September 30, 2006, statement of changes in stockholders' equity (deficit) for the six months ended September 30, 2006, and the consolidated statements of operations and statements of cash flows for the six months ended September 30, 2005 and 2006 are unaudited.

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The unaudited interim consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position and results of operations and cash flows for the six months ended September 30, 2005 and 2006. The financial data and other information disclosed in the notes to the consolidated financial statements related to the three month periods are unaudited. The results for the six months ended September 30, 2006 are not necessarily indicative of the results to be expected for the year ending March 31, 2007 or for any other interim period or for any future year.

***Revenue Recognition***

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

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

The Company applies the revenue recognition principles set forth in Securities and Exchange Commission Staff Accounting Bulletin ("SAB") 104 "Revenue Recognition" with respect to all of its revenue. Accordingly, 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 reasonable 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 a purchase order.

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, 2004, 2005 and 2006 and for the six months ended September 30, 2006 and 2005.

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 180 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

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the revenue until the time of collection. The Company maintains a reserve for amounts which may not be collectible.

During the fiscal year ended March 31, 2005, approximately \$434,000 of sales in Mexico were recognized when cash was collected since collection was not reasonably assured.

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 end 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.

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.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents may be invested in money market funds, commercial paper, and certificates of deposits. Cash equivalents are carried at cost, which approximates fair value.

***Restricted Cash***

In connection with operating lease agreements, the Company is required to maintain cash deposits in a restricted account. Restricted cash held as security under this arrangement amounted to \$45,000, \$44,000 and \$46,000 at March 31, 2005 and 2006, and September 30, 2006, respectively.

***Concentration of Credit Risk***

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. Management believes that the financial institutions that hold the Company's deposits are financially sound and have minimal credit risk.

The Company grants credit to its business customers, which are primarily located in the United States, Mexico, and Europe. Collateral is generally not required for trade receivables. The Company maintains allowances for potential credit losses.

***Accounts Receivable***

Trade accounts receivable are recorded net of allowances for cash discounts for prompt payment, doubtful accounts, government chargebacks and sales returns. Estimates for cash discounts, government chargebacks and sales returns are based on contractual terms, historical trends and expectations regarding the utilization rates for these programs. With respect to government chargebacks, the Mexican Ministry of Health's ("MOH") policy is to levy penalties on its vendors for product received after scheduled delivery times. The Company has not incurred any such chargebacks to date; however such penalties (if incurred) would be recorded as a reduction of revenue and the related accounts receivable balance.

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



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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 Company had a low occurrence of credit losses through 2005 and therefore did not consider it necessary to establish an allowance for doubtful accounts as of March 31, 2005. The allowance for doubtful accounts at March 31, 2006 and September 30, 2006 represents probable credit losses in the amounts of \$90,000 and \$171,000, respectively.

***Inventories***

Inventories of finished goods and raw materials are stated at the lower of cost, determined first-in, first-out under a standard cost method, or market.

The Company also establishes reserves for obsolescence or unmarketable inventory. The Company recorded reserves to reduce the carrying amounts of inventories to their net realizable value in the amounts of \$221,000, \$996,000 and \$44,000 for the years ended March 31, 2005, 2006 and the six months ended September 30, 2006, respectively, which is included in the accompanying statements of operations as a component of cost of goods sold. In the six month period ended September 30, 2006, the Company discarded inventory reserved for in prior periods.

***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. Useful lives by classification is as follows:

	<u>Years</u>
Office equipment	3
Manufacturing and other equipment	5
Furniture and fixtures	7

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

***Debt Issue Costs***

Costs of obtaining lines of credit or revolving credit arrangements (which could include cash or the fair value of equity securities) are deferred and amortized over the term of the related facility in accordance with Accounting Principles Board Opinion ("APB") No. 21 "Debt Issue Costs." ("APB 21").

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

The Company periodically reviews the carrying values of its long lived assets in accordance with SFAS 144 "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.

***Research and Development***

Research and development expense is charged to operations as incurred and consists primarily of personnel expenses, outside services and supplies. For the years ended March 31, 2004, 2005 and 2006, research and development expense amounted to \$1,413,000, \$1,654,000 and \$2,600,000, respectively. For the six months ended September 30, 2005 and 2006, research and development expense amounted to \$965,000 and \$1,595,000, respectively.

***Advertising Costs***

Advertising costs are expensed as incurred. Advertising costs amounted to \$99,000, \$122,000 and \$126,000, for the years ended March 31, 2004, 2005 and 2006, respectively. Advertising costs amounted to \$100,000 and \$27,000 for the six months ended September 30, 2005 and 2006, respectively.

***Shipping and Handling Costs***

The Company applies the guidelines enumerated in Emerging Issues Task Force Issue ("EITF") 00-10 "Accounting for Shipping and Handling Fees and Costs" with respect to its shipping and handling costs. Accordingly, the Company classifies amounts billed to customers related to shipping and handling in sale transactions as revenue. Shipping and handling costs incurred are recorded in cost of sales. To date, shipping and handling costs billed to customers have been insignificant.

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***Foreign Currency Transactions***

Foreign currency gains (losses) relate to working capital loans that the Company's made to its foreign subsidiaries. The Company recorded foreign currency gains (losses) for the years ended March 31, 2004, 2005 and 2006 of (\$4,000), \$134,000, and (\$283,000), respectively, and \$(102,000) and \$(119,000) for the six months ended September 30, 2005 and 2006, respectively. The related gains (losses) were recorded in other income (expense) in the accompanying statements of operations.

***Stock-Based Compensation***

Prior to April 1, 2006, the Company accounted for stock-based employee compensation arrangements in accordance with the provisions of APB No. 25, "Accounting for Stock Issued to Employees," and its related interpretations and applied the disclosure requirements of SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123." The Company used the minimum value method to measure the fair value of awards issued prior to April 1, 2006 with respect to its application of the disclosure requirements under SFAS 123.

Effective April 1, 2006, the Company adopted SFAS No. 123(R) "Share Based Payment" ("SFAS 123(R)"). This statement is a revision of SFAS Statement No. 123, and supersedes APB Opinion No. 25, and its related implementation guidance. SFAS 123(R) addresses all forms of share based payment ("SBP") awards including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. Under SFAS 123(R), SBP awards result in a cost that will be measured at fair value on the awards' grant date, based on the estimated number of awards that are expected to vest and will result in a charge to operations.

The Company had a choice of two attribution methods for allocating compensation costs under SFAS 123(R): the "straight-line method," which allocates expense on a straight-line basis over the requisite service period of the last separately vesting portion of an award, or the "graded vesting attribution method," which allocates expense on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards. The Company chose the former method and amortized the fair value of each option on a straight-line basis over the requisite period of the last separately vesting portion of each award.

Under SFAS 123(R), nonpublic entities, including those that become public entities after June 15, 2005, that used the minimum value method of measuring equity share options and similar instruments for either recognition or pro forma disclosure purposes under Statement 123 are required to apply SFAS 123(R) prospectively to new awards and to awards modified, repurchased, or cancelled after the date of adoption. In addition, SFAS 123(R), requires such entities to continue accounting for any portion of awards outstanding at the date of initial application using the accounting principles originally applied to those awards. Accordingly, stock based compensation expense relating to awards granted prior to April 1, 2006 that are expected to vest in periods ending after April 1, 2006 are being recorded in accordance with the provisions of APB 25 and its related interpretive guidance.

The Company has adopted the prospective method with respect to accounting for its transition to SFAS 123(R). Accordingly, the Company recognized in salaries and related expense in the statement of operations \$104,000 of stock based compensation expense in the six month period ended September 30, 2006, which represents the intrinsic value amortization of options granted prior to April 1, 2006 that the Company is continuing to account for using the recognition and measurement principles prescribed under APB 25. The Company also recognized in salaries and related expense in the statement of operations \$42,000 of stock based compensation expense in the six months ended September 30, 2006, which represents the amortization of the fair value of options granted subsequent to adoption of SFAS 123(R). In the current quarter we have

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reclassified certain components of our stockholders' equity section to reflect the elimination of deferred compensation arising from unvested share-based compensation pursuant to the requirements of Staff Accounting Bulletin No. 107, regarding Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment." This deferred compensation was previously recorded as an increase to additional paid-in capital with a corresponding reduction to stockholders' equity for such deferred compensation. This reclassification has no effect on net income or total stockholders' equity as previously reported. The Company will record an increase to additional paid-in capital as the share-based payments vest.

***Non-Employee Stock Based Compensation***

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123(R) and EITF Issue No. 96-18, "Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," ("EITF 96-18") which requires that such equity instruments are recorded 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. Non-employee stock-based compensation charges are being amortized over the vesting period.

***Income Taxes***

The Company accounts for income taxes in accordance with SFAS No. 109, Accounting for Income Taxes ("SFAS No. 109"). Under SFAS No. 109, 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.

***Comprehensive Loss***

Other comprehensive loss includes all changes in stockholders' equity (deficit) during a period from non-owner sources and is reported in the consolidated statement of stockholders' equity (deficit). To date, other comprehensive loss consists of changes in accumulated foreign currency translation adjustments during the period.

***Net Loss Per Share***

The Company computes net loss per share in accordance with SFAS No. 128 "Earnings Per Share" and has applied the guidance enumerated in Staff Accounting Bulletin No. 98 ("SAB Topic 4D") with respect to evaluating its issuances of equity securities during all periods presented.

Under SFAS No. 128, basic net loss per share is computed 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, 2004, 2005, 2006, and the six months ended September 30, 2005 and 2006 excludes potentially dilutive securities because their inclusion would be anti-dilutive.

In addition to the above, the SEC (under SAB Topic 4D) requires new registrants to retroactively include the dilutive effect of common stock or potential common stock issued for nominal consideration during all periods presented in its computation of basic earnings (loss) per share and diluted earnings per share as if they

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were, in substance, recapitalizations. The Company evaluated all of its issuances of equity securities and determined that it had no nominal issuances of common stock or common stock equivalents to include in its computation of loss per share for any of the periods presented.

Common stock equivalents excluded from the determination of basic and diluted net loss per share because their effect would be anti-dilutive are as follows (in thousands):

	<u>Year Ended March 31,</u>			<u>Six Months Ended</u>	
	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>September 30,</u>	<u>2006</u>
				<u>(unaudited)</u>	
Options to purchase common stock	1,535	1,340	1,969	1,429	2,125
Warrants to purchase common stock	30	464	858	517	875
Convertible preferred stock (as if converted)	1,338	2,352	3,984	3,906	4,068
Warrants to purchase preferred stock (as if converted)	—	17	17	17	88
Convertible debt	20	10	—	—	—
	<u>2,923</u>	<u>4,183</u>	<u>6,828</u>	<u>5,869</u>	<u>7,156</u>

***Fair Value of Financial Instruments***

The carrying amounts reported in the balance sheet for cash, accounts receivable, accounts payable and accrued expenses approximate fair value based on the short-term maturity of these instruments. The carrying amounts of the Company's line of credit obligation and other long term obligations approximate fair value as such instruments feature contractual interest rates that are consistent with current market rates of interest or have effective yields that are consistent with instruments of similar risk, when taken together with equity instruments issued to the holder.

***Preferred Stock***

The Company applies the guidance enumerated in SFAS No. 150 "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" and EITF Topic D-98 "Classification and Measurement of Redeemable Securities," when determining the classification and measurement of preferred stock. Preferred shares subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value in accordance with SFAS 150. All other issuances of preferred stock are subject to the classification and measurement principles of EITF Topic D-98. Accordingly the Company classifies conditionally redeemable preferred shares (if any), which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, the Company classifies its preferred shares in stockholders' equity.

The Company's preferred shares do not feature any redemption rights within the holders control or conditional redemption features not within the Company's control as of March 31, 2005, March 31, 2006 or September 30, 2006. Accordingly all issuances of preferred are presented as a component of stockholders equity (deficit).

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***Convertible Instruments***

The Company accounts for conversion options embedded in convertible instruments in accordance with SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133") and EITF 00-19 "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" ("EITF 00-19"). SFAS 133 generally requires companies to bifurcate conversion options embedded in convertible instruments from their host instruments and to account for them as free standing derivative financial instruments in accordance with EITF 00-19. SFAS 133 provides for certain exceptions to this rule including when the host instrument is deemed to be conventional (as that term is described in the implementation guidance to SFAS 133 and further clarified in EITF 05-2 "The Meaning of 'Conventional Convertible Debt Instrument'" in Issue No. 00-19) and/or when the characteristics of the security issuable upon the exercise of the conversion option are "clearly and closely related" (as that term is clarified in paragraph 611 of the implementation guidance included in Appendix A of SFAS 133) to the characteristics of the host instrument.

The conversion options included in the Company's currently outstanding convertible notes and convertible preferred stock provide for the holders of these instruments to realize the conversion options only by exercising them and receiving the entire proceeds in a fixed number of shares. Accordingly, the convertible notes are deemed to be conventional debt instruments, which host conversion options that the Company accounts for as embedded derivatives. The characteristics of common stock that is issuable upon a holder's exercise of conversion options embedded in the Company's preferred shares are deemed to be clearly and closely related to characteristics of the preferred shares. Accordingly, the convertible preferred shares are deemed to host conversion options that the Company accounts for as embedded derivatives.

The Company accounts for convertible notes (deemed conventional) and convertible preferred stock with embedded conversion options in accordance with the provisions of EITF 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features," ("EITF 98-5") and EITF 00-27 "Application of EITF 98-5 to Certain Convertible Instruments." Accordingly, the Company records, as a discount to convertible notes, the intrinsic value of such conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their earliest date of redemption. The Company also records, as deemed dividends, the intrinsic value of conversion options embedded in preferred shares based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the shares.

The Company's convertible instruments do not host conversion options that are deemed to be free standing derivative financial instruments.

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

The Company accounts for the issuance of common stock purchase warrants issued and other free standing derivative financial instruments in accordance with the provisions of EITF 00-19. Based on the provisions of EITF 00-19, the Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities 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) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

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***Recent Accounting Pronouncements***

In EITF Issue No. 04-8, “The Effect of Contingently Convertible Instruments on Diluted Earnings per Share,” the EITF reached a consensus that contingently convertible instruments, such as contingently convertible debt, contingently convertible preferred stock and other such securities should be included in diluted earnings per share (if dilutive) regardless of whether the market price trigger has been met. The consensus became effective for reporting periods ending after December 15, 2004. The adoption of this pronouncement did not have material effect on the Company’s financial statements.

