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**U.S. SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Quarter ended December 31, 2007

OR

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-33216

**OCULUS INNOVATIVE SCIENCES, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**68-0423298**

(I.R.S Employer  
Identification No.)

**1129 N. McDowell Blvd.**

**Petaluma, CA 94954**

(Address of principal executive offices) (Zip code)

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

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

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

Large Accelerated Filer  Non-Accelerated Filer  Accelerated Filer  Smaller Reporting Company   
(Do not check if a smaller reporting company)

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

As of February 7, 2008 the number of shares outstanding of the registrant's common stock, \$0.0001 par value, was 13,271,035.

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**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except share data)

**PART I: FINANCIAL INFORMATION****Item 1. Financial Statements**

	<u>December 31,</u> <u>2007</u>	<u>March 31,</u> <u>2007</u>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,353	\$ 19,050
Restricted cash	—	2,000
Accounts receivable, net	974	1,364
Inventories	278	282
Prepaid expenses and other current assets	602	1,172
Total current assets	12,207	23,868
Property and equipment, net	2,221	2,207
Restricted cash	54	49
Debt issue costs, net	411	826
Total assets	<u>\$ 14,893</u>	<u>\$ 26,950</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,515	\$ 2,551
Accrued expenses and other current liabilities	2,121	1,421
Current portion of long-term debt	1,709	6,045
Current portion of capital lease obligations	21	17
Total current liabilities	5,366	10,034
Long-term debt, less current portion	753	1,990
Capital lease obligations, less current portion	8	25
Deferred revenue	485	—
Total liabilities	<u>6,612</u>	<u>12,049</u>
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, \$0.0001 par value; 100,000,000 shares authorized, 13,271,035 and 11,844,411 shares issued and outstanding at December 31, 2007 (unaudited) and March 31, 2007, respectively.	1	1
Additional paid-in capital	95,992	85,751
Accumulated other comprehensive loss	(1,361)	(364)
Accumulated deficit	(86,351)	(70,487)
Total stockholders' equity	<u>8,281</u>	<u>14,901</u>
Total liabilities and stockholders' equity	<u>\$ 14,893</u>	<u>\$ 26,950</u>

See accompanying notes

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Operations**  
(In thousands, except per share data)  
(Unaudited)

	Three Months Ended		Nine Months Ended	
	December 31,		December 31,	
	2007	2006	2007	2006
Revenues:				
Product	\$ 843	\$ 801	\$ 2,145	\$ 2,742
Service	223	251	764	639
Total revenues	<u>1,066</u>	<u>1,052</u>	<u>2,909</u>	<u>3,381</u>
Cost of revenues:				
Product	508	542	1,287	1,584
Service	233	218	761	641
Total cost of revenues	<u>741</u>	<u>760</u>	<u>2,048</u>	<u>2,225</u>
Gross profit	<u>325</u>	<u>292</u>	<u>861</u>	<u>1,156</u>
Operating expenses:				
Research and development	2,580	795	7,070	2,390
Selling, general and administrative	3,299	4,614	10,440	12,480
Total operating expenses	<u>5,879</u>	<u>5,409</u>	<u>17,510</u>	<u>14,870</u>
Loss from operations	(5,554)	(5,117)	(16,649)	(13,714)
Interest expense	(199)	(305)	(844)	(565)
Interest income	150	30	556	130
Other income (expense), net	299	565	1,073	657
Net loss	(5,304)	(4,827)	(15,864)	(13,492)
Preferred stock dividends	—	(121)	—	(363)
Net loss available to common stockholders	<u>\$ (5,304)</u>	<u>\$ (4,948)</u>	<u>\$ (15,864)</u>	<u>\$ (13,855)</u>
Net loss per common share: basic and diluted	<u>\$ (0.40)</u>	<u>\$ (1.17)</u>	<u>\$ (1.26)</u>	<u>\$ (3.28)</u>
Weighted-average number of shares used in per common share calculations:				
Basic and diluted	<u>13,264</u>	<u>4,223</u>	<u>12,561</u>	<u>4,222</u>
Other comprehensive loss, net of tax:				
Net loss	\$ (5,304)	\$ (4,827)	\$(15,864)	\$(13,492)
Foreign currency translation adjustments	(281)	(496)	(997)	(639)
Comprehensive loss	<u>\$ (5,585)</u>	<u>\$ (5,323)</u>	<u>\$ (16,861)</u>	<u>\$ (14,131)</u>

See accompanying notes

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Cash Flows**  
(In thousands)  
(Unaudited)

	Nine Months Ended December 31,	
	2007	2006
<b>Cash flows from operating activities:</b>		
Net loss	\$(15,864)	\$(13,492)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	548	498
Stock-based compensation	916	1,060
Non-cash interest expense	415	256
Loss on disposal of equipment	5	—
Unrealized foreign exchange gain	(1,135)	(694)
Changes in operating assets and liabilities:		
Accounts receivable	416	(500)
Inventories	17	(84)
Prepaid expenses and other current assets	582	839
Accounts payable	(1,050)	(787)
Accrued expenses and other liabilities	1,162	(461)
Net cash used in operating activities	<u>(13,988)</u>	<u>(13,365)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(414)	(653)
Net cash used in investing activities	<u>(414)</u>	<u>(653)</u>
<b>Cash flows from financing activities:</b>		
Deferred offering costs	—	(1,036)
Proceeds from the issuance of common stock, net of offering costs	9,124	—
Proceeds from the issuance of common stock in connection with exercise of stock options and warrants	201	10
Proceeds from the issuance of convertible preferred stock	—	2,903
Debt issue costs	—	(75)
Proceeds from the issuance of long-term debt	—	8,381
Decrease in restricted cash for repayment of debt	2,000	—
Principal payments on debt	(5,649)	(1,040)
Payments on capital lease obligations	(12)	(12)
Net cash provided by financing activities	5,664	9,131
Effect of exchange rate on cash and cash equivalents	41	(41)
Net decrease in cash and cash equivalents	(8,697)	(4,928)
Cash and equivalents, beginning of period	19,050	7,448
Cash and equivalents, end of period	<u>\$ 10,353</u>	<u>\$ 2,520</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ 521</u>	<u>\$ 271</u>
Fair value of warrants issued with line of credit	<u>\$ —</u>	<u>\$ 1,151</u>
Financed equipment	<u>\$ 76</u>	<u>\$ —</u>

See accompanying notes

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements**  
(Unaudited)

**Note 1. Organization and Summary of Significant Accounting Policies**

***Organization***

Oculus Innovative Sciences, Inc. (the “Company”) was incorporated under the laws of the State of California in April 1999 and was reincorporated under the laws of the State of Delaware in December 2006. The Company’s principal office is located in Petaluma, California. The Company develops, manufactures and markets a family of products intended to prevent and eliminate infection in acute and chronic wounds. The Company’s platform technology, Microcyn, is a shelf stable, non-irritating, proprietary solution containing oxychlorine compounds that is designed to eliminate a wide range of bacteria, viruses, fungi, spores and drug resistant strains of bacteria such as Methicillin-resistant *Staphylococcus aureus*, or MRSA, and Vancomycin-resistant *Enterococcus*, or VRE, in wounds. The Company conducts its business worldwide, with significant operating subsidiaries in Europe and Mexico.

***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements as of December 31, 2007 and for the three and nine months then ended have been prepared in accordance with the accounting principles generally accepted in the United States of America for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (“SEC”) and on the same basis as the annual audited consolidated financial statements. The unaudited condensed consolidated balance sheet as of December 31, 2007, condensed consolidated statements of operations for the three and nine months ended December 31, 2007 and 2006, and the condensed consolidated statements of cash flows for the nine months ended December 31, 2007 and 2006 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The results for the three and nine months ended December 31, 2007 are not necessarily indicative of results to be expected for the year ending March 31, 2008 or for any future interim period. The condensed consolidated balance sheet at March 31, 2007 has been derived from audited consolidated financial statements. However, it does not include all of the information and notes required by accounting principles generally accepted in the United States of America for complete consolidated financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s Form 10-K/A, which was filed with the SEC on July 27, 2007.

***Significant Accounting Policies***

In June 2006, the Financial Accounting Standards Board issued FASB Interpretation No. 48, “Accounting for Uncertainty in Income Taxes” (“FIN 48”). This Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Interpretation is effective for fiscal years beginning after December 15, 2006. See Note 7 for further discussion of the impact of adoption of this pronouncement on April 1, 2007.

Periodically the Company evaluates its application of all accounting policies. During the three months ended December 31, 2007, the Company evaluated its application of SEC Staff Accounting Bulletin (“SAB”) 104 “Revenue Recognition” to certain distributors purchasing product from its Mexico subsidiary. During the fourth quarter of fiscal 2007, the Company significantly reduced its direct sales force in Mexico while deciding to rely more heavily on an expanded network of distributors. As a result of certain distributors’ inability to provide inventory or product sell-through reports on a timely basis, and as a result of slow payment on accounts receivable where distributors await payment from their customers prior to payment, the Company determined the appropriate treatment for recognizing revenue for those distributors is to defer and recognize revenue when payment is received. The Company believes the receipt of payment is the best indication of product sell-through. The Company will defer recognition of gross profit associated with these customers until payment is received. The gross profit deferral is included in accrued expenses and other current liabilities in the accompanying December 31, 2007 condensed consolidated balance sheet.

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### *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 condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Periodically, the Company evaluates and adjusts estimates accordingly. The allowance for uncollectible accounts receivable balances amounted to \$373,000 and \$207,000, which are included in accounts receivable, net in the accompanying December 31, 2007 and March 31, 2007 condensed consolidated balance sheets, respectively.

### *Foreign Currency Transactions*

Foreign currency gains relate to working capital loans that the parent Company has made to its foreign subsidiaries which are expected to be repaid. The Company recorded foreign currency gains for the three months ended December 31, 2007 and 2006 of \$324,000 and \$52,000, respectively. The Company recorded foreign currency gains for the nine months ended December 31, 2007 and 2006 of \$1,135,000 and \$694,000, respectively. The related gains were recorded in other income (expense) in the accompanying condensed consolidated statements of operations.

### *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 excludes potentially dilutive securities because their inclusion would be anti-dilutive.

The following securities were excluded from basic and diluted net loss per share calculation because their inclusion would be anti-dilutive (in thousands):

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2007	2006	2007	2006
Options to purchase common stock	2,576	2,043	2,576	2,043
Restricted stock units	60	—	60	—
Warrants to purchase common stock	1,829	1,060	1,829	1,060
Convertible preferred stock (as if converted)	—	4,153	—	4,045
Warrants to purchase convertible preferred stock (as if converted)	—	88	—	88
	<u>4,465</u>	<u>7,344</u>	<u>4,465</u>	<u>7,236</u>

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

The Company accounts for the issuance of common stock purchase warrants issued and other freestanding derivative financial instruments in accordance with the provisions of Emerging Issues Task Force Issue (“EITF”) 00-19 “Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock” (“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) give 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).

The Company completed a classification assessment of all of its freestanding derivative financial instruments as of December 31, 2007 and determined that such instruments meet the criteria for equity classification in accordance with EITF 00-19.

### ***Recent Accounting Pronouncements***

In February 2007, FASB issued Statement of Financial Accounting Standards No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities” (“SFAS 159”). SFAS 159, which includes an amendment to Statement of Financial Accounting Standards No. 115, “Accounting for Certain Investments in Debt and Equity Securities” (“SFAS 115”), permits entities the option to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is in the process of determining the impact that SFAS 159 will have on its financial condition, results of operations and cash flows.

In December 2007, the FASB issued SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements—an amendment of Accounting Research Bulletin No. 51” (“SFAS 160”). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective as of the beginning of an entity’s fiscal year that begins after December 15, 2008. The Company is currently evaluating the potential impact, if any, of the adoption of SFAS 160 on its financial condition and results of operations.

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.

### **Note 2. Going Concern, Liquidity and Financial Condition**

The Company incurred a net loss of \$5,304,000 and \$15,864,000 for the three and nine months ended December 31, 2007, respectively. At December 31, 2007 the Company’s accumulated deficit amounted to \$86,351,000. During the nine months ended December 31, 2007, net cash used in operating activities amounted to \$13,988,000. At December 31, 2007, the Company’s working capital amounted to \$6,841,000. The Company needs to raise additional capital from external sources in order to sustain its operations while continuing the longer term efforts contemplated under its business plan. The Company expects to continue incurring losses for the foreseeable future and must raise additional capital to pursue its product development initiatives, to begin its Phase III clinical trial, to penetrate markets for the sale of its products and to continue as a going concern. The Company cannot provide any assurance that it will raise additional capital. If the Company is unable to raise additional capital, it will be required to curtail certain operating activities and implement additional cost reductions in an effort to conserve capital in amounts sufficient to sustain operations and meet its obligations for the next twelve months. Management believes that the Company has access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means; however, the Company has not secured any commitment for new financing at this time nor can it provide any assurance that new financing will be available on commercially acceptable terms, if at all. If the Company is unable to secure additional capital, it may be required to curtail its research and development initiatives, delay clinical trials and take additional measures to reduce costs in order to conserve its cash. These measures could cause significant delays in the Company’s efforts to commercialize its products in the United States, which is critical to the realization of its business plan and the future operations of the Company. The accompanying condensed consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. These matters raise substantial doubt about the Company’s ability to continue as a going concern.

The Company has undertaken initiatives to reduce costs in an effort to conserve liquidity and also to redirect its efforts on the longer term strategy of focusing on its clinical trials and related research and development activities. The Company considers the completion of Phase II and Phase III clinical trials to be critical milestones in the development of the business. The Company completed enrollment and treatment of all patients in its Phase II clinical trial during the three months ended December 31, 2007. The Phase III trials will require significant expenditures and must also be completed in order for the Company to commercialize Microcyn as a drug product in the United States. Commencement of the Phase III clinical trials will be delayed until the Company raises additional capital or secures commitments for additional capital in amounts sufficient to proceed with these trials. Without additional capital, the Company’s Phase III clinical trials would be delayed for a period of time that is currently indeterminate.



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As described in Note 5, on August 13, 2007, the Company closed the private placement of 1,262,500 shares of its common stock at a purchase price of \$8.00 per share, and warrants to purchase an aggregate of 416,622 shares of common stock at an exercise price of \$9.50 per share for gross proceeds of \$10,100,000 and net proceeds of \$9,124,000 (after deducting the placement agent's commission and other offering expenses).

Additionally, pursuant to Amendment No. 1 to the Burlingame loan agreement (Note 3), subsequent to the close of the private placement on August 13, 2007, the Company was required to promptly repay the \$4,000,000 outstanding note balance and interest. The note was originally scheduled to be repaid on November 7, 2007. The note was repaid in full by August 31, 2007.

### **Note 3. Condensed Consolidated Balance Sheet**

#### ***Inventories***

Inventories consisted of the following (in thousands):

	<b>December 31, 2007</b>
Raw materials	\$ 337
Finished goods	116
	453
Less: inventory allowances	(175)
	<u>\$ 278</u>

#### ***Notes Payable***

On June 14, 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. In June 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. As of December 31, 2007, 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.

In connection with the borrowings under this facility, the Company also issued to the lender warrants to purchase up to 71,521 shares of its common stock at an exercise price of \$18.00 per share. The aggregate fair value of all warrants issued to the lender under this arrangement amounts to \$1,046,000. This amount was recorded as debt issue costs in the December 31, 2007 condensed consolidated balance sheet and is being amortized as interest expense over the term of the credit facility of 30 to 33 months.

Borrowings under the growth capital line are collateralized by certain assets of the Company. 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 is not required to direct customer remittances to a lock box, nor does the credit agreement provide for subjective acceleration of the loans.

On March 29, 2007, the Company entered into Amendment No. 1 to the loan agreement evidencing the credit facility described above. Pursuant to the amendment, the lender and the Company agreed that the lender's security interest in the Company's assets would not include the Company's intellectual property unless and until the Company's cash and cash equivalents fall below 600% of the Company's average monthly operating expenses less non-cash charges. At December 31, 2007, the Company's cash and cash equivalents position was not in excess of 600% of its average monthly operating expenses and therefore the lender holds a security

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interest in the Company's intellectual property. On an ongoing basis, the Company will periodically review and assess whether the lender's security interest should include the Company's intellectual property. The Company's intellectual property is used only as collateral and remains in the Company's control unless the lender takes described action after an event of default by the Company under the loan agreements.

In connection with the notes issued under the above credit facility, for the three and nine months ended December 31, 2007, the Company made \$381,000 and \$1,108,000 of principal payments, respectively. Additionally, for the three and nine months ended December 31, 2007, the Company made \$77,000 and \$266,000 of interest payments in connection with these notes, respectively. Also, for the three and nine months ended December 31, 2007, the Company recorded \$107,000 and \$322,000 of non-cash interest expense related to the amortization of debt issue costs, respectively. The aggregate remaining principal balance under this facility amounted to \$2,222,000, including \$1,647,000 in the current portion of long-term debt in the accompanying condensed consolidated balance sheet at December 31, 2007.

On August 13, 2007, after the closure of the \$10,100,000 million private placement of the Company's common stock described in Note 5, the Company became obligated to repay outstanding amounts under the terms of the Amendment No. 1 to the Burlingame loan agreement. The Company paid \$2,000,000 under the loan agreement on August 15, 2007, and the remaining \$2,000,000 and accrued interest on August 31, 2007. Additionally, in connection with the note issued pursuant to this loan agreement, for the nine months ended December 31, 2007, the Company recorded \$93,000 of non-cash interest expense related to the amortization of the debt issue costs. During the nine months ended December 31, 2007, the Company paid \$222,000 of interest expense related to this note of which \$109,000 was accrued at March 31, 2007.