In May 2005, the FASB issued SFAS No. 154, “Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3 (“SFAS 154”). This Statement replaces APB Opinion No. 20, “Accounting Changes,” and FASB Statement No. 3, “Reporting Accounting Changes in Interim Financial Statements,” and changes the requirements for the accounting for and reporting of a change in accounting principle. This Statement applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed.

APB Opinion No. 20 previously required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. This Statement requires retrospective application to prior periods’ financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, this Statement requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings (or other appropriate components of equity or net assets in the statement of financial position) for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, this Statement requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. This Statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company’s does not believe that the adoption of SFAS 154 did not have an effect on its financial statements.

On June 29, 2005, the EITF ratified Issue No. 05-2, “The Meaning of ‘Conventional Convertible Debt Instrument’ in EITF Issue No. 00-19, ‘Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock.’ ” EITF Issue 05-2 provides guidance on determining whether a convertible debt instrument is “conventional” for the purpose of determining when an issuer is required to bifurcate a conversion option that is embedded in convertible debt in accordance with SFAS 133. Issue No. 05-2 is effective for new instruments entered into and instruments modified in reporting periods beginning after June 29, 2005. The Company does not believe that the adoption of this pronouncement did not have a significant effect on its financial statements.

In September 2005, Issue No. 05-4, “The Effect of a Liquidated Damages Clause on a Freestanding Financial Instrument Subject to EITF Issue No. 00-19, ‘Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock.’ ” EITF 05-4 provides guidance to issuers as to how to account for registration rights agreements that require an issuer to use its “best efforts” to file a registration statement for the resale of equity instruments and have it declared effective by the end of a specified grace period and, if applicable, maintain the effectiveness of the registration statement for a period

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of time or pay a liquidated damage penalty to the investor. The Company is currently in the process of evaluating the effect that the adoption of this pronouncement may have on its financial statements.

In September 2005, the FASB ratified EITF Issue No. 05-7, "Accounting for Modifications to Conversion Options Embedded in Debt Instruments and Related Issues," which addresses whether a modification to a conversion option that changes its fair value affects the recognition of interest expense for the associated debt instrument after the modification and whether a borrower should recognize a beneficial conversion feature, not a debt extinguishment if a debt modification increases the intrinsic value of the debt (for example, the modification reduces the conversion price of the debt). This issue is effective for future modifications of debt instruments beginning in the first interim or annual reporting period beginning after December 15, 2005. The Company does not believe that the adoption of this pronouncement will have a significant effect on its financial statements.

In September 2005, the FASB also ratified EITF Issue No. 05-8, "Income Tax Consequences of Issuing Convertible Debt with a Beneficial Conversion Feature," which discusses whether the issuance of convertible debt with a beneficial conversion feature results in a basis difference arising from the intrinsic value of the beneficial conversion feature on the commitment date (which is treated and recorded in stockholder's equity for book purposes, but as a liability for income tax purposes) and, if so, whether that basis difference is a temporary difference under FASB Statement No. 109, "Accounting for Income Taxes." This Issue should be applied by retrospective application pursuant to Statement 154 to all instruments with a beneficial conversion feature accounted for under Issue 00-27 included in financial statements for reporting periods beginning after December 15, 2005. The Company does not believe that the adoption of this pronouncement will have a significant effect on its financial statements.

In February 2006, the FASB issued SFAS No. 155 "Accounting for Certain Hybrid Financial Instruments—an amendment of FASB Statements No. 133 and 140" ("SFAS 155"). SFAS 155 addresses the following: a) permits fair value re-measurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation; b) clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement 133; c) establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation; d) clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives; and e) amends Statement 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. SFAS 155 is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. The Company is currently evaluating the requirements of SFAS 155, but does not expect that the adoption of this pronouncement will have a material effect on its financial statements.

In March 2006, the FASB issued SFAS 156 "Accounting for Servicing of Financial Assets — an amendment of FASB Statement No. 140" ("SFAS 156"). SFAS 156 is effective for the first fiscal year beginning after September 15, 2006. SFAS 156 changes the way entities account for servicing assets and obligations associated with financial assets acquired or disposed of. The Company has not yet completed its evaluation of the impact of adopting SFAS 156 on its results of operations or financial position, but does not expect that the adoption of SFAS 156 will have a material impact.

The FASB issued FASB Interpretation No. ("FIN") 48, "Accounting for Uncertainty in Income Taxes," on July 13, 2006. The new rules will be effective for the Company in fiscal 2008. At this time, the Company has not completed its review and assessment of the impact of the adoption of FIN 48.



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Other accounting standards that have been issued or proposed by the FASB 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.

In September 2006, the FASB issued SFAS No. 157, "Accounting for Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, and establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosure about fair value measurements. SFAS 157 is effective for financial statements issued subsequent to November 15, 2007. We do not expect the new standard to have any material impact on our financial position, results of operations or cash flows.

**NOTE 4 — Accounts Receivable**

Accounts receivable consisted of the following (in thousands):

	<u>March 31,</u>		<u>September 30,</u>
	<u>2005</u>	<u>2006</u>	<u>2006</u>
			(unaudited)
Accounts receivable	\$ 227	\$ 1,166	\$ 1,872
Less: allowance for doubtful accounts	—	(90)	(171)
	<u>\$ 227</u>	<u>\$ 1,076</u>	<u>\$ 1,701</u>

**NOTE 5 — Inventories**

Inventories consisted of the following (in thousands):

	<u>March 31,</u>		<u>September 30,</u>
	<u>2005</u>	<u>2006</u>	<u>2006</u>
			(unaudited)
Raw materials	\$ 272	\$ 267	\$ 351
Finished goods	817	1,046	48
	1,089	1,313	399
Less: inventory allowances	(221)	(996)	(44)
	<u>\$ 868</u>	<u>\$ 317</u>	<u>\$ 355</u>

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

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

	<u>March 31,</u>		<u>September 30,</u>
	<u>2005</u>	<u>2006</u>	<u>2006</u>
			(unaudited)
Prepaid expenses	\$ 355	\$ 304	\$ 333
Value added tax receivable	—	722	588
Other current assets	144	360	187
	<u>\$ 499</u>	<u>\$ 1,386</u>	<u>\$ 1,108</u>

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**NOTE 7 — Property and Equipment**

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

	<b>March 31,</b>		<b>September 30,</b>
	<b>2005</b>	<b>2006</b>	<b>2006</b>
			<b>(unaudited)</b>
Manufacturing and other equipment	\$ 1,834	\$ 1,866	\$ 2,187
Office equipment	447	653	688
Furniture and fixtures	200	209	213
Leasehold improvements	219	498	482
Capital projects in progress	51	—	251
	<u>2,751</u>	<u>3,226</u>	<u>3,821</u>
Less accumulated depreciation and amortization	<u>(792)</u>	<u>(1,286)</u>	<u>(1,597)</u>
	<u>\$ 1,959</u>	<u>\$ 1,940</u>	<u>\$ 2,224</u>

Fixed assets include \$217,000 and \$186,000 of equipment purchases that were financed under capital lease obligations as of March 31, 2005 and 2006, respectively (Note 10). The Company made approximately \$40,000 and \$37,000 of such purchases during the years ended March 31, 2004 and 2005, respectively. The accumulated amortization on these assets amounted to \$80,000, \$108,000 and \$126,000 as of March 31, 2005 and 2006 and September 30, 2006, respectively.

Depreciation expense (including amortization of leased assets) amounted to \$163,000, \$434,000 and \$651,000 for the years ended March 31, 2004, 2005 and 2006, respectively, and \$307,000 and \$328,000 for the six months ended September 30, 2005 and 2006, respectively.

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

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

	<b>March 31,</b>		<b>September 30,</b>
	<b>2005</b>	<b>2006</b>	<b>2006</b>
			<b>(unaudited)</b>
Accrued salaries	\$ 220	\$ 267	\$ 371
Accrued professional fees	641	673	566
Estimated liability for pending litigation	335	300	300
Investor deposits	497	—	—
Accrued stock option rescission	250	—	—
Accrued value added tax payable	285	220	187
Deferred revenue	—	156	163
Accrued other	107	70	218
	<u>\$ 2,335</u>	<u>\$ 1,686</u>	<u>\$ 1,805</u>

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**NOTE 9 — Long-Term Debt**

From May 1, 1999 through January 7, 2003, the Company issued various notes for aggregate principal amounting to \$385,000 with interest rates ranging from 8% to 10.3% per annum. The proceeds of these notes were used to fund the Company's operations. The Company made the remaining principal payments on these notes which amounted to \$84,000 and \$185,000 during the years ending March 31, 2004 and 2005, respectively. Aggregate interest expense under these obligations amounted to \$19,000 and \$9,000 for the years ended March 31, 2004 and 2005, respectively.

On May 1, 1999, the Company issued a note payable in the amount of \$64,000 with interest at 8% per annum and a final payment due on December 31, 2009. The remaining balance on this obligation, which amounts to \$68,000 including accrued interest, is included in non-current portion of long-term debt in the accompanying balance sheet at March 31, 2006. Contractual interest expense under this note amounted to \$7,000 for each of the years ended March 31, 2004 and 2005. In the six months ended September 30, 2006, the Company made principal payments on this note in the amount of \$15,000.

On February 7, 2003, the Company issued a \$40,000 convertible note to a director of the Company bearing interest at the rate of 10% per annum. The note was convertible, at the option of the holder, into such number shares of the Company's common stock or Series A preferred stock determined by dividing the amount to be converted by the conversion price of \$1.00 per share.

On February 26, 2003, the Company issued a \$40,000 convertible note to a director of the Company bearing interest at the rate of 10% per annum with a maturity date of August 26, 2004. The note was convertible, at the option of the holder, into such number shares of the Company's common stock or Series A preferred stock determined by dividing the amount to be converted by the conversion price of \$4.00 per share.

The proceeds of these notes were used to finance operating activities. The fair value of the underlying stock, measured at the commitment date of each of these financing transactions, was \$8.00 per share. Accordingly, the Company recorded a \$40,000 discount against the principal values of the each of these notes and a corresponding increase in stockholders' equity for the intrinsic value of the beneficial conversion feature in accordance with EITF 98-5. The principal balance of the note originated on February 2, 2003 was repaid in October 2004. The principal balance of the note originated on February 23, 2003 was converted into 40,000 shares of convertible series A preferred stock in June 2005.

Aggregate contractual interest expense under the convertible notes amounted to \$3,000, \$8,000 and \$4,000 for the years ended March 31, 2004, 2005 and 2006, respectively.

On April 30, 2003, the Company completed a \$500,000 financing transaction through the issuance of a note bearing variable interest at the rate of 18% to 22% per annum and warrants to purchase up to 20,618 shares of the Company's common stock (Note 12). In accordance with APB Opinion No. 14 "Accounting for Convertible Debt Issued with Stock Purchase Warrants," the Company allocated \$538,000 of the proceeds to the note and \$117,000 of proceeds to the warrants. The difference between the carrying amount of the note and its contractual redemption amount was accreted as interest expense through July 31, 2005, its earliest date of redemption. Accretion of the aforementioned discount amounted to \$36,500, \$60,100 and \$20,400 for the years ended March 31, 2004, 2005, and 2006, respectively and is included as a component of interest expense in the accompanying statements of operations. The proceeds from this note were used to fund operating activities. Contractual interest expense under this obligation amounted to \$72,500, \$99,700 and \$30,100 for the years ended March 31, 2004, 2005 and 2006, respectively. Principal payments on this note amounted to \$100,000 and \$400,000 during the years ended March 31, 2005 and 2006, respectively, including the final payment made in July 2005.

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From November 2003 to March 2006, the Company issued various notes for aggregate principal amounting to \$443,000 with interest rates ranging from 6.65% to 8.2% per annum. The proceeds of these notes were used to fund certain operating activities. The Company made principal payments on these notes which amounted to \$21,300, \$91,500 and \$191,200 during the years ending March 31, 2004, 2005 and 2006, respectively, and \$85,000 for the six months ended September 30, 2006. Interest expense under these note obligations amounted to \$900, \$2,000 and \$4,800 for the years ended March 31, 2004, 2005 and 2006, respectively, and \$5,000 for the six months ended September 30, 2006. The aggregate remaining principal balance of these notes, which amounts to \$139,000, is included in the current portion of long-term debt in the accompanying balance sheet at March 31, 2006.

In March 2004, the Company entered into an equipment financing facility providing it with up to \$1,000,000 of available credit to finance equipment purchases through March 31, 2005. During the year ended March 31, 2005, the Company drew an aggregate of \$994,000 of advances under this facility, which are payable in 33 monthly installments with interest at the rate of 13.5% per annum and mature at various times through May 1, 2007. The Company also paid approximately \$82,000 of fees to the lender under this arrangement including \$5,000 in cash and \$77,000 representing the fair value of warrants to purchase up to 16,666 shares of the Company's Series A preferred stock (Note 12). The company recorded the fair value of warrants and other fees as interest expense during the year ended March 31, 2005, the one year period in which the Company was permitted to draw advances under this facility. All borrowings under this arrangement are collateralized by the equipment financed under this facility. The Company made principal payments on these notes which amounted to \$288,000 and \$337,000 during the years ending March 31, 2005 and 2006 respectively, and \$187,000 for the six months ended September 30, 2006. Interest expense under this obligation amounted to \$83,000 and \$73,000 for the years ended March 31, 2005 and 2006, respectively, and \$19,000 for the six months ended September 30, 2006. The remaining principal balance on this long-term debt amounted to \$350,000 at March 31, 2006, including \$332,000 included in the current portion of notes payable obligations in the accompanying balance sheet.

From January 2004 to March 2006, the Company issued various notes for aggregate principal amounting to \$182,000 with interest rates ranging from 6.25% to 14.44% percent per annum. The proceeds of these notes were used to purchase automobiles and software. The Company made principal payments on these notes of \$1,000, and \$24,000 during the years ending March 31, 2005 and 2006, respectively, and \$17,000 for the six months ended September 30, 2006. Aggregate interest expense under these obligations amounted to \$1,000 and \$8,900 for the years ended March 31, 2005 and 2006, respectively, and \$6,000 for the six months ended September 30, 2006. These notes are payable in aggregate monthly installments of \$3,000 through March 14, 2011. The remaining balance of these notes amounted to \$156,000 at March 31, 2006, including \$33,000 in the current portion of long-term debt in the accompanying balance sheet.

In June 2006, the Company entered into a credit facility providing it with up to \$5,000,000 of available credit. The facility permitted the Company to borrow up to a maximum of \$2,750,000 for growth capital, \$1,250,000 for working capital based on eligible accounts receivable and \$1,000,000 in equipment financing. During the three months ended June 30, 2006, the Company drew an aggregate of \$4,182,000 of borrowings under this facility. These borrowings are payable in 30 to 33 fixed monthly installments with interest at rates ranging from 12.4% to 12.7% per annum, maturing at various times through April 9, 2009. The Company has no unused availability under this credit facility since amounts drawn under the working capital facility were based upon an initial measurement of eligible accounts receivable.

The Company also issued to the lender warrants to purchase up to 71,534 shares of its Series B preferred stock upon originating the loan. In addition, the Company will issue warrants to purchase up to 3,466 additional shares of its Series B preferred stock in connection with its utilization of the line of credit. The aggregate fair value of all warrants issued to the lender under this arrangement amounts to \$1,047,000

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(Note 12). This amount was recorded as debt issue costs in the September 30, 2006 balance sheet and is being amortized as interest expense over the term of the credit facility.

Borrowings under the growth capital line are collateralized by the total assets of the Company other than the Company's intellectual property, and the security interest extends to the intellectual property under certain circumstances. Borrowings under the equipment line are collateralized by the underlying assets funded, and borrowings under the working capital line are collateralized by eligible accounts receivable. On a monthly basis, the Company must maintain a 1:1 ratio of borrowing under the working capital line to eligible accounts receivable. The Company has 30 days from each measurement date to either increase eligible accounts receivable or pay the excess principal in the event that the ratio is less than 1:1. No restrictive covenants exist for either the equipment line or the growth capital line. The Company made \$167,000 of principal payments and paid \$101,000 of interest on these notes during the six months ended September 30, 2006. The Company is not required to direct customer remittances to a lock box, nor does the credit agreement provide for subjective acceleration of the loans. The aggregate remaining principal balance under this facility amounted to \$4,013,000, including \$1,410,000 in the current portion of long term debt in the accompanying balance sheet at September 30, 2006.

In June 2006, the Company entered into a note agreement for \$69,000 with interest rate of 7.94% percent per annum. The proceeds of this note were used to purchase an automobile. This note is payable in monthly installments of \$1,200 through May 2012. The Company made principal payments of \$2,900 and interest payments of \$2,000 in the six months ended September 30, 2006. The remaining balance of this note amounted to \$66,000 at September 30, 2006, including \$9,300 in the current portion of long-term debt in the accompanying balance sheet.

From July 2006 to September 2006, the Company entered into note agreements for \$129,000 with interest rates ranging from 9.6% to 9.7% percent per annum. The proceeds of these notes were used to finance insurance premiums. These notes are payable in monthly installments of \$11,400 through June 2007. The Company made principal payments of \$40,700 and interest payments of \$770 in the six months ended September 30, 2006. The remaining balance of these notes amounted to \$88,300 at September 30, 2006, and is included in the current portion of long-term debt in the accompanying balance sheet.

A summary of principal payments due in years subsequent to March 31, 2006 is as follows (in thousands):

**For years ending March 31,**

2007	\$ 504
2008	54
2009	39
2010	106
2011	11
Total principal payments	714
Less: current portion	(504)
Long-term portion	<u>\$ 210</u>

**NOTE 10 — Capital Lease Obligations**

From September 1, 2001, through July 1, 2002, the Company entered into various capital leases under which the aggregate present value of the minimum lease payments amounted to \$123,000. In accordance with

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SFAS 13, "Accounting for Leases" ("SFAS 13"), the present value of the minimum lease payments was calculated using discount rates ranging from 10% to 17%. Lease payments, including amounts representing interest, amounted to \$38,000, \$36,000 and \$15,000, for the years ended March 31, 2004, 2005 and 2006, respectively. These capital leases were paid in full by March 2006.

From September 1, 2003, through October 1, 2003, the Company entered into various capital leases under which the aggregate present value of the minimum lease payments amounted to \$40,000. The present value of the minimum lease payments was calculated using discount rates of ranging from 13% to 18%. Lease payments, including amounts representing interest, amounted to \$3,000, \$11,000 and \$11,000 for the years ended March 31, 2004, 2005 and 2006, respectively, and \$6,000 for the six months ended September 30, 2006. The remaining principal balance on these obligations amounted to \$27,000 at March 31, 2006, including \$7,700 included in the current portion of capital lease obligations in the accompanying balance sheet.

On November 10, 2004, the Company entered into a capital lease under which the present value of the minimum lease payments amounted to \$37,000. The present value of the minimum lease payments was calculated using a discount rate of 10%. Lease payments, including amounts representing interest, amounted to \$3,900 and \$8,500 for the years ended March 31, 2005 and 2006, respectively, and \$4,600 for the six months ended September 30, 2006. The remaining principal balance on these obligations amounted to \$29,000 at March 31, 2006, including \$7,000 included in the current portion of capital lease obligations in the accompanying balance sheet.

The Company recorded interest expense in connection with these lease agreements in the amounts of \$9,600, \$11,000 and \$8,900 for the years ended March 31, 2004, 2005 and 2006, respectively, and \$3,500 for the six months ended September 30, 2006.

Minimum lease payments due in years subsequent to March 31, 2006 are as follows (in thousands):

**For years ending March 31,**

2007	\$ 21
2008	21
2009	21
2010	6
Total minimum lease payments	69
Less: amounts representing interest	(13)
Present value of minimum lease payments	56
Less: current portion	(15)
Long-term portion	<u>\$ 41</u>

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**NOTE 11 — Commitments, Contingencies and Other Matters**

***Lease Commitments***

The Company has entered into various non-cancelable operating leases, primarily for office facility space, that expire at various time through April 2011. Minimum lease payments for non-cancelable operating leases are as follows (in thousands):

**For years ending March 31,**

2007	\$ 341
2008	177
2009	163
2010	92
2011	<u>105</u>
Total minimum lease payments	<u>\$ 878</u>

Rent expense amounted to \$273,000, \$510,000 and \$535,000 for the years ended March 31, 2004, 2005 and 2006, respectively. Rent expense amounted to \$351,000 and \$268,000 for the six months ended September 30, 2005 and 2006, respectively.

In September 2006, the Company extended its operating lease on its Petaluma facility. This lease was extended through September 2007.

***Employment Agreements***

During years ended March 31, 2005 and 2006, the Company entered into employment agreements with five of its key executives. The agreements provide, among other things, for the payment of aggregate annual salaries of approximately \$880,000 and up to twenty four months of severance compensation for terminations under certain circumstances. Aggregate potential severance compensation amounted to \$1,284,000 at March 31, 2006.

In October 2005, the Board of Directors also authorized the Company to grant 60,000 stock options at an exercise price of \$3.00 per share to its Chief Financial Officer upon the successful completion of its proposed IPO (if completed). These options, if awarded, would be fully vested and non-forfeitable at the date of grant.

***Legal Matters***

The Company was named as a defendant in an employment related matter under a complaint filed by one of its former employees in the Superior Court of the State of California in the County of Sonoma in April 2005. The Company entered into a settlement agreement with the plaintiff in November 2006, which provides for the payment of \$250,000 and the issuance of a warrant to purchase 50,000 shares of our common stock exercisable at \$3.00 per share. The issuance of the warrant is subject to our obtaining appropriate waivers from our preferred stockholders and the cash payment is subject to the closing of an equity financing resulting in gross proceeds to the Company of \$10 million or more, or the completion of our initial public offering of securities. Under the terms of the agreement, the plaintiff has agreed to dismiss his claim and has waived any other previous claims against us. Although the Company believes that the employee's claim is without merit and intends to defend its position with respect to this matter, a \$300,000 reserve was established based on the Company's estimate of potential loss. Although the Company believes that its estimate is reasonable with respect to this matter, there can be no assurance that the Company will successfully defend itself against this

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litigation. The reserve is a component of accrued expenses and other current liabilities in the accompanying balance sheets.

In November 2005, the Company identified a possible criminal misappropriation of its technology in Mexico, and it notified the Mexican Attorney General's office. The Company believes the Mexican Attorney General is currently conducting an investigation.

On March 14, 2006, the Company filed suit in the U.S. District Court for the Northern District of California against Nofil Corporation and Naoshi Kono, Chief Executive Officer of Nofil, for breach of contract, misappropriation of trade secrets and trademark infringement. The Company believes that Nofil Corporation violated key terms of both an exclusive purchase agreement and non-disclosure agreement by contacting and working with a potential competitor in Mexico. In the complaint, the Company seeks damages of \$3,500,000 and immediate injunctive relief. No trial date has been set.

The Company is currently a party in two trademark matters asserting confusion in trademarks with respect to the Company's use of the name Microcyn60 in Mexico. Although the Company believes that the nature and intended use of its products are different from those with the similar names, it has agreed with one of the parties to stop using the name Microcyn60 by September 2007. Although such plaintiff referred the matter to the Mexico Trademark Office, the Company is not aware of a claim for monetary damages. Company management believes that the name change will satisfy an assertion of confusion; however, Company management believes that the Company could incur a possible loss of approximately \$100,000 for the use of the name Microcyn60 during the twelve month period following the date of settlement.

In June 2006, the Company received a written communication from the grantor of a license to an earlier version of its technology indicating that such license was terminated due to an alleged breach of the license agreement by the Company. The license agreement extends to the Company's use of the technology in Japan only. While the Company does not believe that the grantor's revocation is valid under the terms of the license agreement and no legal claim has been threatened to date, the Company cannot provide any assurance that the grantor will not take legal action to restrict the Company's use of the technology in the licensed territory.

While the Company management does not anticipate that the outcome of this matter is likely to result in a material loss, there can be no assurance that if the grantor pursues legal action, such legal action would not have a material adverse effect on the Company's financial position or results of operations.

In August 2006, the Company received a "show cause" letter from the U.S. Environmental Protection Agency ("EPA"), which stated that, in tests conducted by the EPA, Cidalcyn was found to be ineffective in killing certain specified pathogens when used according to label directions. Based on its results, the EPA strongly recommended that the Company immediately recall all Cidalcyn distributed on and after September 28, 2005. Accordingly, the Company has commenced a voluntary recall of Cidalcyn. Although the Company has not marketed Cidalcyn on a large commercial scale, it has provided it in small quantities to numerous hospitals solely for use in product evaluation exercises. In a second letter, the EPA stated it intended to file a civil administrative complaint against the Company for violation of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Under FIFRA, the EPA could assess civil penalties related to the sale and distribution of a pesticide product not meeting the label's claims as a broad-spectrum hospital disinfectant. The Company believes that such civil penalties could be up to \$200,000. The Company currently cannot estimate the actual amount of penalties which may be incurred. The Company does not believe this issue will have a material impact on future operations.

In September 2006, a consulting firm in Mexico City contacted the Company threatening legal action in Mexico, alleging breach of contract and claiming damages of \$225,000. A formal complaint has not been served and no trial date has been set. The Company is currently in settlement negotiations with the plaintiff. If



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these negotiations are not successful, the Company intends to vigorously defend this action. If the claims are litigated, the Company may incur considerable litigation costs.

The Company, from time to time, is involved in legal matters arising in the ordinary course of its business. While management believes that such matters are currently insignificant, 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.

***Consulting Agreements***

On October 1, 2005 the Company entered into a consulting agreement with White Moon Medical. Akihisa Akao, a member of the Board of Directors, is the sole stockholder of White Moon Medical. Under the terms of the agreement, the individual will be compensated for services provided outside his normal Board duties. Total compensation to be paid amounts to \$146,000, payable in monthly installments over the one year term of the agreement. In accordance with the terms of this agreement, the Company made payments in the amount of \$146,000 for the period of October 1, 2005 to September 30, 2006. The Company extended the agreement for an additional one-year term.

As described in Note 18, the Company entered into a consulting agreement with Mr. Robert Burlingame, one of the Company's directors who also provided the company with a \$4.0 million bridge loan which is described in Note 18.

***Proposed Initial Public Offering***

On September 1, 2005 the Board of Directors authorized the Company to file a registration statement with the SEC in connection with its proposed IPO. The Company incurred \$478,000 of costs during the year ended March 31, 2006 and \$927,000 of costs in the six months ended September 30, 2006 in connection with its proposed IPO, which amounts are presented as deferred offering costs in the accompanying balance sheet at March 31, 2006 and September 30, 2006.

The Company expects to receive net proceeds of approximately \$36.8 million from this offering, based on an assumed initial public offering price of \$13.00 per share, after deducting the underwriting discount and estimated offering expenses. If the underwriters exercise their over-allotment option in full, our estimated net proceeds will be approximately \$42.4 million. The Company currently intends to use the proceeds of this offering as follows: approximately \$14.3 million will be used to expand sales and marketing capabilities, including the expansion of a direct sales force in the U.S. and Europe, approximately \$13.0 million will be used to fund clinical trials and related research, to repay the principal and interest of our Bridge Loan and the remaining proceeds are to be used for general corporate purposes, including working capital.

The Company cannot provide any assurance that it will complete its proposed IPO. The Company expects to incur substantial additional costs in connection with its efforts to complete this offering. If the Company completes its IPO, these costs will be recorded as a reduction of the proceeds received. If the Company does not successfully complete its IPO, the costs will be recorded as a charge to operations.

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**NOTE 12 — Stockholders' Equity**

*Authorized Capital*

The Company is authorized to issue up to 25,000,000 shares of common stock and 7,500,000 shares of preferred stock of which 1,375,000 shares have been designated as Series A preferred stock, 2,805,555 shares have been designated as Series B preferred stock and 875,000 shares have been designated Series C preferred stock.

*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, subject to the prior right of the preferred Series A stockholders to cumulative dividends that accrue beginning January 1, 2006.