On April 12, 2007, the Company entered into a note agreement to purchase an automobile for \$75,800 with interest at the rate of 7.75 % percent per annum. This note is payable in monthly installments of \$1,500 through April 2012. During the three and nine months ended December 31, 2007, the Company made principal payments of \$3,200 and \$8,300 respectively. Additionally, during the three and nine months ended December 31, 2007, the Company made interest payments of \$1,400 and \$4,000, respectively. The remaining balance of this note amounted to \$68,000 at December 31, 2007, including \$14,000 in the current portion of long-term debt in the accompanying condensed consolidated balance sheet.

### **Note 4. Commitments and Contingencies**

#### *Legal Matters*

In November 2005, the Company identified a possible criminal misappropriation of its technology in Mexico, and notified the Mexican Attorney General's office of the matter. The Company believes the Mexican Attorney General is currently conducting an investigation.

In March 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, alleging that defendants had wrongfully infringed the Company's intellectual property rights in its Microcyn technology. Defendants later asserted counter-claims against the Company. On November 15, 2007 the Court granted the Company's Motion to Dismiss the claims against the Company. Additionally, the Court issued an Order finding that defendants had violated key terms of both an Exclusive Purchase Agreement and a Non-Disclosure Agreement by contacting and working with a competitor in Mexico. The Court also permanently enjoined defendants from any further misuse of the Company's Microcyn technology. On January 23, 2008, after an evidentiary hearing, the Court ordered the defendants to pay the Company \$6,644,000 in damages for lost profits as a result of defendants' breach of the Exclusive Purchase Agreement and the Non -Disclosure Agreement. The Company does not expect an appeal and will seek to collect on this judgment from defendants. The Company notes that collection may be impeded or delayed by the fact that defendants are a non-U.S. corporation and citizen, respectively, with unknown assets.

The Company is currently in discussions regarding two trademark matters asserting confusion in trademarks with respect to the Company's use of the name Microcyn60 in Mexico. The Company settled one of the trademark matters in August 2006. Although the Company believes that the nature and intended use of its products are different from those with the similar names, the Company has agreed with one of the parties to market its product in Mexico under a different name. Although such plaintiff referred the matter to the Mexico Trademark Office, the Company is not aware of a claim for monetary damages. The Company is in discussions with the other party and believes that the name change will satisfy an assertion of confusion; however, management believes that the Company

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will incur a loss of up to \$100,000 as a result of this matter. The Company accrued \$100,000 in connection with this matter, which is included in accrued expenses and other current liabilities in the accompanying December 31, 2007 condensed consolidated balance sheet.

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

In February 2007, the Company's Mexico subsidiary served Quimica Pasteur ("QP"), a former distributor of the Company's products in Mexico, with a claim alleging breach of contract under a note made by QP. A trial date has not yet been set.

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 not material, there can be no assurance that matters arising in the ordinary course of business for which the Company is or could become involved in litigation, will not have a material adverse effect on its business, financial condition or results of operations.

### ***Employment Agreements***

The Company has 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 \$1,065,000 and twelve to twenty four months of severance compensation for terminations under certain circumstances. Aggregate potential severance compensation amounted to \$1,492,500 at December 31, 2007. Additionally, during the nine months ended December 31, 2007, the Company added an additional member to the executive team who receives an annual salary of \$242,000. The Company has not undertaken severance payment obligations with respect to this employee.

### ***Property Lease Extension***

On September 13, 2007, the Company entered into Amendment No. 4 to the property lease agreement for its facility in Petaluma, California. The amendment extends the lease expiration date to September 30, 2010. Lease payments pursuant to the amendment amounted to \$902,000, with \$123,000 to be paid in the fiscal year ending March 31, 2008, \$302,000 to be paid in the fiscal year ending March 31, 2009, \$315,000 to be paid in the fiscal year ending March 31, 2010 and \$161,000 to be paid thereafter.

### ***Service Agreements***

On November 19, 2007, the Company entered into a one year agreement with an investor relations service provider. The agreement may be terminated by either party at anytime with thirty days notice. The Company will pay the service provider \$120,000 over the term of the agreement. Additionally, if the agreement is not terminated prior to April 1, 2008, the service provider will be issued 12,000 shares of the Company's common stock.

### ***Commercial Agreements***

On May 8, 2007, and June 11, 2007, the Company entered into separate commercial agreements with two unrelated customers granting such customers the exclusive rights to sell the Company's products in specified territories or for specific uses. Both customers are required to maintain certain minimum levels of purchases of the Company's products in order to maintain exclusivity. Up-front payments amounting \$475,000 under these agreements have been included in deferred revenue in the accompanying balance sheet and will be amortized in accordance with the terms of the underlying agreements.

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### ***Other Matters***

On September 16, 2005, the Company entered into a series of agreements with 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, the Company was concurrently granted an option to acquire all except a minority share of the equity of QP directly from its principals in exchange for 150,000 shares of common stock, contingent upon QP's attainment of certain financial milestones. The Company's distribution and related agreements were cancelable by the Company on thirty days' notice without cause and included certain provisions to hold the Company harmless from debts incurred by QP outside the scope of the distribution and related agreements. The Company terminated these agreements on March 26, 2006 without having exercised the option.

Due to its liquidity circumstances, QP was unable to sustain operations without the Company's subordinated financial and management support. Accordingly, QP was deemed to be a variable interest entity in accordance with FIN 46(R) and its results were consolidated with the Company's consolidated financial statements for the period of September 16, 2005 through March 26, 2006, the effective termination date of the distribution and related agreement, without such option having been exercised.

Subsequent to having entered into the agreements with QP, the Company became aware of an alleged tax avoidance scheme involving the principals of QP. The audit committee of the Company's Board of Directors engaged an independent counsel, as well as tax counsel in Mexico to investigate this matter. The audit committee of the Board of Directors was advised that QP's principals could be liable for up to \$7,000,000 of unpaid taxes; 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.

Based on an opinion of Mexico counsel, the Company's management and the audit committee of the Board of Directors do not believe that the Company is likely to experience any loss with respect to this matter. However, there can be no assurance that the Mexican tax authorities will not pursue this matter and, if pursued, that it would not result in a material loss to the Company.

### **Note 5. Stockholders' Equity**

#### ***Common Stock Issued in Private Placement***

On August 13, 2007, the Company completed a private placement of 1,262,500 shares of common stock to certain accredited investors at a price of \$8.00 per share pursuant to the terms of a Securities Purchase Agreement, dated August 7, 2007. In addition, the investors received warrants to purchase an aggregate of 416,622 additional shares of common stock at an exercise price of \$9.50 per share (described below). Gross proceeds from the private placement were \$10,100,000 and net proceeds of \$9,124,000 (after the placement agent's commission and other offering expenses). Pursuant to the terms of a Registration Rights Agreement, dated August 7, 2007, the shares of common stock issued to the investors in the private placement and the shares of common stock to be issued upon the exercise of the warrants issued in the private placement were registered on a Form S-1 (File No. 333-145810), which was declared effective on September 12, 2007. If the Registration Statement ceases to remain continuously effective, or the Holders of the Registrable Securities are not permitted to utilize the related Prospectus to resell the securities registered under the Registration Statement for more than ten consecutive calendar days, or more than a total of fifteen calendar days in any twelve month period, the Company will be required to pay the security holders, until cured, partial liquidated damages in cash equal to 1% monthly, up to a maximum of 15%, of the aggregate purchase price paid pursuant to the terms of the Securities Purchase Agreement. If the Company is required to pay liquidated damages and payments are not made seven days from the due date, the holders will become entitled to interest payments of 18% per annum on the amount due. The Company, after having evaluated the registration payment arrangement, has determined that it is unlikely to incur any mandatory liability based on its past experience in filing registration statements. Accordingly, the Company does not believe it is necessary to record any reserves for contingent transfer of consideration in accordance with EITF FSP 00-19-2, "Accounting for Registration Payment Arrangements".

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The Company also issued a warrant to purchase 88,375 shares of common stock to a placement agent in connection with the private placement (described below). The warrant has the same terms, including exercise price and registration rights, as the warrants issued in the private placement.

### ***Common Stock Purchase Warrants Issued in Financing Transactions***

On August 13, 2007 the Company issued warrants to purchase 416,622 shares of common stock at an exercise price of \$9.50 per share to investors in conjunction with the private placement of common stock described above. The warrants are exercisable 181 days after August 13, 2007, and have a term of five years. The warrants are subject to adjustment in certain circumstances and require settlement in shares of the Company's common stock. The Company accounted for the issuance of the common stock purchase warrants in accordance with the provisions of EITF 00-19. Based on the provisions of EITF 00-19, the Company classified the warrants as equity. The securities that are issuable upon exercise of the warrants were issued in the private placement were registered on a Form S-1 (File No. 333-145810), which was declared effective on September 12, 2007.