*Convertible Preferred Stock*

During the year ended March 31, 2004, the Company issued in a private placement transaction, 1,337,709 shares of its Series A convertible preferred stock for net proceeds of \$6,628,000 (gross proceeds of \$8,027,000 less offering costs of \$1,399,000).

The Company also issued in a private placement transaction, an aggregate of 2,635,744 shares of its Series B for net proceeds of \$43,722,000 (gross proceeds of \$47,446,000 less offering costs of \$3,724,000) including 1,014,093 shares issued during the year ended March 31, 2005 for net proceeds of \$16,696,000 and 1,621,651 shares issued during the year ended March 31, 2006 for net proceeds of \$27,026,000.

In addition to the above, during the six months ended September 30, 2006, the Company issued in a private placement transaction, an aggregate of 84,539 shares of its Series C stock for net proceeds of \$1,370,000 (gross proceeds of \$1,521,700 less offering costs of \$152,170).

The Series A is convertible into common stock at any time, at the option of the holder at a conversion price of \$6.00 per share. The Series B and Series C is convertible into common stock at any time, at the option of the holder, at a conversion price of \$18.00 per share.

The number of shares issuable under the conversion features of the Series A, Series B and Series C is subject to adjustment for stock splits, stock dividends, recapitalizations, dilutive issuances and other anti-dilution provisions, including future issuances of equity securities (at the Company's option) or convertible instruments that feature prices more favorable than the conversion rates specified in the Series A, B and C preferred shares. The Series A, Series B and Series C are also automatically convertible into shares of the Company's common stock, at the then applicable conversion price, (i) in the event that the holders of two-thirds of the outstanding shares of Series A, Series B and Series C consent to such conversion; or (ii) upon the closing of a firm commitment underwritten public offering of shares of common stock of the Company yielding aggregate proceeds of not less than \$20 million (before deduction of underwriters commissions and expenses); or (iii) Company's going public by means of a merger or acquisition which has a resultant market capitalization of greater than \$75 million.

The Company has reserved 5,055,555 shares of its common stock for issuance upon the conversion of its convertible preferred stock.

Each share of Series A, Series B and Series C preferred has voting rights equal to an equivalent number of common shares into which it is convertible and votes together as one class with common stock. The holders of the Series A are entitled to receive cumulative dividends in preference to any dividend on the common stock at the rate of 6% per annum on the initial investment amount commencing January 1, 2006. Dividends

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accrued but unpaid with respect to this feature amounted to \$121,000 for both the year ended March 31, 2006 and \$242,000 for the six months ended September 30, 2006, and is presented as an increase in net loss available to the common stockholders for the year ended March 31, 2006 and six months ended September 30, 2006. The Company has the option of paying the dividend in either common stock or cash. The holders of Series B are entitled to receive non-cumulative dividends when and if declared by the Board. The holders of Series C are entitled to non-cumulative dividends when and if declared by the Board and only after the Series A have been paid all accrued but unpaid dividends and any dividends declared by the Board and payable to the Series B have been paid. The holders of Series A, Series B and Series C are also entitled to participate pro rata in any dividends paid on the common stock, if declared by the board of directors on an as converted basis.

In the event of any liquidation or winding up of the Company, the holders of the Series A shall be entitled to participate in the ratable distribution of the assets of the Company until the holders of the Series A have received a per share amount equal to \$12.00 plus any declared but unpaid dividends. The holders of Series B are entitled to participate in the ratable distribution of the assets of the Company after the holders of Series A have received a per share amount equal to \$12.00 and holders of Series B have received a per share amount equal to \$22.50, plus any declared but unpaid dividends. The holders of Series C are entitled to participate in the ratable distribution of the assets of the Company after the holders of Series A have received a per share amount equal to \$12.00, Series B have received a per share amount equal to \$22.50 and Series C have received a per share amount equal to \$22.50, plus any declared but unpaid dividends. Thereafter, any remaining assets would be distributed ratably to the holders of common stock until the common stockholders have received a per share amount equal to \$12.00. Any remaining assets of the Company thereafter would be distributed ratably to the Series A preferred stockholders, Series B preferred stockholders, Series C preferred stockholders and to the common stockholders, on an as converted basis.

Liquidation events include (i) a final dissolution or winding up of the Company's affairs requiring a liquidation of all classes of stock, (ii) a merger, consolidation or similar event resulting in a more than 50% change in control, (iii) the sale of all or substantially all of the Company's assets and (iv) the effectuation (at the Company's election) of any transaction or series of transactions resulting in a more than 50% change in control.

Under the terms of Series A, Series B and Series C registration rights agreements between the Company and its preferred stockholders, any time after six months following the Company's IPO (if completed), the Series A, Series B and Series C investors may request that the Company file a registration statement covering the public sale of the underlying common stock under the Securities Act of 1933, as amended (the "1933 Act") with limited rights to delay by the Company. The investors are also entitled to unlimited piggyback registration rights on all 1933 Act registrations of the Company (except for registrations relating to employee benefit plans on Form S-8 and corporate reorganizations on Form S-4). The foregoing demand and piggyback registration rights terminate on the earlier of (i) one year after the Company's IPO or (ii) such time as Rule 144 or another similar exemption under the 1933 Act is available for sale of all of an Investor's shares during a three-month period without registration. The Investors Rights Agreement also places certain restrictions on the preferred stockholders from selling their shares and provides them with certain rights of first refusal, co-sale and drag along and tag along rights for sales effectuated under certain circumstances.

As described in (Note 2), the Company applies the classification and measurement principles enumerated in EITF Topic D-98 with respect to accounting for its issuances of the Series A, Series B and Series C preferred stock. The Company is required, under California law, to obtain the approval of its board of directors in order to effectuate a merger, consolidation or similar event resulting in a more than 50% change in control or a sale of all or substantially all of its assets. The board of directors is then required to submit proposals to enter into these types of transactions to its stockholders for their approval by majority vote. The Company's

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preferred stockholders do not (i) have control of the Company's Board of Directors and (ii) currently do not have sufficient voting rights to control a redemption of these shares by either of these events. In addition the effectuation of any transaction or series of transactions resulting in a more than 50% change in control of the Company can be made only by the Company at its own election. Based on these provisions, the Company classified its Series A, Series B and Series C preferred shares in stockholders' equity in the accompanying balance sheet because the liquidation events are deemed to be within the Company's control in accordance with the provisions of EITF Topic D-98.

Also as described in Note 2, the Company evaluated the conversion options embedded in the Series A, Series B and Series C securities to determine (in accordance with SFAS 133 and EITF 00-19) whether they should be bifurcated from their host instruments and accounted for as separate derivative financial instruments. The Company determined, in accordance with SFAS 133, that the risks and rewards of the common shares underlying the conversion feature are clearly and closely related to those of the host instrument. Accordingly the conversion features, which are not deemed to be beneficial at the commitment dates of these financing transactions, are being accounted for as embedded conversion options in accordance with EITF 98-5 and EITF 00-27.

The Company evaluates the Series A, Series B and Series C convertible preferred stock at each reporting date for appropriate balance sheet classification.

***Stock Purchase Warrants Issued in Financing Transactions***

During the year ended March 31, 2004, the Company issued a warrant to purchase 15,618 shares of common stock in connection with bridge financing at an exercise price equal to the lesser of \$8.00 per share or the price offered to any other investor in subsequent stock offerings prior to the expiration date of the warrants. The warrants were valued using the Black-Scholes pricing model. Assumptions used were as follows: Fair value of the underlying stock \$8.00; risk-free interest rate 3.03%; contractual life of 5 years; dividend yield of 0%; and volatility of 70%. The fair value of these warrants, which amounted to \$88,478, was recorded as interest expense in the accompanying statement of operations for the year ended March 31, 2004.

During the year ended March 31, 2005, the Company issued a warrant to purchase 5,000 shares of common stock in connection with bridge financing at an exercise price equal to the lesser of \$6.00 per share or the price offered to any other investor in subsequent stock offerings prior to the expiration date of the warrants. The warrants were valued using the Black-Scholes pricing model. Assumptions used were as follows: Fair value of the underlying stock \$1.41; risk-free interest rate 2.94%; contractual life of 4 years; dividend yield of 0%; and volatility of 70%. The fair value of the warrants amounted to \$28,309 and was recorded as interest expense in the accompanying statement of operations for the year ended March 31, 2005.

During the year ended March 31, 2005, the Company issued a warrant to purchase 16,666 shares of Series A preferred stock at an exercise price of \$6.00 per share in connection with an equipment leasing arrangement. The warrants were valued using the Black-Scholes pricing model. Assumptions used were as follows: Fair value of the underlying stock \$5.76; risk-free interest rate 5.55% percent; contractual life of 10 years; dividend yield of 0%; and volatility of 70%. The fair value of the warrants, which amounted to \$77,000, was recorded as interest expense in the accompanying statement of operations for the year ended March 31, 2005.

During the year ended March 31, 2005, the Company issued a warrant to purchase 433,774 shares of common stock at an exercise price of \$3.00 per share to the placement agent that managed the Series A offering. The warrants were fully exercisable at the date of issuance with no future performance obligations by the placement agent and expire the second year following an IPO by the Company.

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During the year ended March 31, 2006, the Company issued a warrant to purchase 329,471 shares of common stock at an exercise price of \$18.00 per share to the placement agent that managed the Series B stock offering. The warrants were fully exercisable at the date of issuance with no future performance obligations by the placement agent and expire the second year following an IPO by the Company.

During the six month period ended September 30, 2006, the Company issued warrants to purchase 71,534 shares of Series B preferred stock at an exercise price of \$18.00 per share in connection with the new financing facility described in Note 9. The warrants were valued using the Black-Scholes pricing model. Assumptions used were as follows: Fair value of the underlying stock \$18.00; risk-free interest rate 5.15% percent; contractual life of 11 years; dividend yield of 0%; and volatility of 70%. The fair value of the warrants, which amounted to \$1,047,000, was recorded as deferred debt issue costs and is being amortized as interest expense over the term of the credit facility. Amortization of these costs amounted to \$125,000 and is included as a component of interest expense in the accompanying statement of operations for the six months ended September 30, 2006.

During the six months ended September 30, 2006, the Company issued a warrant to purchase 10,567 shares of common stock at an exercise price of \$18.00 per share to the placement agent of the Series C stock offering. The warrants were fully exercisable at the date of issuance with no future performance obligations by the placement agent and expire five years from the date of issuance.

During the six months ended September 30, 2006, the Company issued warrants to purchase 16,907 shares of common stock at an exercise price of \$18.00 per share to investors in conjunction with the purchase of 84,539 Series C stock units. The warrants require settlement in shares of the Company's common stock. The Company accounts for the issuance of common stock purchase warrants issued in connection with sales of its Units in accordance with the provisions of EITF 00-19 "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock". Based on the provisions of EITF 00-19, the Company classified the warrants as equity. In addition, the Company determined the preferred stock was issued with no effective beneficial conversion feature and therefore it was not necessary to record a deemed dividend.

***Common Stock and Common Stock Purchase Warrants Issued to Non-Employees for Services***

During the year ended March 31, 2004, the Company issued warrants to purchase 9,664 shares of common stock to various consultants at exercise prices ranging from \$3.00 to \$8.00 per share. The warrants were fully exercisable at date of issuance and expire on dates ranging from May 31, 2013 to February 14, 2014. The warrants were valued using the Black-Scholes pricing model. Assumptions used were as follows: Fair value of the underlying stock of \$5.24 to \$8.00; risk-free interest rate 3.69% to 4.35%; contractual life of 10 years; dividend yield of 0%; and a volatility of 70%. The fair value of the warrants amounted to \$44,000 and was recorded as selling, general and administrative expense in the accompanying statement of operations for the year ended March 31, 2004.

During the year ended March 31, 2006, the Company issued 12,500 shares of common stock to a consultant in exchange for services provided. The fair value of the underlying stock was valued at \$10.16 per share. The shares were fully earned when issued with no future performance obligation by the consultant. The aggregate fair value of the shares amounted to \$127,000 and was recorded as a selling, general and administrative expense in the accompanying statement of operations for the year ended March 31, 2006.

During the year ended March 31, 2006, the Company issued warrants to purchase 73,843 shares of common stock to various consultants at an exercise price of \$18.00 per share. Fair value of the underlying stock at the date of grant was \$10.16 per share. The warrants become exercisable at various dates through November 11, 2009 and expire at various dates through August 31, 2015. The fair value of the warrants

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amounted to \$153,000, \$82,000 and \$70,000 and was recorded as a selling, general and administrative expense in the accompanying statement of operations for the year ended March 31, 2006 and the six months ended September 30, 2005 and 2006, respectively. The non-vested portion of the warrants were adjusted to fair value at each reporting date using the following weighted average assumptions:

	<b>Year Ended</b>	<b>Six Months Ended</b>	
	<b>March 31,</b>	<b>September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>
		<b>(unaudited)</b>	
Fair market value of common stock	\$ 12.00	\$ 10.16	\$ 13.00
Estimated life	6.24 yrs	5.47 yrs	6.35 yrs
Risk-free interest rate	4.85%	4.11%	4.64%
Dividend yield	0.00%	0.00%	0.00%
Volatility	70%	70%	70%

The Company accounted for its issuance of stock based compensation to non-employees for services using the measurements date guidelines enumerated in SFAS 123 and EITF 96-18. Accordingly, the value of any awards that were vested and non forfeitable at their date of issuance were measured based on the fair value of the equity instruments at the date of issuance. The non-vested portion of awards that are subject to the future performance of the counterparty are adjusted at each reporting date to their fair values based upon the then current market value of the company's stock and other assumptions that management believes are reasonable.

During the six month period ended September 30, 2006, the Company issued 3,750 shares of common stock to a consultant in exchange for services provided. The fair value of the underlying stock was valued at \$11.28 per share. The shares were fully vested and were non-forfeitable when issued with no future performance obligation by the consultant. The aggregate fair value of the shares, which amounted to \$43,000, was recorded as a selling, general and administrative expense in the accompanying statement of operations for the six months ended September 30, 2006.