On August 20, 2007, the Company issued a warrant to purchase 88,375 shares of common stock at an exercise price of \$9.50 per share to the placement agent for the private placement described above. The warrant is exercisable 181 days after August 13, 2007, and has a term of five years. The warrant has the same terms as the warrants issued in the private placement and was accounted for in accordance with the provisions of EITF 00-19. The securities underlying the warrant were registered on the same registration statement.

### ***Common Stock and Common Stock Purchase Warrants Issued to Non-Employees for Services***

During the nine months ended December 31, 2007, the Company recorded \$2,000 for certain warrants with service conditions issued in prior periods. In April 2007, the Company terminated the service agreements with the service providers and accelerated the vesting of the outstanding warrants and extended the exercise period to two years. The non-vested portion of the warrants were adjusted to fair value at the time of acceleration using the Black Scholes pricing model and the following weighted average assumptions: fair value of the underlying stock of \$5.92; risk-free interest rate of 4.87% percent; contractual life of 2 years; dividend yield of 0.00%; and volatility of 70.00%.

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 issued the director a warrant to purchase 75,000 shares of the Company's common stock, exercisable at a price equal to the Company's common stock in its initial public offering in consideration of corporate advisory services. The warrant was fully exercisable and non-forfeitable at date of issuance. The warrant was valued using the Black-Scholes option pricing model. Assumptions used were as follows: fair value of the underlying stock of \$9.00, which represented the expected mid-point of the IPO at the December 31, 2006 reporting date; risk-free interest rate of 4.70% percent; contractual life of 5 years; dividend yield of 0%; and volatility of 70%. The fair value of the warrants amounted to \$416,000. Following the guidance enumerated in Issue 2 of EITF 96-18 "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", the Company is amortizing the fair value of the warrants over the two-year term of the consulting agreement which is consistent with its treatment of similar cash transactions. For the three and nine months ended December 31, 2007, the amortized fair value of the warrant amounted to \$44,000 and \$132,000, respectively, and was recorded as selling, general and administrative expense in the accompanying condensed consolidated statements of operations.

### **Note 6. 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," ("APB 25") and its related interpretations and applied the disclosure requirements of SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of Statement of Financial Accounting Standard No. 123 'Share-Based Payments'" ("SFAS 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.

The Company recognized in salaries and related expense in the condensed consolidated statements of operations \$36,000 and \$112,000 of stock-based compensation expense during the three and nine months ended December 31, 2007, respectively, which represents the intrinsic value amortization of options granted prior to April 1, 2006 that the Company is continuing to account for

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using the recognition and measurement principles prescribed under APB 25. At December 31, 2007, there was \$216,000 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 remaining amortization period of 1.74 years.

Effective April 1, 2006, the Company adopted Statement of Financial Accounting Standard No. 123(R) "Share Based Payment" ("SFAS 123(R)") using the prospective transition method, which requires the fair value 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 condensed consolidated financial statements as of December 31, 2007 and for the three and nine months ended December 31, 2007 reflect the impact of SFAS 123(R). In accordance with the prospective transition method, the Company's financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

The effect of recording stock-based compensation expense in accordance with the provisions of SFAS 123(R) is as follows (in thousands, except per share amounts):

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2007	2006	2007	2006
Cost of service revenue	\$ 3	\$ 1	\$ 7	\$ 3
Research and development	40	—	101	—
Selling, general and administrative	283	334	556	376
Total stock-based compensation	\$ 326	\$ 335	\$ 664	\$ 379
Effect on basic and diluted net loss per common share	\$ (0.02)	\$ (0.08)	\$ (0.05)	\$ (0.09)

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

The Company estimated the fair value of employee stock awards 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:

	Three Months Ended December 31		Nine Months Ended December 31	
	2007	2006	2007	2006
Expected life	6.0 years	2.0 years	5.6 years	5.0 years
Risk-free interest rate	4.14%	4.70%	4.76%	4.63%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Volatility	79%	70%	72%	70%

The estimated expected life 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 three months ended December 31, 2007 was determined by examining the historical trading history of the Company's common stock. In the prior periods, the expected volatility was determined by examining the historical volatilities of the Company's industry peers and using an average of the historical volatilities of the industry peers as the Company did not have adequate trading history for its 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 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 based on historical experience. Prior to the adoption of SFAS 123(R), the Company accounted for forfeitures as they occurred.

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A summary of all option activity as of December 31, 2007 and changes during the nine months then ended is presented below:

<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, 2007	2,020	\$ 4.91		
Granted	791	7.21		
Exercised	(119)	0.56		
Forfeited or expired	(116)	6.32		
Outstanding at December 31, 2007	2,576	\$ 5.75	7.07	\$ 2,776
Exercisable at December 31, 2007	1,409	\$ 3.85	5.64	\$ 2,712

The aggregate intrinsic value is calculated as the difference between the exercise price of the stock options and the underlying fair value of the Company's common stock (\$4.10) for stock options that were in-the-money as of December 31, 2007.

During the three and nine months ended December 31, 2007, the Company granted stock options to employees with a weighted-average grant date fair value of \$4.45 and \$4.62 per share, respectively. At December 31, 2007, there was unrecognized compensation costs of \$4,075,000 related to stock options accounted for in accordance with the provisions of SFAS 123(R). The cost is expected to be recognized over a weighted-average amortization period of 3.79 years.

On April 26, 2007, the Company modified a stock option grant to its Chief Financial Officer. The Company cancelled the original stock option grant to purchase 60,000 shares of the Company's common stock and replaced the grant with a restricted stock grant with similar terms to the original grant. The modification of this award did not result in incremental fair value or an additional charge to Company's condensed consolidated statements of operations.

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

As provided under the Company's 2006 Stock Incentive Plan ("2006 Plan"), the aggregate number of shares authorized for issuance as awards under the 2006 Plan automatically increased on April 1, 2007 by 592,220 shares (which number constitutes 5% of the 11,844,411 outstanding shares on the last day of the fiscal year ended March 31, 2007). Remaining shares authorized for issuance from the 2006 Plan at December 31, 2007 was 928,969.

### 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 using the following weighted-average assumptions:

	<b>Nine Months Ended December 31, 2007</b>
Estimated life	2.60 years
Risk-free interest rate	4.50%
Dividend yield	0.00%
Volatility	70%

Stock-based compensation expense will fluctuate as the fair market value of the common stock fluctuates. In April 2007, the Company accelerated the vesting of certain non-employee stock options and extended the option exercise period to two years after termination of the underlying agreement. During the nine months ended December 31, 2007, the Company recorded \$6,000 of stock-based compensation expense related to non-employees.

### Note 7. Income Taxes

In June 2006, the Financial Accounting Standards Board ("FASB") issued Interpretation 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"), which became effective for the Company beginning April 1, 2007. FIN 48 addresses how tax benefits

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claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under FIN 48, the tax benefit from an uncertain tax position can be recognized only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. The adoption of FIN 48 had no impact on the Company's financial condition, results of operations or cash flows.

Utilization of the Company's net operating loss ("NOL") carryforwards could become subject to potentially substantial annual limitations due to ownership change that could occur in the future as provided in Section 382 of the Internal Revenue Code of 1986, as well as similar state and foreign provisions. These ownership changes could limit the amount of NOL and R&D tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than fifty percentage points over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock which, combined with the purchasing shareholders' subsequent disposition of those shares, could result in a change of control in the future upon subsequent disposition.

The Company has completed a study to assess whether a change in control has occurred or whether there have been multiple changes of control since the Company's formation. The study concluded that no change in control occurred for purposes of Section 382 and therefore no additional adjustments were recorded or disclosed. Interest and penalties related to uncertain tax positions will be reflected in income tax expense. If the Company experiences a change of control at any time, utilization of NOL or R&D tax credit carryforwards would be subject to an annual limitation under Section 382. This annual limitation is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and could then be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D tax credit carryforwards before utilization. As of December 31, 2007, the Company had not recorded any tax penalties or interest in its condensed consolidated financial statements. All tax years since the Company's inception remain subject to future examination by the major jurisdictions in which it is subject to taxation.

### **Note 8. Segment and Geographic Information**

The Company is organized primarily on the basis of operating units which are segregated by geography.

The following tables present information about reportable segments (in thousands):

	<u>U.S</u>	<u>Europe</u>	<u>Mexico</u>	<u>Total</u>
<b>Three months ended December 31, 2007</b>				
Product revenues	\$ 39	\$ 208	\$ 596	\$ 843
Service revenues	223	—	—	223
Total revenues	262	208	596	1,066
Depreciation and amortization expense	108	57	24	189
Loss from operations	(4,963)	(330)	(261)	(5,554)
Interest expense	(199)	—	—	(199)
Interest income	150	—	—	150
<b>Three months ended December 31, 2006</b>				
Product revenues	\$ 51	\$ 91	\$ 659	\$ 801
Service revenues	251	—	—	251
Total revenues	302	91	659	1,052
Depreciation and amortization expense	95	56	21	172
Loss from operations	(3,243)	(790)	(1,084)	(5,117)
Interest expense	(305)	—	—	(305)
Interest income	30	—	—	30
<b>Nine months ended December 31, 2007</b>				
Product revenues	\$ 146	\$ 446	\$ 1,553	\$ 2,145
Service revenues	764	—	—	764
Total revenues	910	446	1,553	2,909
Depreciation and amortization expense	311	168	69	548
Loss from operations	(14,268)	(1,276)	(1,105)	(16,649)
Interest expense	(844)	—	—	(844)
Interest income	556	—	—	556



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Nine months ended December 31, 2006	U.S	Europe	Mexico	Total
Product revenues	\$ 106	\$ 920	\$ 1,716	\$ 2,742
Service revenues	639	—	—	639
Total revenues	745	920	1,716	3,381
Depreciation and amortization expense	284	148	66	498
Loss from operations	(8,990)	(959)	(3,765)	(13,714)
Interest expense	(565)	—	—	(565)
Interest income	130	—	—	130

During the three months ended December 31, 2007 and 2006, sales to a customer in India were \$56,000 and \$21,000, respectively. During the nine months ended December 31, 2007 and 2006, sales to a customer in India were \$83,000 and \$604,000, respectively. These sales were reported as part of the Europe segment.

The following table shows property and equipment balances by segment (in thousands):

	December 31, 2007
U.S.	\$ 1,097
Europe	752
Mexico	372
	<u>\$ 2,221</u>

The following table shows total asset balances by segment (in thousands):

	December 31, 2007
U.S.	\$ 11,938
Europe	1,516
Mexico	1,439
	<u>\$ 14,893</u>

### **Note 9. Subsequent Events**

#### ***Nofil Litigation***

On January 23, 2008, after an evidentiary hearing, the Court ordered Nofil to pay the Company \$6,644,000 in damages for lost profits as a result of their breach of an Exclusive Purchase Agreement and a Non-Disclosure Agreement (Note 4). The Company does not expect an appeal and will seek to collect on this judgment from Nofil. The Company notes that collection may be impeded or delayed by the fact that defendants are a non-U.S. corporation and citizen, respectively, with unknown assets.

### **Item 2. 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 in conjunction with the condensed consolidated financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q as of December 31, 2007 and our audited consolidated financial statements for the year ended March 31, 2007 included in our 10K/A, which was with the Securities and Exchange Commission on July 27, 2007.*

*This Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this Report, the words "expects," "anticipates," "intends," "estimates," "plans," "projects," "continue," "ongoing," "potential," "expect," "predict," "believe," "intend," "may," "will," "should," "could," "would" and similar expressions are intended to identify forward-looking statements. These are statements that relate to future periods and include statements about, but*

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*not limited to: the progress and timing of our development programs and regulatory approvals for our products; the benefits and effectiveness of our products; the development of protocols for clinical studies; enrollment in clinical studies; the progress and timing of clinical trials and physician studies; our expectations related to the use of our cash; our ability to manufacture sufficient amounts of our product candidates for clinical trials and products for commercialization activities; the outcome of discussions with the FDA and other regulatory agencies; 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 ability of our products to meet existing or future regulatory standards; 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; our expectations and capabilities relating to the sales and marketing of our current products and our product candidates; the execution of distribution agreements; the expansion of our sales force and distribution network; the establishment of strategic partnerships for the development or sale of 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 ability to continue to expand our intellectual property portfolio; our expectations about the outcome of litigation and controversies with third parties; our ability to attract and retain qualified directors, officers and employees ; our relationship with 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 ability to expand to and commercialize products in markets outside the wound care market; our estimates regarding future operating performance, earnings and capital requirements; our ability to attract capital on terms acceptable to us, if at all; our ability to control and to reduce our costs; our expectations with respect to our microbiology contract testing laboratory; 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*

*Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These risks and uncertainties include, but are not limited to, those risks discussed below, as well as our ability to develop and commercialize new products; the risks in obtaining patient enrollment for our studies; the risk of unanticipated delays in research and development efforts; the risk that we may not obtain reimbursement for our existing test and any future products we may develop; the risks and uncertainties associated with the regulation of our products by the FDA; the ability to compete against third parties; our ability to obtain capital when needed; our history of operating losses; the risks associated with protecting our intellectual property; and the risks set forth under “Risks Related to our Business.” These forward-looking statements speak only as of the date hereof. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the Company’s expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.*

*In the section of this report entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Factors that May Affect Results,” all references to “Oculus,” “we,” “us,” or “our” mean Oculus Innovative Sciences, Inc.*

## **Business Overview**

We have developed, and we manufacture and market, a family of products intended to 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 proprietary oxychlorine small molecule formulation that is designed to treat a wide range of organisms that cause disease, or 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, nor do we have the necessary regulatory clearance or approval to market Microcyn in the United States as a medical device for an antimicrobial or wound healing indication. However, our device product is cleared for sale in the United States as a medical device for wound cleaning, or debridement, lubricating, moistening and dressing; is a device under CE Mark in Europe with anti-infective claims; and is approved as a drug in India and as an antiseptic in Mexico.

Clinical testing we conducted in connection with our submissions to the FDA, as well as physician clinical studies, suggest that our Microcyn-based product kills a wide range of pathogens in acute and chronic wounds. These physician clinical studies suggest that our Microcyn-based product is easy to use and complementary to most existing treatment methods in wound care. Physician clinical studies in the United States suggest that our 510(k) product may shorten hospital stays, lower aggregate patient care costs and, in certain cases, reduce the need for systemic (oral or injectable) and topical antibiotics.

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Common methods of controlling infection, including antibiotics and topical antiseptics, have several significant disadvantages in combating infection in the wound bed. First, topical antiseptics tend to inhibit the healing process due to their toxicity and may require specialized preparation or handling. Second, antibiotics can lead to the emergence of resistant bacteria, including MRSA and VRE. Third, systemic antibiotics may be less effective in controlling infection in patients with disorders affecting circulation, such as diabetes, which are commonly associated with chronic wounds. As a result, no single treatment is used across all types of wounds and stages of healing. Fourth, oral and injectable antibiotics also carry the potential for systemic side effects and adverse reactions that are less likely with topical agents.

We believe Microcyn provides advantages over current methods of care in the treatment of a wide range of chronic and acute wounds throughout all stages of treatment. These stages include cleaning, or debridement, prevention and treatment of infections and wound healing. 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 irritation of or damage to 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 vision is to become a worldwide leader in treating infections. We currently have, and intend to seek additional regulatory clearances and approvals to market our Microcyn-based products worldwide. In July 2004, we began selling 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, India and Mexico have conducted 20 physician clinical studies assessing Microcyn's use in the treatment of infections in a variety of wound types, including hard-to-treat wounds such as diabetic ulcers and burns. These studies were not intended to be rigorously designed or controlled clinical trials and, as such, did not have all of the controls required for clinical trials used to support a New Drug Application, or NDA, submission to the FDA in that they often did not include blinding, randomization, predefined clinical end points, use of placebo and active control groups or U.S. good clinical practices requirements.

We used the data generated from some of these studies to support our application for the CE Mark, or European Union certification, for wound cleaning and reduction of the amount of bacteria in wounds. 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 wound cleaning, or debridement, lubricating, moistening and dressing, including traumatic wounds and acute and chronic dermal lesions.

In the first fiscal quarter of 2008, we began enrolling patients in a Phase II randomized open label clinical trial, which is designed to evaluate the effectiveness of Microcyn in mildly infected diabetic foot ulcers with endpoints of clinical cure and improvement of infection (resolution of signs and symptoms of infection) supported by microbiological response. We used 15 clinical sites to enroll a total of 67 patients in one of three arms of the study: Microcyn alone, Microcyn plus an oral antibiotic, and saline plus an oral antibiotic. We completed enrollment and treatment of patients of our Phase II trial in the fourth calendar quarter of 2007 and expect to announce results in the first calendar quarter of 2008. A well known contract research organization is coordinating, monitoring, documenting and auditing the results of this trial. Following the completion of this trial and analysis of resulting data, we plan to request a formal review meeting with the FDA. Depending on the outcome of those discussions, we plan to continue our development program, which is intended to provide the clinical basis for submission to the FDA of an NDA for the treatment of mildly infected diabetic foot ulcers. In the event that we obtain drug approval from the FDA, we may seek clearance for treatment of other types of wounds. We are currently pursuing strategic partnerships to assess potential applications for Microcyn in several other markets, including respiratory, ophthalmology, dermatology, dental and veterinary markets, and FDA or other governmental approvals may be required for any potential new products or new indications. Our international strategy includes the reduction of expenses in order to focus our resources on our United States clinical trials.