#### ***Valuation of Common Stock***

For the year ended March 31, 2004, all stock options that the Company granted to employees and non-employees under its 1999, 2000 and 2003 Stock Option Plans were recorded at their cash settlement value due to a compliance matter for which the statute of limitations has expired (Note 13). In July 2005, the Company engaged Valuation Research Corporation, an outside valuation specialist to determine the fair value of its common stock. The fair value of the Company's common stock, based on this valuation study, was determined to be \$10.16 per share. Accordingly, the fair value of the Company's common stock underlying all equity transactions completed during the years ended March 31, 2004, 2005 and 2006 (other than options granted under the 1999, 2000 and 2003 stock option plans) was based on the results of the valuation study. The results were adjusted to the date of grant based on an analysis performed by management. The results were assessed for reasonableness by comparing such amounts to concurrent sales of other equity instruments to unrelated parties for cash and intervening events reflected in the price of the Company's stock.

In June 2006, the Company engaged Valuation Research Corporation, an outside valuation specialist, to determine the fair value of its common stock. The fair value of the Company's common stock, based on this valuation study, was determined to be \$11.28 per share. The fair value of the Company's common stock underlying all equity transactions completed during the six months ended September 30, 2006 was based on the mid point of the Company's proposed IPO which was determined to be 13.00.

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**NOTE 13 — Stock Compensation Plans**

***1999, 2000 and 2003 Stock Plans***

The 1999, 2000 and 2003 Stock Option Plans became effective May 1999, June 2000 and July 2003, respectively. The Plans provide for grants of both incentive stock options (ISO's) and non-qualified stock options (NSO's) to employees, consultants and directors. A total of 1,151,250, 348,750 and 1,000,000 common shares were reserved for issuance under the 1999, 2000 and 2003 Plans, respectively.

In accordance with the Plans, stated exercise price shall 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 ISO's and NSO's, 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 Plan have a ten-year term and generally became exercisable over a five-year period.

As of March 31, 2006, the Company's compensation committee of the board of directors determined that it would not approve any further grants under its 1999, 2000, and 2003 Plans. At March 31, 2006 there were 1,436,317 options available for issue in the 1999, 2000, and 2003 Plans that will not be issued.

On June 29, 2006, the compensation committee of the Company's board of directors adopted a resolution authorizing the Company to cancel these plans. Accordingly, 1,436,317 options previously available for issue are no longer available for future grants.

***2004 Stock Plan***

The 2004 Stock Option Plan ("the 2004 Plan") became effective July 2004. The 2004 Plan provides for the issuance of both ISO's and NSO's. Nonqualified and incentive stock options may be granted to employees, consultants and directors. A total of 1,500,000 common shares were reserved for issuance under the 2004 Plan at March 31, 2005. As of March 31, 2006, 550,411 shares are available for future grant under the Plan.

In accordance with the Plan, the stated exercise price shall not be less than 100% and 85% of the estimated fair market value of common stock on the date of grant for ISO's and NSO's, 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 shall not be less than 110% of the estimated fair market value per share on the date of grant.

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

***Options Granted Outside of Plans***

In May 2004, the Company granted an option to purchase 300,000 shares of the Company's common stock with an exercise price of \$0.16 per share to the Chief Executive Officer of the Company. The fair value of the underlying common stock at the date of grant was \$5.96 per share. The options were fully exercisable on the date of grant. Stock compensation expense related to these options amounted to \$1,740,000 and was recorded in selling, general and administrative expense in the year ended March 31, 2005.

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***Options Subject to Repurchase***

In the period from May 1999 to December 2003, the Company granted an aggregate of 1,827,405 stock options to various employees and non-employees under its 1999, 2000, and 2003 Plans. Subsequent to making such grants, the Company determined that such grants may not have been exempt from registration or qualification rights under the provisions of applicable state securities laws. A failure to comply with applicable state securities laws may give rise to claims optionees against the Company for the repurchase of their unexercised options at an amount determined by a formula specified by state securities law regulators, plus legal interest, or rescission of the purchase of the shares of common stock issued upon exercise of the options at an amount equal to the exercise price of the options, plus interest from the date of exercise. The repurchase and rescission rights held by the Company's security holders, if any, are subject to applicable statute of limitations prescribed by state law. In California, the statute of limitation is two years. During the period from May 2001 to December 2005 the statute of limitations would have lapsed for bringing claims against the Company related to options granted during the period from May 2001 to December 2005 subject to California law.

The Company accounted for the repurchase and rescission rights in accordance with APB 25 paragraph 25 and SFAS 123 paragraph 25, both of which are titled "Awards That Call for Settlement in Cash". These standards require entities to record stock based compensation awards as liability instruments when the optionee has the ability to compel the entity to settle the award by transferring cash or other assets. In addition, other accounting literature (including literature relating to accounting for derivative financial instruments) requires liability classification when a net cash settlement is in the holder's control. The Company believes that if the holders of these awards possess a free standing right to require cash settlement that liability classification of these awards is required under APB 25 and SFAS 123 (the standards applicable at the time of grant) and that such treatment is consistent with the principles of other literature relating to the classification of financial instruments. Accordingly, these awards were classified as liability instruments for their estimated cash settlement amounts. The Company reclassified the liability instruments to permanent equity at the time the statute of limitations lapsed and the holder could no longer control settlement of the award in cash.

In the year ended March 31, 2004, 2005, 2006, and the six months ended September 30, 2005, the Company included in the accompanying statements of operations stock compensation expense of \$343,000, \$22,000, \$6,000, and \$6,000 respectively. In addition, included in accrued liabilities in the accompanying balance sheet at March 31, 2005 are liabilities relating to the repurchase offers, including statutory interest, of \$250,169.

***Stock-Based Compensation Before Adoption of SFAS No. 123(R)***

Prior to April 1, 2006, the Company accounted for stock-based employee compensation arrangements in accordance with the provisions of APB No. 25, "Accounting for Stock Issued to Employees," and its related interpretations and applied the disclosure requirements of SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123." The Company used the minimum value method to measure the fair value of awards issued prior to April 1, 2006 with respect to its application of the disclosure requirements under SFAS 123.



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The following table illustrates the effect on net loss as if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based compensation arrangements (in thousands, except per share data):

	<b>Year Ended March 31,</b>			<b>Six Months Ended</b>	
	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>	<b>2006</b>
				<b>September 30,</b>	
				<b>(unaudited)</b>	
Net loss available to common stockholders, as reported	\$ (7,298)	\$ (16,530)	\$ (23,220)	\$ (9,744)	\$ (8,965)
Add: Total stock-based employee compensation expenses included in Net loss	30	2,297	279	157	104
Deduct: Total stock-based employee compensation determined under the fair-value based method for all awards	(81)	(2,448)	(503)	(227)	(258)
Net loss available to common stockholders, pro forma	<u>\$ (7,349)</u>	<u>\$ (16,681)</u>	<u>\$ (23,444)</u>	<u>\$ (9,814)</u>	<u>\$ (9,119)</u>
Net loss per common share, basic and diluted:					
As reported	\$ (1.88)	\$ (4.22)	\$ (5.60)	\$ (2.38)	\$ (2.11)
Pro forma	\$ (1.88)	\$ (4.26)	\$ (5.65)	\$ (2.40)	\$ (2.16)

In accordance with the provisions of SFAS No. 123, the fair value of each employee option granted in reporting periods prior to the adoption of SFAS 123(R) was estimated on the date of grant using the minimum value method with the following weighted-average assumptions:

	<b>Year Ended March 31,</b>			<b>Three Months</b>
	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>Ended Sept 30,</b>
				<b>2005</b>
Estimated life	6 yrs	6 yrs	6 yrs	6 yrs
Risk-free interest rate	3.18%	3.95%	4.27%	3.76%
Dividend yield	0.00%	0.00%	0.00%	0.00%

The weighted-average estimated minimum values of options granted were \$0.96, \$5.00 and \$3.12 for the years ended March 31, 2004, 2005 and 2006, respectively, and \$7.12 for the six months ended September 30, 2005.

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A summary of activity under option Plans as of March 31, 2006 is presented below

	Options Available for Grant	Options Outstanding	
		Number of Options	Weighted Average Exercise Price
Balance at March 31, 2003	451,100	1,027,000	\$ 0.45
Options authorized	1,000,000	—	—
Options granted	(544,405)	544,405	3.00
Options exercised	—	(30,500)	0.18
Options canceled	6,500	(6,500)	2.69
Balance at March 31, 2004	913,195	1,534,405	1.35
Options authorized	1,500,000	—	—
Options granted	(313,089)	313,089	3.00
Options exercised	—	—	3.00
Options canceled	507,575	(507,575)	1.30
Balance at March 31, 2005	2,607,681	1,339,919	1.75
Options authorized	—	—	—
Options granted	(786,998)	786,998	9.20
Options exercised	—	(291,828)	1.02
Options canceled	166,050	(166,050)	6.17
Balance at March 31, 2006	1,986,733	1,669,039	\$ 4.96

The options outstanding and currently exercisable under Plans by exercise price at March 31, 2006 are as follows:

Exercise Price	Options Outstanding and Exercisable			Options Vested	
	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.11-\$0.85	396,000	3.41	\$ 0.37	396,000	\$ 0.37
\$1.10-\$2.50	56,000	4.53	\$ 2.10	56,000	\$ 2.10
\$3.00-\$3.00	547,791	7.77	\$ 3.00	249,073	\$ 3.00
\$4.40-\$4.40	90,000	9.05	\$ 4.40	10,000	\$ 4.40
\$10.16-\$12.00	579,248	9.57	\$ 10.30	—	\$ —
	<u>1,669,039</u>	7.32	\$ 4.96	<u>711,073</u>	\$ 1.49

**Stock-Based Compensation After Adoption of SFAS 123(R) (Unaudited)**

Effective April 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment*, using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards granted, modified and settled to the Company's employees and directors after April 1, 2006. The Company's financial statements as of and for the six months ended September 30, 2006 reflect the impact of SFAS No. 123(R). In accordance with the prospective transition method, the Company's

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financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R).

The effect of the change of recording stock-based compensation expense from the original provisions of APB No. 25 to the provisions of SFAS No. 123(R) for the six months ended September 30, 2006 is as follows (unaudited):

	<b>Impact from SFAS No. 123(R) Provisions for Six Months Ended September 30, 2006</b>
Cost of revenues service	\$ 1,000
Selling, general and administrative	41,000
<b>Total stock based compensation</b>	<b>\$ 42,000</b>
Effect on basic and diluted net loss per common share	\$ (0.01)

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 implementation of SFAS No. 123(R) did not have an impact on cash flows from financing activities during the six months ended September 30, 2006.

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 period of the awards. The fair value of employee stock options was estimated using the following weighted-average assumptions for the six months ended September 30, 2006 (unaudited):

	<b>Six Months Ended</b>
Estimated life	6 yrs.
Risk-free interest rate	4.76%
Dividend yield	0.00%
Volatility	70%

The expected term of stock options represents the average period the stock options are expected to remain outstanding and is based on the expected term calculated using the approach prescribed by SAB 107 for "plain vanilla" options. The Company used this approach as it did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. The expected stock price volatility for the Company's stock options for the six months ended September 30, 2006 was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of the Company's industry peers as the Company did not have any trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

In addition, SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated

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based on historical experience. Prior to the adoption of SFAS No. 123(R), the Company accounted for forfeitures as they occurred.

A summary of all option activity, including options issued outside of plans, as of September 30, 2006 (unaudited), and changes during the six month period ended September 30, 2006 is presented below (unaudited):

<b>Options</b>	<b>Shares (000)</b>	<b>Weighted-Average Exercise Price</b>	<b>Weighted-Average Contractual Term</b>	<b>Aggregate Intrinsic Value (\$000)</b>
Outstanding at April 1, 2006	1,969	\$ 4.22		
Granted	170	12.00		
Forfeited or expired	(14)	10.16		
Outstanding at September 30, 2006	<u>2,125</u>	<u>4.81</u>	<u>7.16</u>	<u>\$ 17,402</u>
Exercisable at September 30, 2006	<u>1,103</u>	<u>\$ 1.28</u>	<u>5.66</u>	<u>\$ 12,939</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 (\$13.00) for stock options that are in-the-money as of September 30, 2006.

At September 30, 2006, there was \$598,000 of unrecognized compensation cost related to options that the Company accounted for under APB 25 through March 31, 2006. These costs are expected to be recognized over a weighted average amortization period of 1.82 years.

During the six months ended September 30, 2006, the Company granted 170,124 stock options to employees with a weighted-average grant date fair value of \$7.92 per share. At September 30, 2006, there was unrecognized compensation costs of \$1,299,000 related to these stock options. The cost is expected to be recognized over a weighted-average amortization period of 4.82 years.

The weighted-average estimated minimum values of options granted were \$0.96, \$5.00 and \$3.12 for the years ended March 31, 2004, 2005 and 2006, respectively and \$7.12 for the six months ended September 30, 2005.

In the six months ended September 30, 2006, the Company did not modify any stock options granted to employees or non-employees under share based arrangements or capitalize the cost associated with stock based compensation.

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

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**Non-Employee Options**

The Company believes that the fair value of the stock options issued to non-employees is more reliably measurable than the fair value of the services received. The fair value of the stock options granted was calculated using the Black-Scholes option-pricing model as prescribed by SFAS No. 123 using the following weighted-average assumptions:

	<u>Year Ended March 31,</u>			<u>Six Months Ended</u>	
	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>September 30,</u>	
				<u>(unaudited)</u>	
Estimated life	8.25 yrs	9.06 yrs	8.67 yrs	8.73 yrs	8.52 yrs
Risk-free interest rate	3.88%	4.50%	4.27%	4.00%	4.67%
Dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%
Volatility	70%	70%	70%	70%	70%

The stock-based compensation expense will fluctuate as the fair market value of the common stock fluctuates. In connection with stock options granted to non-employees, the Company recorded \$7,000, \$30,000, \$32,000 of stock-based compensation expense in the years ended March 31, 2004, 2005 and 2006, respectively, and \$22,000 and \$10,000 for the six months ended September 30, 2005 and 2006, respectively.