We currently make Microcyn available under our 510(k) clearances in the United States primarily through our website and several regional distributors. We plan for a more aggressive commercialization and product launch in the event we obtain drug approval from the FDA. Most of our current marketing efforts in the United States are designed to test market and obtain market feedback. In Europe, we have limited our sales efforts through only a few local distributors while preparing for potential partnerships. In Mexico, we sell Microcyn through a network of distributors and through a contract sales force, including salespeople, nurses and clinical support staff. In India, we sell through Alkem Limited Laboratories, a large pharmaceutical company based in India. In China, we signed a distribution agreement with China Bao Tai, which intends to distribute Microcyn to hospitals, doctors and clinics through Sinopharm, the largest pharmaceutical company in China, and to retail pharmacies through Lianhua Supermarkets after required regulatory approval in China.

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is obtained. During the third fiscal quarter of 2008, China Bao Tai completed and submitted the results of two randomized and controlled clinical trials of Microcyn on burn and chronic wound patients to the Chinese State Food and Drug Administration (“SFDA”). SFDA approval is required in order to market Microcyn-based products in China.

### Financial Operations Overview

#### *Comparison of Three Months Ended December 31, 2007 and 2006*

##### *Revenues*

We experienced growth in product revenues and a decline in our services business resulting in reported revenues of \$1.1 million during the three months ended December 31, 2007. The \$42,000, or 5%, increase in product revenues was due primarily to \$82,000 higher sales in Europe and \$35,000 increase in sales in India, offset in part by a decline in sales in Mexico and in the U.S. The \$63,000, or 10%, decline in Mexico revenues was primarily due to lower sales to hospitals in both volume (42% decrease) and average selling price (35% decrease). However, these declines were offset in part by higher sales to pharmacies in Mexico in both volume (21% increase) and average selling price (20% increase). Overall, the mix in sales continues to shift in Mexico to the pharmacy markets, and away from the hospital markets, as pharmacy sales represented 78% of total Mexico sales during the three months ended December 31, 2007 as compared to 49% in the year ago period. India sales were \$35,000, or 167%, higher during the three months ended December 31, 2007 than the prior year period due to the increased sales volumes of our customer Alkem Laboratories Limited, which subassembles bulk quantities of our product into private labeled units and sells such units to hospitals and pharmacies in India.

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

	Three months ended December 31,		Increase (Decrease)
	2007	2006	
U.S.	\$ 39	\$ 51	\$ (12)
Mexico	596	659	(63)
India	56	21	35
Europe	152	70	82
Total	<u>\$ 843</u>	<u>\$ 801</u>	<u>\$ 42</u>

The \$28,000, or 11%, decline in service revenues was due to a decrease in the number of tests provided by our services business. We expect that our service revenues will continue to decline in future periods, as we continue to implement our strategy of focusing primarily on our Microcyn business.

##### *Gross Profit / Loss*

We reported gross profit from our Microcyn products business of \$335,000, or 40% of product revenues, during the three months ended December 31, 2007, compared a gross profit of \$259,000, or 32%, in the year ago period. This increase was primarily due to the higher sales volumes in Europe. We reported a gross loss from our services business of \$10,000, or -4% of service revenues, during the three months ended December 31, 2007, compared to the prior year reported gross profit of \$33,000, or 13% of service revenues.

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We expect gross profit to fluctuate as a percentage of sales in future periods as we continue to experience irregular product revenues. As product revenues grow, however, we expect our profit to grow as a percentage of sales as we move further away from our low margin services business.

### *Research and Development Expense*

Research and development expense consists primarily of costs associated with personnel, materials, and clinical trials within our product development, regulatory and clinical organizations. Research and development expense increased \$1.8 million, or 225%, to \$2.6 million for the three months ended December 31, 2007, from \$795,000 for the three months ended December 31, 2006. This increase was primarily the result of \$1.5 million higher clinical development costs, which included \$1.0 million of contract research organization fees. Clinical development costs are related to the completion of our Phase II clinical trials and the preparation for our Phase III clinical trials for the treatment of diabetic foot ulcer infections. In addition, our other research and development expense increased as we grew our product development and regulatory teams and expanded the scope of our new product development initiatives.

We expect research and development expense to increase significantly in future periods as we incur costs associated with our FDA trials for the treatment of diabetic foot ulcer infections, and as we further expand the scope of our new product development programs.

### *Selling, General and Administrative Expense*

Selling, general and administrative expense consist primarily, of costs for sales, marketing and administrative personnel, as well as other corporate expenses such as legal, accounting, and insurance. Selling, general and administrative expense decreased \$1.3 million, or 29%, to \$3.3 million for the three months ended December 31, 2007, from \$4.6 million for the three months ended December 31, 2006. Primarily, this decrease was due to a \$1.3 million decrease in our selling, general and administrative expenses in our Europe and Mexico subsidiaries as we shifted our company resources away from expanding markets internationally. Stock compensation charges were also \$413,000 lower, and U.S. travel expenses were \$121,000 lower in the current period. These decreases were offset in part by increases in U.S. selling, general, and administration expense including a \$420,000 increase in outside services expense associated with being a public company such as legal, accounting, and investor relations expenses, \$204,000 in higher compensation charges, and \$106,000 in higher insurance expense.

We expect that selling, general and administrative expense will increase moderately in future periods to support the growth of the company.

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

Interest expense decreased \$106,000, or 35%, to \$199,000 for the three months ended December 31, 2007, from \$305,000 in the year ago period, due to the lower debt over the prior year. Total outstanding debt decreased \$5.6 million to \$2.5 million at December 31, 2007, from \$8.1 million at December 31, 2006. Interest income increased \$120,000, or 400%, to \$150,000 for the three months ended December 31, 2007, from \$30,000 in the year ago period, primarily due to the higher interest bearing cash balance in the current year.

Other income and expense decreased \$266,000, or 47%, to net other income of \$299,000 for the three months ended December 31, 2007, from net other income of \$565,000 for the three months ended December 31, 2006. This account primarily consists of charges due to the fluctuation of foreign exchange rates, and the resulting gain or loss recognized for the revaluation of our intercompany notes payable denominated in non-local currencies. The net other income recognized during the three months ended December 31, 2007 and 2006 are primarily due to the U.S. dollar becoming weaker in relation to the Euro and the Mexican Peso during those periods. The decrease in the charge in the current period is a result of a lower relative fluctuation in the exchange rates, offset in part by a higher intercompany note balance in the current year.

Due to the difficulty of predicting foreign currency fluctuations, we do not know the affect that such fluctuations may have on our operating results in future periods.

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### *Comparison of Nine Months Ended December 31, 2007 and 2006*

#### *Revenues*

We experienced a decline in product revenues and growth in our services business resulting in reported revenues of \$2.9 million during the nine months ended December 31, 2007, a decline of \$472,000, or 14%, from the prior year level of \$3.4 million. The \$597,000, or 22%, decline in product revenues was due primarily to \$521,000 lower recurring sales to our customer Alkem Laboratories Limited, in India. Sales to Alkem in the prior year were driven by large initial stocking orders of samples used during their initial product launch. As the sample orders have not recurred in the subsequent year, the sales volumes have decreased. Sales growth in Mexico and Europe has decreased with the reduction in our sales forces internationally. Additionally, the decline in revenues in Mexico was partially due to the application of our revenue recognition policies on a group of hospital distributors, which has become our customer, requiring receipt of payment in order to recognize revenue. This resulted in a net \$122,000 reduction in revenues during the period that will not be recognized until cash has been received from the customer.

The following table shows our product revenues by country (in thousands); note that sales in India are reported as part of our Europe business:

	Nine months ended December 31,		Increase (Decrease)
	2007	2006	
U.S.	\$ 146	\$ 106	\$ 40
Mexico	1,553	1,716	(163)
India	83	604	(521)
Europe	363	316	47
<b>Total</b>	<b>\$ 2,145</b>	<b>\$ 2,742</b>	<b>\$ (597)</b>

The \$125,000, or 20%, increase in service revenues was due primarily to an increase in the number of tests provided by our services business.

#### *Gross Profit / Loss*

We reported gross profit from our Microcyn product business of \$858,000, or 40% of product revenues, during the nine months ended December 31, 2007, compared to gross profit of \$1.2 million, or 42%, in the year ago period. This decrease is due primarily to the lower sales volumes in India, and the relatively high fixed cost component in our European facility where this product is produced. We reported near break-even margins in our services business of \$3,000 during the nine months ended December 31, 2007, compared to the prior year reported gross loss of \$2,000.

#### *Research and Development Expense*

Research and development expense increased \$4.7 million, or 196%, to \$7.1 million for the nine months ended December 31, 2007, from \$2.4 million for the nine months ended December 31, 2006. This increase was primarily the result of \$3.8 million higher clinical development costs, which include \$2.3 million in contract research organization fees, and other management costs, and other outside consulting fees related to the completion of our Phase II clinical trials and preparation of our Phase III clinical trials. In addition, our other research and development expenses increased as we grew our product development and regulatory teams, expanded the scope of our new product development initiatives, and continued to enhance our cGMP manufacturing capabilities at our U.S. research and development facility.

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

Selling, general and administrative expense decreased \$2.1 million, or 16%, to \$10.4 million for the nine months ended December 31, 2007, from \$12.5 million for the nine months ended December 31, 2006. Primarily, this decrease was due to \$2.9 million lower selling, general and administrative expenses in our Europe and Mexico subsidiaries as we shifted our company resources away from expanding markets internationally. This decrease was offset in part by increases in our U.S. selling, general, and administrative expenses, including higher compensation expense, of \$584,000, and higher expenses related to being a public company including \$627,000 in legal and accounting fees and \$334,000 in insurance expense.

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

Interest expense increased \$279,000, or 49%, to \$844,000 for the nine months ended December 31, 2007, from \$565,000 in the year ago period, primarily due to higher average debt balance during the nine months ended December 31, 2007 as compared to the year ago period. Interest income increased \$426,000, or 328%, to \$556,000 for the nine months ended December 31, 2007, from \$130,000 in the year ago period, primarily due to the higher interest bearing cash balance in the current year.

Other income and expense increased \$416,000, or 63%, to net other income of \$1.1 million for the nine months ended December 31, 2007, from net other income of \$657,000 for the nine months ended December 31, 2006. This account primarily consists of charges due to the fluctuation of foreign exchange rates, and the resulting gain or loss recognized for the revaluation of our intercompany notes payable denominated in non-local currencies. The net other income recognized during the nine months ended December 31, 2007 and 2006 are primarily due to the U.S. dollar becoming weaker in relation to the Euro and the Mexican Peso during those periods. The increase in the charge is due both to the greater relative fluctuation in the exchange rates, and the increased size of the intercompany notes in the current year as compared to a year ago.

### Liquidity and Capital Resources

Since our inception, we have incurred significant losses. As of December 31, 2007, we had an accumulated deficit of \$86.4 million. We have not yet achieved profitability, and we expect that our operating losses will continue to increase. As a result, we will need to raise additional capital to sustain our business until such time that we are able to generate sufficient product revenues to achieve profitability.

### *Sources of Liquidity*

As of December 31, 2007, we had unrestricted cash and cash equivalents of \$10.4 million. Since our inception, substantially all of our operations have been financed through sales of equity securities. Other sources of financing that we have used to date include our revenues, as well as various loans.

In June 2006, we entered into a loan and security agreement with a financial institution to borrow a maximum of \$5.0 million. Under this facility we have borrowed \$4.2 million, and have paid back \$2.1 million in principal as of December 31, 2007. The terms of this facility include monthly principal payments over three years, plus interest payments of 8.5% per annum.

On November 7, 2006, we signed a loan agreement with Robert Burlingame, under which Mr. Burlingame advanced to us \$4.0 million, which funded on November 10, 2006, accruing interest at an annual rate of 7%. The principal and all accrued interest under the loan agreement were to be paid promptly after the closure of a private placement of securities, such as our private placement in August 2007. In August 2007, we paid all principal and outstanding interest under this loan agreement from cash, including \$2.0 million of restricted cash.

### *Cash Flows*

As of December 31, 2007, we had unrestricted cash and cash equivalents of \$10.4 million, compared to \$19.1 million at March 31, 2007. Additionally, at March 31, 2007 we had \$2.0 million of restricted cash reserved for the repayment of the Burlingame loan.

Net cash used in operating activities was \$14.0 million during the nine months ended December 31, 2007, as compared to \$13.4 million during the nine months ended December 31, 2006. Net cash used in the nine months ended December 31, 2007 reflected primarily the \$15.9 million net loss for the period, and to a lesser extent the \$1.1 million decrease in accounts payable due to the timing of payments made to our vendors, particularly legal, accounting, and printing costs associated with our initial public offering, a \$1.2 million increase in accrued expenses due primarily to the discretionary bonus amounts accrued during the fiscal year, and non-cash charges including \$916,000 of stock-based compensation, \$548,000 of depreciation and \$415,000 of non-cash interest expense. Net cash used in the nine months ended December 31, 2006 reflected primarily the \$13.5 million net loss for the period, and to a lesser extent a \$500,000 increase in accounts receivable due to the timing of payments made from our customers, a \$787,000 decrease in

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accounts payable due to the timing of payments made to our vendors, and non-cash charges including \$1.1 million of stock-based compensation, \$498,000 of depreciation and \$256,000 of non-cash interest expense.

Net cash used in investing activities was \$414,000 during the nine months ended December 31, 2007, as compared to \$653,000 during the nine months ended December 31, 2007. Net cash used during the nine months ended December 31, 2007 was used primarily to invest in fixed assets and to make other capital expenditures to support increased personnel and to enhance our cGMP manufacturing capabilities at our U.S. research and development facility. During the nine months ended December 31, 2006, net cash was used primarily to invest in fixed assets to support the expansion of our worldwide manufacturing capacity.

Net cash provided by financing activities was \$5.7 million during the nine months ended December 31, 2007 primarily due to the gross \$10.1 million private placement of our common stock to certain accredited investors, which provided \$9.1 million of net cash, net of certain direct fees and commissions. These amounts were offset by \$5.6 million of principal payments on debt due primarily to the \$4.0 million Burlingame note that was paid off during the period. Net cash provided by financing activities was \$9.1 million for the nine months ended December 31, 2006 primarily due to the addition of \$8.4 million of new debt during the period including the \$4.0 million Burlingame note, and \$4.2 million of other new debt, as well as \$2.9 million in proceeds from the sale of convertible preferred stock.

### *Operating Capital and Capital Expenditure Requirements*

We incurred a net loss of \$5.3 million and \$15.9 million for the three and nine months ended December 31, 2007, respectively. At December 31, 2007 and March 31, 2007, our accumulated deficit amounted to \$86.4 and \$70.5 million, respectively. During the nine months ended December 31, 2007, we used \$14.0 million of net cash for operating activities. At December 31, 2007, our working capital amounted to \$6,841,000. We need to raise additional capital from external sources in order to sustain our operations while continuing the longer term efforts contemplated under our business plan. We expect to continue incurring losses for the foreseeable future and must raise additional capital to pursue our product development initiatives, to begin our Phase III clinical trial, to penetrate markets for the sale of our products and for us to continue as a going concern. We cannot provide any assurance that we will raise additional capital. If we are unable to raise additional capital, we will be required to curtail certain operating activities, and implement additional cost reductions in an effort to conserve capital in amounts sufficient to sustain operations and meet its obligations for the next twelve months. These matters raise substantial doubt about our ability to continue as a going concern. We believe that we have access to capital resources through public or private equity offerings, debt financings, corporate collaborations or other means; however, we have not secured any commitment for new financing at this time nor can we provide any assurance that new financing will be available on commercially acceptable terms, if at all. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives, delay our Phase III clinical trials and take additional measures to reduce costs in order to conserve cash. These measures could cause significant delays in our efforts to commercialize our products in the United States, which is critical to the realization of our business plan and our future operations.

We have undertaken initiatives to reduce costs in an effort to conserve liquidity and to also redirect our efforts on the longer term strategy of focusing on our clinical trials and related research and development activities. We consider the completion of Phase II and Phase III clinical trials to be critical milestones in the development of our business. We completed enrollment and treatment of all patients in its Phase II clinical trial in during the three months ended December 31, 2007. The Phase III trials will require significant spending and must also be completed in order for us to commercialize Microcyn as a drug product in the United States. Commencement of the Phase III clinical trials will be delayed until we raise additional capital or secures commitments for additional capital in amounts sufficient to proceed with these trials. Without additional capital, our Phase III clinical trials will be delayed for a period of time that is currently indeterminate.

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;



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- 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.

### *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 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.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

There have been no material changes in our quantitative and qualitative disclosures about market risk for the three and nine-months ended December 31, 2007 from our Annual Report on Form 10-K/A for the year ended March 31, 2007. For further discussion of quantitative and qualitative disclosures about market risk, reference is made to our Annual Report on Form 10-K/A for the year then ended, which was filed with the SEC on July 27, 2007.

### **Item 4T. Controls and Procedures**

(a) ***Evaluation of disclosure controls and procedures.*** We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. In response to comments from our auditors and our own investigations, our disclosure controls and procedures have been designed to meet, and management believes that they meet, reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our chief executive officer and chief financial officer have concluded that, subject to the limitations noted above, our disclosure controls and procedures were effective to ensure that material information relating to us, including our consolidated subsidiaries, is made known to them by others within those entities, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared.

(b) ***Changes in internal controls*** In connection with our implementation of the provisions of Section 404 of Sarbanes-Oxley, we have made various improvements to our system of internal control. We continue to review, revise and improve the effectiveness of our internal controls. There were no significant changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 4(a) above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II — OTHER INFORMATION**

### **Item 1. Legal Proceedings**

#### ***Legal Matters***

In November 2005, we identified a possible criminal misappropriation of our technology in Mexico, and we notified the Mexican Attorney General's office. We believe the Mexican Attorney General is currently conducting an investigation.