**NOTE 14 — Taxes**

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

	<u>March 31,</u>	
	<u>2005</u>	<u>2006</u>
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 8,870	\$ 17,290
Tax credits carryforwards	123	212
Stock-based compensation	964	1,070
Reserves and accruals	327	186
Total deferred tax assets	<u>10,284</u>	<u>18,758</u>
<b>Deferred tax liabilities:</b>		
Basis difference in assets	(100)	(78)
State taxes	(508)	(897)
Total deferred tax liabilities	<u>(608)</u>	<u>(975)</u>
Net deferred tax asset	9,676	17,783
Valuation allowance	(9,676)	(17,783)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

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

	Year Ended March 31,		
	2004	2005	2006
Income tax benefit	\$ 2,479	\$ 6,019	\$ 8,107
Change in valuation allowance	(2,479)	(6,019)	(8,107)
Net income tax benefit	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

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

	Year Ended March 31,		
	2004	2005	2006
Expected statutory rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(3.0)%	(3.8)%	(3.3)%
Foreign earnings taxed at different rates	1.4%	1.0%	1.8%
Effect of permanent differences	1.7%	0.3%	0.3%
	<u>(33.9)%</u>	<u>(36.5)%</u>	<u>(35.2)%</u>
Change in valuation allowance	33.9%	36.5%	35.2%
Totals	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

At March 31, 2006, the Company had net operating loss carryforwards for federal, state and foreign income tax purposes of approximately \$28,800,000, \$25,900,000 and \$17,400,000, respectively. The carryforwards expire beginning 2020, 2010 and 2014, respectively. The Company also had, at March 31, 2006, federal and state research credit carryforwards of approximately \$104,000 and \$108,000, respectively. The federal credits expire beginning in 2026 and the state credits do not expire.

The Company experienced substantial ownership changes in connection with financing transactions it completed through the year ended March 31, 2006. Accordingly, the Company's utilization of its net operating loss and tax credit carryforwards against taxable income in future periods, if any, is subject to substantial limitations under the Change in Ownership rules of Section 382 of the Internal Revenue Code. 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 six months ended September 30, 2006 and anticipates it will incur such losses for the year ended March 31, 2007. 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 standard of SFAS No. 109, the valuation allowance will be reduced accordingly.

**NOTE 15 — Employee Benefit Plan**

In 2002, the Company established a program to contribute and administer individual retirement accounts for regular full time employees. Under the plan the Company matches employee contributions to the plan up to 3% of the employee's salary. The Company contributed \$34,000, \$63,000 and \$53,000 to the program for

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the years ended March 31, 2004, 2005 and 2006, respectively, and \$25,000 and \$32,000 for the six months ended September 30, 2005 and 2006, respectively.

**NOTE 16 — Segment and Geographic Information**

In accordance with SFAS No. 131, "Disclosures About Segments of an Enterprise and Related Information" ("SFAS 131"), operating segments are identified as components of an enterprise for which separate and discreet financial information is available and is used by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief decision-makers, as defined by SFAS 131, are the Chief Executive Officer and his direct reports.

The Company's chief decision-makers review financial information presented on a consolidated basis, accompanied by disaggregated information about revenue and operating profit by operating unit. This information is used for purposes of allocating resources and evaluating financial performance.

The accounting policies of the segments are the same as those described in the "Summary of Significant Accounting Policies." Segment data includes segment revenue, segment operating profitability, and total assets by segment. Shared corporate operating expenses are reported in the U.S. segment.

The Company is organized primarily on the basis of operating units which are segregated by geography.

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The following tables present information about reportable segments (in thousands):

	<u>U.S.</u>	<u>Europe</u>	<u>Mexico</u>	<u>Total</u>
<b>Year ended March 31, 2004:</b>				
Product revenues	\$ —	\$ —	\$ 95	\$ 95
Service revenues	807	—	—	807
Total revenues	807	—	95	902
Depreciation expense	159	2	2	163
Operating loss	(4,914)	(209)	(1,974)	(7,097)
Interest expense	(178)	—	—	(178)
Interest income	3	—	—	3
Total assets	2,150	245	597	2,992
<b>Year ended March 31, 2005:</b>				
Product revenues	\$ 4	\$ 35	\$ 434	\$ 473
Service revenues	883	—	—	883
Total revenues	887	35	434	1,356
Depreciation expense	368	49	17	434
Operating loss	(12,242)	(1,529)	(2,541)	(16,312)
Interest expense	(372)	—	—	(372)
Interest income	8	—	—	8
Total assets	5,017	858	1,065	6,940
<b>Year ended March 31, 2006:</b>				
Product revenues	\$ 109	\$ 69	\$ 1,788	\$ 1,966
Service revenues	618	—	—	618
Total revenues	727	69	1,788	2,584
Depreciation expense	463	96	92	651
Operating loss	(12,621)	(2,685)	(5,545)	(20,851)
Interest expense	(172)	—	—	(172)
Interest income	282	—	—	282
Total assets	8,977	1,652	2,060	12,689
<b>Six months ended September 30, 2005 (unaudited):</b>				
Product revenues	\$ 88	\$ 64	\$ 655	\$ 807
Service revenues	275	—	—	275
Total revenues	363	64	655	1,082
Depreciation expense	227	42	39	307
Operating loss	(5,518)	(913)	(3,003)	(9,434)
Interest expense	(103)	—	—	(103)
Interest income	68	—	—	68
Total assets	19,069	1,187	7,098	27,354



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	<u>U.S.</u>	<u>Europe</u>	<u>Mexico</u>	<u>Total</u>
<b>Six months ended September 30, 2006 (unaudited):</b>				
Product revenues	\$ 56	\$ 828	\$ 1,058	\$ 1,942
Service revenues	388	—	—	388
Total revenues	444	828	1,058	2,330
Depreciation expense	190	92	46	328
Operating loss	(5,715)	(1,053)	(1,829)	(8,597)
Interest expense	(261)	—	—	(261)
Interest income	100	—	—	100
Total assets	5,172	2,514	2,370	10,056

**NOTE 17 — Discontinued Operations**

On June 16, 2005, the Company entered into a series of agreements with Quimica Pasteur, or QP, a Mexico-based company engaged in the business of distributing pharmaceutical products to hospitals and health care entities owned or operated by the Mexican Ministry of Health. These agreements provided, among other things, for QP to act as the Company's exclusive distributor of Microcyn to the Mexican Ministry of Health for a period of three years. In connection with these agreements, an individual designated by the Company who is also one of the Company's executive officers concurrently acquired, in his individual capacity and for no additional consideration, a 0.25% equity interest in QP. The Company was granted an option to acquire the remaining 99.75% directly from its principals in exchange for 600,000 shares of common stock, contingent upon QP's attainment of certain financial milestones. The Company's distribution and related agreements were cancelable by the Company on thirty days' notice without cause and included certain provisions to hold the Company harmless from debts incurred by QP outside the scope of the distribution and related agreements. The Company terminated these agreements on March 26, 2006.

Due to its liquidity circumstances, QP was unable to sustain operations without the Company's subordinated financial and management support. Accordingly, QP was deemed to be a variable interest entity in accordance with FIN 46(R) and its results were consolidated with the Company's financial statements for the period of June 16, 2005 through March 26, 2006, the effective termination date of the distribution and related agreements.

In accordance with SFAS 144, the Company has reported QP's results for the period of June 16, 2005 through March 26, 2006 as discontinued operations because the operations and cash flows of QP have been eliminated from the Company's ongoing operations as a result of having terminated these agreements. The Company no longer has any continuing involvement with QP as of the date in which the agreements were terminated. Amounts associated with the Company's loss upon the termination of its agreements with QP, which consists of funds advanced by the Company for working capital, are presented separately from QP's operating results.

Subsequent to having entered into the agreements with QP, the Company became aware of an alleged tax avoidance scheme involving the principals of QP. The audit committee of the Company's board of directors engaged an independent counsel, as well as tax counsel in Mexico to investigate this matter. The audit committee of the board of directors was advised that QP's principals could be liable for up to \$7,000,000 of unpaid taxes; however, the Company is unlikely to have any loss exposure with respect to this matter because the alleged tax omission occurred prior to the Company's involvement with QP. The Company has not received any communications to date from Mexican tax authorities with respect to this matter.

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Based on an opinion of Mexico counsel, the Company management and the audit committee of the board of directors do not believe that the Company is likely to experience any loss with respect to this matter. However, there can be no assurance that the Mexican tax authorities will not pursue this matter and, if pursued, that it would not result in a material loss to the Company.

**NOTE 18 — Subsequent Events**

***Private Placement of Series C Preferred Stock***

On October 20, 2006, the Company sold 108,486 units, consisting of 108,486 shares of Series C convertible preferred stock and warrants to purchase 21,697 shares of the Company's common stock at \$18.00 per share, at a per unit price of \$18.00. Gross proceeds from this sale amounted to \$1,952,748 and proceeds net of commissions amounted to \$1,757,473. In addition, the Company issued to the placement agent warrants to purchase 13,560 shares of the Company's common stock at \$18.00 per share. These shares were sold in connection with an agreement entered into between the Company and a placement agent in May 2006. The Series C shares are described in (Note 12).

***Termination of Distribution Agreement***

In October 2006, the Company agreed to pay a distributor \$90,000 to terminate an agreement which provided the distributor with exclusive rights to sell the Company's products in the United Kingdom. This agreement was reached between the Company and distributor without legal action.

***Consulting Agreement***

On November 7, 2006, the Company entered into a two-year consulting agreement with its new director, Robert Burlingame. Under the terms of the agreement, the Company has issued the consultant a warrant to purchase 75,000 shares of the Company's common stock, exercisable at \$13.00 per share in consideration of corporate advisory services.

***Bridge Financing***

On November 7, 2006, the Company signed a loan agreement with Robert Burlingame, one of the company's directors, in the amount of \$4.0 million, which amount will accrue interest at an annual rate of 7%. Concurrently, Mr. Burlingame became a consultant to the Company under a two-year consulting agreement, and he was appointed to fill the vacancy on the Company's board of directors. The principal and all accrued interest under the loan agreement will become due and payable in full with interest on the earlier of 12 months after the date of the loan agreement or five business days after the completion of the proposed IPO. The loan will be secured by all of our assets, other than our intellectual property, but will be subordinate to the security interest held by our secured lender. At the time the principal is advanced to us, Brookstreet Securities Corporation will be paid a fee of \$50,000 and will be granted a warrant to purchase 25,000 shares of the Company's common stock at an exercise price of \$18.00 per share.

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***Settlement Agreement***

In November 2006, the Company entered into a settlement agreement with a former director and chief operating officer. The settlement agreement provides for a \$250,000 cash payment, which is subject to the Company closing equity financing with gross proceeds of \$10 million or more, or its initial public offering. In addition, the plaintiff will be provided a warrant to purchase 50,000 shares of the Company's common stock at an exercise price of \$3.00 per share. Issuance of the warrant is subject to the waiver of any applicable rights by the holders of the Company's preferred stock under the Company's Amended and Restated Investors Rights Agreement. The Company previously reserved for this litigation (Note 11).

***Engagement Letter***

In November 2006, the Company engaged an investment bank (the "Underwriter") as financial advisors and lead underwriter in connection with a proposed offering of approximately \$40 million of the Company's common stock, plus a 15% over-allotment option and agreed to pay a fee equal to 7% and a non-accountable expense allowance of 1.0% of the gross proceeds from the offering. In addition, contingent upon the closing of the offering, the Company will issue to the Underwriter warrants to purchase common stock equal to 7% of the total shares issued and outstanding upon the final closing of the offering at an exercise price of 165% of the offering price.

***Board Nomination***

On November 7, 2006, the Board of Directors appointed an individual to fill the vacant Series A board seat. Pursuant to the terms of the Director Agreement, the Company will issue the individual an option to purchase 75,000 shares of the Company's common stock at \$13.00 per share. The options vest immediately and are exercisable for a period of five years.

***2006 Stock Incentive Plan***

On November 7, 2006, the board authorized and reserved 1,250,000 shares for issuance of options that may be granted under the Company's 2006 Stock Incentive Plan, which was previously adopted by the board of directors.

***Stock-split***

On November 7, 2006, the board of directors authorized the Company to effectuate a reverse split of its common stock within a specified range to satisfy a pre-condition requiring it to complete a reverse split of its stock prior to completing its proposed IPO. Accordingly, the accompanying financial statements give retroactive effect to a 1 for 4 reverse stock split for all periods presented. The reverse stock split is subject to stockholder approval and may be subject to possible change based on the final terms and conditions of the underwriting commitment that the Company anticipates it will enter into in connection with completing its proposed IPO. Although management believes that the Company's stockholders will approve the reverse split, there can be no assurance that such approval will be obtained. The Company also cannot provide any assurance that the proposed IPO will be completed according to the terms that are currently contemplated, if at all. The Company expects that the pre-split offering price of the common stock will amount to approximately \$3.25 per share, and the reverse split will be within a range of 1 for 2, 1 for 4 or 1 for 6 in order to adjust the per share offering price to an amount considered appropriate for this IPO.



Shares



**OCULUS**  
Innovative Sciences  
**Oculus Innovative Sciences, Inc.**  
Common Stock  
**ROTH CAPITAL PARTNERS**

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**MAXIM GROUP LLC**

**BROOKSTREET SECURITIES CORPORATION**

The date of this prospectus is \_\_\_\_\_, 2006

Until \_\_\_\_\_, 2006, all dealers that effect transaction in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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**Part II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the various expenses expected to be incurred by the Registrant in connection with the sale and distribution of the securities being registered hereby, other than underwriting discounts and commissions. All amounts listed are estimated except the Securities and Exchange Commission registration fee, the National Association of Securities Dealers, Inc. filing fee and the Nasdaq Global Market listing fee.

SEC registration fee	\$ 8,614
National Association of Securities Dealers, Inc. filing fee	8,550
Nasdaq Global Market listing fee	100,000
Blue Sky fees and expenses	10,000
Accounting fees and expenses	*
Legal fees and expenses	*
Printing and engraving expenses	*
Registrar and Transfer Agent's fees	*
Miscellaneous fees and expenses	*
Total	<u>\$ *</u>

\* To be filed by amendment

**Item 14. Indemnification of Directors and Officers**

In connection with the completion of this offering, the Registrant intends to reincorporate into Delaware. Section 145 of the Delaware General Corporation Law provides for the indemnification of officers, directors, and other corporate agents in terms sufficiently broad to indemnify such persons under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933 (the "Securities Act"). The Registrant's form of Restated Certificate of Incorporation to be effective upon completion of this offering (Exhibit 3.3 hereto) and the Registrant's form of Bylaws to be effective upon completion of this offering (Exhibit 3.6 hereto) provide for indemnification of the Registrant's directors, officers, employees and other agents to the fullest extent permitted by the Delaware General Corporation Law. The Registrant has also entered into agreements with our directors and officers that will require the Registrant, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent not prohibited by law.

The Underwriting Agreement (Exhibit 1.1) will provide for indemnification by the Underwriters of the Registrant, our directors and officers, and by the Registrant, of the Underwriters, for certain liabilities, including liabilities arising under the Act, and affords certain rights of contribution with respect thereto.

**Item 15. Recent Sales of Unregistered Securities**

The following information does not give effect to the Registrant's reverse common stock split to be effected prior to the completion of this offering.

*Exercises of Stock Options*

On various dates between January 14, 2002 and October 31, 2006, the Registrant sold 1,334,916 shares of its common stock to employees and directors pursuant to the exercise of options granted under our 1999, 2000, 2003 and 2004 stock plans. The exercise prices per share ranged from \$0.03 to \$0.75, for an aggregate consideration of \$297,585.

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The sales of the above securities were considered to be exempt from registration under the Securities Act in reliance on Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The sale of the above securities in a 12 months period did not exceed the greater of (a) \$1,000,000, (b) 1% of total assets as of the Registrant's most recent balance sheet or (c) 15% of the number of outstanding shares of the Registrant's common stock sold in reliance on this Rule.

*Issuances of Capital Stock in Financing Rounds*

On various dates between August 7, 2003 and February 25, 2004, the Registrant sold 5,391,244 shares of series A convertible preferred stock for aggregate consideration of \$8,066,866 to 198 accredited investors. In connection with these sales the Registrant paid to Brookstreet Securities Corporation, or Brookstreet, as placement agent, an aggregate of \$1,123,746 in commissions and issued to Brookstreet and its affiliates warrants to purchase an aggregate of 1,735,123 shares of the Registrant's common stock. The Registrant also issued a warrant to purchase 66,667 shares of its series A convertible preferred stock and a promissory note that could be converted into 40,000 shares of series A convertible preferred stock. On June 30, 2005, this convertible note was converted into 40,000 shares of the Registrant's Series A convertible preferred stock.

The sales of the above securities were considered to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D promulgated under the Securities Act, as transactions by an issuer not involving a public offering. The purchasers of these securities were accredited investors, represented their intention to acquire the securities for investment only and not with a view to or for sale with any distribution thereof, and appropriate legends were affixed to the share certificates and instruments issued in the transaction. All purchasers had adequate access, through their relationship with the Registrant, to information about the Registrant.

On various dates between April 30, 2004 and October 27, 2005, the Registrant sold 10,543,474 shares of series B convertible preferred stock for aggregate consideration of \$47,445,663 to 361 accredited investors. In connection with these sales the Registrant paid to Brookstreet, as placement agent, an aggregate of \$3,413,818 in commissions and issued to Brookstreet and its affiliates warrants to purchase an aggregate of 1,317,933 shares of the Registrant's common stock.

The sales of the above securities were considered to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D promulgated under the Securities Act, as transactions by an issuer not involving a public offering. The purchasers of these securities were accredited investors, represented their intention to acquire the securities for investment only and not with a view to or for sale with any distribution thereof, and appropriate legends were affixed to the share certificates and instruments issued in the transaction. All purchasers had adequate access, through their relationship with the Registrant, to information about the Registrant.

In September and October 2006, the Registrant sold 772,100 units, consisting of 772,100 shares of Series C convertible preferred stock at a per unit price of \$4.50, and warrants to purchase 154,419 shares of common stock at \$4.50 per share, for aggregate gross proceeds of \$3,474,450 to one qualified institutional buyer and one institutional accredited investor. In connection with this sale, the Registrant paid to Brookstreet Securities Corporation, as placement agent, an aggregate of \$347,444 in commissions and issued to Brookstreet fully vested warrants to purchase an aggregate of 96,512 shares of the Registrant's common stock.

The sales of the above securities were considered to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D promulgated under the Securities Act, as transactions by an issuer not involving a public offering. The purchasers of these securities were qualified institutional buyers or institutional accredited investors, represented their intention to acquire the securities for investment only and not with a view to or for sale with any distribution thereof, and appropriate legends were affixed to the share certificates and instruments issued in the transaction. All purchasers had adequate access, through their relationship with the Registrant, to information about the Registrant.

*Issuance of Securities in Debt Financing*

In June 2006, the Registrant entered into a loan and security agreement with a financial institution. In conjunction with this agreement, the Registrant issued warrants to purchase an aggregate of 300,000 shares of its series B preferred stock at an exercise price of \$4.50 per share. The sale of these securities was considered to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D promulgated under the Securities Act, as a transaction by an issuer not involving a public offering. The purchaser is an accredited investor, represented its intention to acquire the securities for investment only and not with a view to or for sale with any distribution thereof, and appropriate legends were affixed to the instruments issued in the transaction. The purchaser had access, through its relationship with the Registrant, to information about the Registrant.

*Issuance of Securities to Consultant*

In November 2006, the Registrant issued a warrant to purchase an aggregate of 300,000 shares of its common stock at an exercise price of \$3.25 per share to a consultant providing consulting services for the Registrant. The sale of these securities was considered to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D promulgated under the Securities Act, as a transaction by an issuer not involving a public offering. The purchaser is an accredited investor, represented his intention to acquire the securities for investment only and not with a view to or for sale with any distribution thereof, and appropriate legends were affixed to the instruments issued in the transaction. The purchaser had access, through its relationship with the Registrant, to information about the Registrant.

**Item 16. Exhibits and Financial Statement Schedules**

(a) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
1.1*	Form of Underwriting Agreement.
3.1**	Amended and Restated Articles of Incorporation of the Registrant.
3.2**	Certificate of Amendment of Articles of Incorporation of the Registrant.
3.3**	Certificate of Amendment of Articles of Incorporation of the Registrant.
3.4*	Certificate of Incorporation of the Registrant's subsidiary, OIS Reincorporation Sub, Inc., a Delaware corporation.
3.5**	Form of Restated Certificate of Incorporation of the Registrant, to be filed upon the completion of the offering to which this Registration Statement relates.
3.6**	Bylaws of the Registrant, as amended (composite copy).
3.7*	Bylaws of the Registrant's subsidiary, OIS Reincorporation Sub, Inc., a Delaware corporation.
3.8**	Form of Bylaws of the Registrant, to be effective upon the completion of the offering to which this Registration Statement relates.
3.9*	Certificate of Amendment to the Articles of Incorporation of the Registrant.
4.1*	Specimen Common Stock Certificate.
4.2**	Warrant to Purchase Series A Preferred Stock of Registrant by and between the Registrant and Venture Lending & Leasing III, Inc., dated April 21, 2004.
4.3**	Warrant to Purchase Series B Preferred Stock of Registrant by and between the Registrant and Venture Lending & Leasing IV, Inc., dated June 14, 2006.
4.4**	Form of Warrant to Purchase Common Stock of Registrant.
4.5**	Form of Warrant to Purchase Common Stock of Registrant.
4.6*	Amended and Restated Investors Rights Agreement, effective as of September 14, 2006.
4.7**	Form of Promissory Note issued to Venture Lending & Leasing III, Inc.
4.8**	Form of Promissory Note (Equipment and Soft Cost Loans) issued to Venture Lending & Leasing IV, Inc.
4.9**	Form of Promissory Note (Growth Capital Loans) issued to Venture Lending & Leasing IV, Inc.



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<b>Exhibit Number</b>	<b>Description</b>
4.10**	Form of Promissory Note (Working Capital Loans) issued to Venture Lending & Leasing IV, Inc.
4.11**	Form of Warrant to Purchase Common Stock of Registrant.
5.1*	Opinion of Pillsbury Winthrop Shaw Pittman LLP.
10.1**	Form of Indemnification Agreement between the Registrant and its officers and directors.
10.2**	1999 Stock Plan and related form stock option plan agreements
10.3**	2000 Stock Plan and related form stock option plan agreements.
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10.5**	2004 Stock Plan and related form stock option plan agreements.
10.6**	Form of 2006 Stock Incentive Plan and related form stock option plan agreement.
10.7**	Office Lease Agreement, dated October 26, 1999, between the Registrant and RNM Lakeville, L.P.
10.8**	Amendment to Office Lease No. 1, dated September 15, 2000, between Registrant and RNM Lakeville L.P.
10.9**	Amendment to Office Lease No. 2, dated July 29, 2005, between the Registrant and RNM Lakeville L.P.
10.10**	Office Lease Agreement, dated May 15, 2005, between Oculus Technologies of Mexico, S.A. de C.V. and Antonio Sergio Arturo Fernandez Valenzuela (translated from Spanish).
10.11**	Office Lease Agreement, dated July 2003, between Oculus Innovative Sciences Netherlands, B.V. and Artikona Holding B.V. (translated from Dutch).
10.12**	Loan and Security Agreement, dated March 25, 2004, between the Registrant and Venture Lending & Leasing III, Inc.
10.13**	Loan and Security Agreement, dated June 14, 2006, between the Registrant and Venture Lending & Leasing IV, Inc.
10.14**	Employment Agreement, dated January 1, 2004, between the Registrant and Hojabr Alimi.
10.15**	Employment Agreement, dated January 1, 2004, between the Registrant and Jim Schutz.
10.16**	Employment Agreement, dated June 1, 2004, between the Registrant and Robert Miller.
10.17**	Employment Agreement, dated June 1, 2005, between the Registrant and Bruce Thornton.
10.18**	Employment Agreement, dated March 23, 2005, between the Registrant and Theresa Mitchell.
10.19**	Employment Agreement, dated June 10, 2006, between the Registrant and Mike Wokasch.
10.20**	Form of Director Agreement.
10.21**	Consultant Agreement, dated October 1, 2005, by and between the Registrant and White Moon Medical.
10.22**	Leasing Agreement, dated May 5, 2006, made by and between Mr. Jose Alfonso I. Orozco Perez and Oculus Technologies of Mexico, S.A. de C.V.
10.23**	Amendment No. 3 to Lease dated August 23, 2006, between the Registrant and RNM Lakeville, L.P.
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10.29**	Termination of Registrant and Oculus Technologies de Mexico, S.A. de C.V. Agreements with Quimica Pasteur, S de R.L. by Francisco Javier Orozco Gutierrez (translated from Spanish).
10.30*	Loan and Security Agreement, dated November 8, 2006, between the Registrant and Robert Burlingame.
10.31*	Non-Negotiable Secured Promissory Note, dated November 10, 2006, between the Registrant and Robert Burlingame.

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<b>Exhibit Number</b>	<b>Description</b>
10.32*	Subordination Agreement, dated November 7, 2006, by and among the Registrant, Robert Burlingame, Venture Lending & Leasing III, LLC, and Venture Lending & Leasing IV, LLC.
10.33*	Consulting Agreement, dated November 8, 2006, by and between the Registrant and Robert Burlingame.
10.34*	Director Agreement, dated November 8, 2006, by and between the Registrant and Robert Burlingame.
16.1**	Letter regarding change in certifying accountants.
21.1**	List of Subsidiaries.
23.1	Consent of Marcum & Kliegman LLP.
23.2*	Consent of Pillsbury Winthrop Shaw Pittman LLP (included in Exhibit 5.1).
23.3**	Consent of Cheryl Bongiovanni, Ph.D., RVT, CWS
23.4**	Consent of Tom A. Wolvos, M.D., F.A.C.S
23.5**	Consent of David Armstrong, M.D.
23.6**	Consent of David E. Allie, M.D.
23.7**	Consent of Dr. Alfredo Barrera
23.8**	Consent of Valuation Research Corporation
23.9**	Consent of Chevez, Ruiz, Zamarripa y Cia, S.C.
23.10**	Consent of Luca Dalla-Paola, M.D.
23.11**	Consent of Andrew Boulton, M.D.
23.12**	Consent of Dr. Ariel Miranda
24.1**	Power of Attorney (see page II-5 of this Registration Statement).

\* To be filed by amendment.

\*\* Previously filed.

**Item 17. Undertakings**

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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(3) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.]

(4) For the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(5) It will provide to the underwriters at the closing(s) specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.



**Exhibit Index**

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23.6**	Consent of David E. Allie, M.D.
23.7**	Consent of Dr. Alfredo Barrera
23.8**	Consent of Valuation Research Corporation
23.9**	Consent of Chevez, Ruiz, Zamarripa y Cia, S.C.
23.10**	Consent of Luca Dalla-Paola, M.D.
23.11**	Consent of Andrew Boulton, M.D.
23.12**	Consent of Dr. Ariel Miranda
24.1**	Power of Attorney (see page II-5 of this Registration Statement).

\* To be filed by amendment.

\*\* Previously filed.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of Oculus Innovative Sciences, Inc. and Subsidiaries on Amendment No. 2 to Form S-1 (File No. 333-135584) of our report dated June 26, 2006 with respect to our audits of the consolidated financial statements of Oculus Innovative Sciences, Inc. and Subsidiaries as of March 31, 2005 and 2006 and for each of the three years in the period ended March 31, 2006, which report appears in the Prospectus, which is part of this Registration Statement. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus.

/s/ Marcum & Kliegman llp

Marcum & Kliegman llp  
New York, New York  
November 10, 2006



Pillsbury  
Winthrop  
Shaw  
Pittman...

2475 Hanover Street  
Palo Alto, CA 94304-1114

Tel 650.233.4500  
Fax 650.233.4545  
www.pillsburylaw.com

November 13, 2006

Sylvia K. Burks  
Phone: 650.233.4606  
sylvia.burks@pillsburylaw.com

**VIA ELECTRONIC TRANSMISSION**

Securities and Exchange Commission  
100 F Street, N.W.  
Washington, D.C. 20549-0406  
Mail Stop 6010  
Attn: Mr. Thomas A. Jones

Re: Oculus Innovative Sciences, Inc.-Registration Statement on Form S-1  
(File No. 333-135584)

Ladies and Gentlemen:

On behalf of Oculus Innovative Sciences, Inc. (the "Registrant"), we enclose for filing under the Securities Act of 1933, as amended (the "Securities Act"), Amendment No. 2 to the above-referenced registration statement (the "Registration Statement"), together with exhibits thereto.

Amendment No. 2 to the Registration Statement contains revisions that have been made in response to comments received from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") in its letter dated October 12, 2006. In addition, the Registrant notes for the Staff that this Amendment No. 2 contains financial statements and results for the quarter ended September 30, 2006, gives effect to a proposed 1-to-4 reverse stock split, describes and updates recent events, and contains proposed pricing information based on discussions with the Registrant's new underwriters. Set forth below are the Registrant's responses to the Staff's comments. The number of the responses and headings set forth below correspond to the numbered comments and headings on the letter from the Staff. Marked copies of Amendment No. 2 to the Registration Statement are being provided supplementally with copies of this letter for the convenience of the Staff.

**General**

1. *Please revise your disclosure to clarify technical terms used throughout your filing. For example, we note the third sentence on page 9 concerning three pathogens.*
-



**Response:** The Registrant has revised the Registration Statement as requested.

Because all of our products are based on our Microcyn platform technology, page 8

2. *The fourth sentence of this section is not consistent with the fifth sentence of this section. Please advise or revise.*

**Response:** The Registrant has revised the disclosure as requested.

We may agree to change the brand name of our product in Mexico, page 13

3. *Please disclose the percentage of your revenues from Microcyn60.*

**Response:** The Registrant has revised the disclosure as requested.

Overview, page 50

4. *We note your response to prior comment 20 and reissue that comment, which sought revised disclosure in the first paragraph here and in the summary.*

**Response:** The Registrant has revised the disclosure as requested.

Our Products — Microcyn Platform, page 55

5. *We note your response to prior comment 21. Please revise your tabular disclosure here and in the summary (in a footnote or otherwise) to clarify (i) the reasons why the indications for your products differ from one another and (ii) whether similarly named products have different or identical formulations.*

**Response:** The Registrant has revised the disclosure as requested.

Principal Stockholders, page 94

6. *Please disclose the natural person who has voting or investment power for the shares held by Brookstreet Securities Corporation.*

**Response:** The Registrant has revised the disclosure as requested.

Financial Statements, page F-1

Consolidated Statements of Stockholders' Equity (Deficit), page F-5

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7. *We note that during the three months ended June 30, 2006 you issued warrants in exchange for services with a fair value of \$26,000. Please revise to include a description of the warrants, including the number of shares the warrants are exercisable for, the exercise price, the term, and the significant assumptions used to value the warrants.*

**Response:** The Registrant advises the Staff that it recorded expense related to warrants in the three months ended June 30, 2006 with a fair value of \$26,000. The Registrant has revised the footnotes to clarify the warrants were issued with service conditions and the expense represents the mark to market change in the fair value of the warrants at the reporting date. The Registrant has also added a table to disclose the weighted average assumptions used for calculating the fair value of the warrants at each reporting date and revised the Statement of Stockholders' Equity (Deficit) to clarify the warrants contain service conditions.

Note 3 — Summary of Significant Accounting Policies, page F-9

Stock-Based Compensation, page F-14

8. *We see that you adopted SFAS 123(R) during the three months ended June 30, 2006. When you adopt a new accounting standard in an interim period the notes to interim financial statements should present all of the relevant disclosures required by that standard in the period of adoption. Please expand your disclosures as required by paragraph 84 of SFAS 123(R)*

**Response:** The Registrant has expanded the SFAS 123(R) disclosure as required by paragraph 84 of SFAS 123(R).

Note 8 — Accrued Expenses and Other Current Liabilities, page F-22

9. *We note your response to prior comment 47. Please revise your disclosure to clearly describe the accrued stock option rescission and the basis for your accounting. Include in your discussion when the options were granted and when the statutes of limitations lapsed.*

**Response:** The Registrant has revised Note 13 to more clearly describe the accounting treatment of the stock option rescission. The Registrant has included the period of time in which the options were granted and period of time in which the statute of limitations lapsed on the rescission rights.

Note 12 — Stockholders' Equity, page F-28

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Valuation of Common Stock, page F-31

10. *We note your response to prior comment 49. Please address the following:*

- *Tell us why there was no increase in the fair value of your common stock from July 2005 when you obtained an independent valuation to when you issued options in October 2005 and January 2006.*
- *Considering that your initial organizational meeting with investment bankers took place on July 27, 2005, tell us how you determined that it was appropriate to discount the fair value of your common stock 58% and 50% from the mid-point of the expected IPO filing range, particularly for the more recent issuances such as the options granted on July 27, 2006.*
- *Tell us how you determined a 44% and 33% discount from the preferred stock purchase price was appropriate.*
- *Tell us why you issued warrants to your Advisory Board, law firm, placement agent, and consultants at \$4.50 per share in September, October and November 2005 and January 2006 but issued options to employees and Board members at \$2.54 and \$3.00 during this same period and subsequent period, respectively. Include in your response a detailed analysis of any differences between the options and warrants and why you concluded that no compensation expense was necessary for the option grants.*
- *Tell us why the \$2.82 per share July 2006 valuation was significantly lower than the expected IPO filing range and \$4.50 warrant exercise price issued in conjunction with your June 2006 financing.*
- *Tell us when the underwriters provided you with the estimated IPO offering price range.*
- *Clearly discuss significant changes or events that occurred over the last 12 months that would support the substantial discounts and the variations in the prices assigned to your options and warrants.*

**Response:** The Registrant advises the Staff of the following:

In general, the exercise prices of options granted to employees were based on the valuations performed by an independent third party valuation firm, and the exercise price of the warrants to vendors was based on the price for Series B preferred stock and the value of the services that were being provided by the vendor.

The Registrant advises the Staff of the following responses to the more specific questions raised by the Staff:

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- The Registrant did not increase the exercise price of stock options granted to employees from July 2005 to October 2005 and January 2006 because the Registrant did not believe that there was a significant change in the value of the company from July 2005, the time the first independent valuation was issued, to warrant an increase. The Registrant believes the July 2006 valuation supported the Registrant's view of appropriate valuation for the common stock.
  - While the organizational meeting with investment bankers did occur in July 2005, the Registrant respectfully submits that it had concerns regarding its ability to complete an IPO and the timeframe to do so. In fact, it took almost a year to get the Registration Statement on file, and discussions with the Registrant's investment bankers concerning valuation were ongoing during that year and until the Registrant and its original investment bankers terminated their relationship. The Registrant's former underwriters provided the Registrant an initial filing range in August 2006, which was after the Registrant's Board made its good faith determination of the exercise price of the related stock options. Since that time, the Registrant engaged new underwriters are now filing Amendment No. 2 to the Registration Statement, which reflects a filing range of \$12 to \$14 (post 1-to-4 reverse stock split) or an equivalent pre-split mid-point of \$3.25. Using the mid-point of the expected filing range for the referenced options, the discount is \$0.71 and \$0.25, or 22% and 8%, respectively. Given the length of this process, uncertainty in the market, the changes in underwriters and the logistical challenges in completing its IPO in 2006, the Registrant respectfully submits that the discount is not inappropriate.
  - The Registrant relied upon the valuation of an independent valuation firm in determining a discount from the preferred stock. The independent valuation firm completed multiple valuation approaches to determine the discount.
  - The Registrant determined the exercise price of the warrants issued to service providers based upon the services provided and the price of the preferred stock. In some cases the Registrant used the option pricing model to determine the number of warrants to issue for the value of the services provided. The exercise price of the stock options was based on the value of the common stock determined by the independent valuation firm. The exercise price of the warrant was above the price at the time used to calculate the compensation charge and, therefore, the Registrant took no charge.
  - The \$2.82 was determined based upon an independent valuation. The valuation firm performed multiple types of analysis to derive that value, and considered the
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price and terms of the Series B preferred stock in determining the first valuation and Series C preferred stock price in determining the second valuation of \$2.82. The expected IPO filing range initially communicated to the Staff in September 2006 was determined after the stock options were granted.

- The underwriters provided the Registrant with a proposed estimated filing range August 2006, which was communicated to the Staff on August 18, 2006. In connection with the filing of Amendment No. 2, questions arose as to whether the underwriters could sell the Registrant's common stock at that price. The Registrant engaged new underwriters in late October and this Amendment No. 2 reflects current consensus between the Registrant and its underwriters concerning valuation, given the state of the Registrant's business and the current environment around healthcare-related IPOs.
  - The Registrant believes the events described in the Registration Statement concerning increases in revenues and positive clinical results, as well as the change in auditors, communications with FDA and EPA, the continuing need for cash, the state of the capital markets, the time and expense of going public, the change in underwriters and in valuation and the uncertainty as to whether or not the Registrant can reasonably expect to complete its IPO in 2006 support the discounts and fluctuations in the prices of the Registrant's securities.
11. *We note your response to prior comment 50, the inclusion of the consent for the July 2005 valuation report, and the disclosures on page F-32 to a June 2006 valuation report. While you are not required to make references to an independent valuation, when you do so, in this case the June 2006 report, you must name the expert and file their written consent as an exhibit to the registration statement. See Item 601(b) of Regulation S-K.*

**Response:** The Registrant has revised Note 12 to include the name of the valuation specialist.

Note 13 — Stock Compensation Plans, page F-32

12. *We note that you removed the tables disclosing the option activity under all your plans and the options outstanding and currently exercisable for the years ended March 31, 2004 through 2006. Please revise to include these disclosures.*

**Response:** The Registrant notes the Staff's observation that the option activity table and options outstanding and currently exercisable for the periods ended

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March 31, 2004 through 2006 were removed from Amendment No. 1. The Registrant has revised Note 13 to include the tables.

Note 18 — Subsequent Events

13. *We note that you have issued Series C convertible preferred stock and warrants on September 14, 2006.*
14. *Please tell us and revise the filing to clearly disclose all the material terms of the convertible preferred stock and warrants, including but not limited to, the conditions under which the company or the holder may convert into common shares, the conversion rate and all conditions that may result in adjustments to that rate, any conditions under which the company or the holder may redeem the stock, and the dividend rates and any adjustments thereto. Likewise, please clearly describe the material terms of all related agreements, such as registration rights agreements and guarantee agreements.*

**Response:** The Registrant notes the Staff's observation that Series C convertible preferred stock units have been issued. The Registration Statement, including Note 12, has been revised to include a discussion of the terms of the Series C convertible preferred stock and to include a discussion of the warrants issued to the investors and the placement agent.

15. *Describe clearly how you have or will account for the Series C convertible preferred stock, including any related discounts, any beneficial conversion features pursuant to EITF 98-5 or any embedded derivatives requiring bifurcation pursuant to SFAS 133 and EITF 00-19.*

**Response:** The Registrant advises the Staff of the following regarding its accounting for the Series C preferred stock:

The Registrant applied the classification and measurement principles enumerated in EITF Topic D-98 with respect to accounting for its issuance of the Series C preferred stock. Under California law, a merger, consolidation or similar event resulting in a more than 50% change in control or a sale of all or substantially all of its assets must be initiated and recommended to the stockholders by the Board of Directors. The Board of Directors is then required to submit proposals to enter into these types of transactions to its stockholders for their approval by the requisite vote (which varies by transaction). The Registrant's preferred stockholders do not (i) have control of the Board of Directors and (ii) currently do

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not have sufficient voting rights to force a redemption of these shares with respect to any of these events. In addition, the effectuation of any transaction or series of transactions resulting in a more than 50% change in control can be made only by the Registrant at its own election. Based on these provisions, the Registrant classified its Series C preferred shares in stockholders' equity in the accompanying balance sheet because the liquidation events are deemed to be within the Registrant's control in accordance with the provisions of EITF Topic D-98.

Also, as described in Note 2, the Registrant evaluated the conversion options embedded in the Series C securities to determine (in accordance with SFAS 133 and EITF 00-19) whether they should be bifurcated from their host instruments and accounted for as separate derivative financial instruments. The Registrant determined, in accordance with SFAS 133, that the risks and rewards of the common shares underlying the conversion feature are clearly and closely related to those of the host instrument. Accordingly, the conversion features, which are not deemed to be beneficial at the commitment dates of these financing transactions, are being accounted for as embedded conversion options in accordance with EITF 98-5 and EITF 00-27.

16. *Provide a similar discussion of your accounting for the warrants.*

- *Revise the Critical Accounting Estimates section of MD&A to disclose the methodology and significant estimates used to value any of instruments you carry at fair value.*

*In this regard, as applicable, please refer to the guidance provided in SFAS 150, EITF 05-04, EITF 00-19 and the Division of Corporation Finance's Current Accounting and Disclosure Issues Outline at <http://www.sec.gov/division/corpfina/acctdis120105.pdf>.*

**Response:** The Registrant advises the Staff that it accounted for warrants issued to investors in connection with the sale of Series C convertible preferred stock units in accordance with EITF 00-19 "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" (EITF 00-19). Accordingly, the Registrant classified the warrants in permanent equity.

The warrants issued to investors are subject to registration rights; however, the registration rights provisions in the agreements by which the Registrant is bound do not provide for liquidated damages if a registration statement for resale of the

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instruments is not effectuated within a specified period of time. Accordingly, these provisions do not have an effect on the classification of these instruments or require accounting as separate freestanding instruments.

17. *Please clearly disclose your assessment of the impact that the recall is expected to have on your business and operations.*

**Response:** The Registrant has revised the Registration Statement as requested.

Item 17. Undertakings, page II-5

18. *We note your response to prior comment 55. We note that in the event that you rely on Rule 424(b)(3), you would be subject to Rule 430C(d) of the Securities Act, which requires you to furnish the undertakings required by Item 512(a) of Regulation S-K. We therefore ask that you provide the undertakings contained in Item 512(a)(5)(ii).*

**Response:** The Registrant has revised the disclosure as requested.

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Questions or comments regarding any matters with respect to the Registration Statement may be directed to the undersigned at (650) 233-4606. Comments can also be sent via facsimile at (650) 233-4545.

Very truly yours,

/s/ Sylvia K. Burks

Sylvia K. Burks

cc: Hojabr Alimi  
G. A. Lombardi  
N.A. Matteson