In March 2006, we 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, alleging that defendants' had wrongfully infringed our intellectual property rights in our Microcyn technology. Defendants later asserted counter-claims against us. On November 15, 2007 the Court granted us a Motion to Dismiss the claims against us. Additionally, the Court issued an Order finding that defendants had violated key terms of both an Exclusive Purchase Agreement and a Non-Disclosure Agreement by contacting and working with a competitor in Mexico. The Court also permanently enjoined defendants from any further misuse of our Microcyn technology. On January 23, 2008, after an evidentiary hearing, the Court ordered defendants to pay us \$6,644,000 in damages for lost profits as a result of defendants' breach of the Exclusive Purchase Agreement and the Non-Disclosure Agreement. We do not expect an appeal and will seek to collect on this judgment from defendants. We note that collection may be impeded or delayed by the fact that defendants are a non-U.S. corporation and citizen, respectively, with unknown assets.

We are currently in discussions regarding two trademark matters asserting confusion in trademarks with respect to our use of the name Microcyn60 in Mexico. We settled one of the trademark matters in August 2006. Although we believe that the nature and intended use of our products are different from those with the similar names, we have agreed with one of the parties to change the name under which we market our products. Although such plaintiff referred the matter to the Mexico Trademark Office, we are not aware of a claim for monetary damages. We are in discussions with the other party and believe that the name change will satisfy an assertion of confusion; however, management believes that we will incur a possible loss of approximately \$100,000 for the use of the name Microcyn60 following the date of settlement.

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

In February 2007, our Mexico subsidiary served Quimica Pasteur ("QP"), a former distributor of the Company's products in Mexico, with a claim alleging breach of contract under a note made by QP. A trial date has not yet been set.

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

#### **Item 1A. Risk Factors**

##### **Factors that May Affect Results**

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

***If we fail to obtain the capital necessary to fund our operations, we may be forced to delay or cancel our planned Phase III trial or otherwise curtail our operations.***

As of December 31, 2007, we had unrestricted cash of approximately \$ 10.4 million. We will need to raise a significant amount of capital in order to fund our first drug candidate through regulatory approval and commercialization in the United States. If we are not

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able to raise sufficient capital, we will be required to delay or cancel our planned clinical trial, curtail some operating activities and implement additional cost reductions. Additionally, as of December 31, 2007, we had \$2.5 million of outstanding secured loans of which \$1.7 million is due within the next twelve months. Without sufficient additional capital, the combination of these conditions raises substantial doubt about our ability to continue as a going concern. We cannot assure you that we will be able to obtain capital on a timely basis, if at all, or on terms that are reasonably acceptable to us.

### ***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 \$19.8 million, \$23.1 million and \$16.5 million for the years ended March 31, 2007, 2006 and 2005, respectively and \$15.9 million during the nine months ended December 31, 2007. Our accumulated deficit as of December 31, 2007 was \$86.4 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:

- conduct preclinical studies and clinical trials on our products and product candidates;
- seek 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;
- establish additional and expand existing manufacturing facilities; and
- grow our sales and marketing capabilities in the United States and internationally.

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 secured lenders 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.

### ***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 fiscal year 2007. For example, product revenues from countries outside of Mexico were just 9% of our product revenues for the year ended March 31, 2006. However, during the year ended March 31, 2007, the percentage of product revenues from outside of Mexico increased to 32% and during the nine months ended December 31, 2007 was 28%. 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. We recently decreased our sales and marketing activities in Europe and Mexico, which could materially affect our revenues in the geographic areas in the future.

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

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

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

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

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

If we raise additional funds by issuing equity or convertible debt securities, dilution to our stockholders could result. Any equity or convertible debt 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 equity securities below the then current exercise price in certain outstanding warrants, the issuance could trigger anti-dilution rights and result in additional dilution to the existing holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. A failure to obtain adequate funds may cause us to curtail certain operational activities, including regulatory trials, sales and marketing, and international operations, in order to reduce costs and sustain the business, and would have a material adverse effect on our business and financial condition.

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

We have obtained 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.

We have sponsored the majority of physician clinical studies of Microcyn and in some cases, the physicians who performed these studies also hold equity in our company. The physician clinical studies were performed in the United States, Mexico and Italy, and used various endpoints, methods and controls. These studies were not intended to be rigorously designed or

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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 often did not include blinding, randomization, predefined clinical endpoints, use of placebo and active control groups or U.S. good clinical practice requirements. Consequently, the results of these physician clinical studies may not be used by us to support an NDA submission for Microcyn to the FDA. In addition, any results obtained from clinical trials designed to support an NDA submission for Microcyn to the FDA may not be as favorable as results from such physician clinical studies and otherwise may not be sufficient to support an NDA submission or FDA approval of any Microcyn NDA.

The FDA approval process is expensive and uncertain, requires detailed and comprehensive formulation scientific and other data and generally takes several years. Despite the time and expense exerted, approval is never guaranteed. We will need to raise additional capital in order to commence our Phase III clinical trial, and our failure to do so would seriously harm our ability to commercialize Microcyn. We also 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.

### ***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:

- the 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. In addition, further studies and trials could show different results. For example, 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, Cidalcyn, as a hospital grade disinfectant, but the EPA conducted subsequent tests and informed us that Cidalcyn did not meet efficacy standards when tested against three specific pathogens. In response to this test, we voluntarily recalled samples of the product previously distributed and later entered into a Consent Agreement and Final Order with the EPA, allowing us to amend our EPA registration and pay a \$20,800 fine without admitting or denying any wrongdoing. In addition, in an independent physician study of 10 patients in which procedures were not fully delineated, published in February 2007, four patients discontinued treatment with Demacyn due to pain, and beneficial change in wound microbiology was found in only one of the six remaining patients. We will be required to conduct additional clinical trials prior

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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.

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

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

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 conducting a Phase II study and are planning to conduct a pilot study of Microcyn for the treatment of wound infections. 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, changes to formulation or clinical testing that could adversely affect the time to market and sale of products as drugs. If we do not obtain the requisite regulatory clearances and approvals, we will be unable to commercialize our products as drugs or devices and may never recover any of the substantial costs we have invested in the development of Microcyn.

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

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### ***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 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 change the name under which we market our products in Mexico. 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. During the nine months ended December 31, 2007 and the year ended March 31, 2007 the percentage of our product revenues derived from Mexico were 72% and 68%, respectively. 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. We cannot assure you that the reserve we have taken will be sufficient to offset the losses we may incur as a result of changing our brand name.

### ***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.

### ***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. We may incur significant costs in the use of third parties to identify and assist in establishing relationships with potential collaborators.

To penetrate our target markets, we may need to enter into additional collaborative agreements to assist in the development and commercialization of 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

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commercialization ourselves. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Our discussions with potential collaborators may not lead to the establishment of new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property filings and next generation formations. We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborations or potential products. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our collaborators may not develop or commercialize products that arise out of our collaborative arrangements or devote sufficient resources to the development, manufacture, marketing or sale of these products. By entering into 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 are unable to expand our direct domestic sales force, we may not be able to successfully sell our products in the United States.***

We have very limited commercialization capability and make Microcyn-based products available primarily through our website, one national distributor and several regional distributors. We plan for a more aggressive commercialization and product launch in the event we obtain drug approval from the FDA. 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. 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 salespeople. 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.



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***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 gathered 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, including our intellectual property, under two loan and security agreements. 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.

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

On occasion, we may receive notices of claims of infringement, misappropriation or misuse of other parties' proprietary rights. We may have disputes regarding intellectual property rights with the parties that have licensed those rights to us. For example, in June 2006, we received written notice from Coherent Technologies, the licensor of exclusive licenses to six issued Japanese patents and five Japanese published pending patent applications, advising us that our patent license from Coherent Technologies was terminated, citing various reasons with which we disagree. Since that time, we have engaged in discussions with Coherent Technologies 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. Some claims received from third parties may lead to litigation. We cannot predict whether 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. For example, we brought a claim against Nofil Corporation for misappropriation of our trade secrets and Nofil Corporation filed a cross-complaint against us in February 2007 claiming ownership of our technology. 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. In addition, the outcome of such litigation may be unpredictable. If there is a successful claim of infringement against us, we may be required to pay substantial

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damages (including treble damages if we were to be found to have willfully infringed a third party's patent) to the party claiming infringement, develop non-infringing technology, stop selling our products or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, modifying our products to exclude infringing technologies could require us to seek re-approval or clearance from various regulatory bodies for our products, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our technology. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our products or using technology that contains the allegedly infringing intellectual property, which could harm our business.

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 changed the name under which we market our products in Mexico. 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, which may impair our ability to enforce our trademark rights against infringers in those countries. 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

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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. During the nine months ended December 31, 2007, 69% of our total revenues were generated from sales outside of the United States. Our business is highly regulated for the use, marketing and manufacturing of our Microcyn products both domestically and internationally. Our international operations are subject to risks, including:

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

We plan to continue to market and sell our products internationally to respond to customer requirements and market opportunities. We currently have international manufacturing facilities in Mexico and the 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 operations in any foreign country are unsuccessful, we could incur significant losses and we may not achieve profitability.

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

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

A substantial portion of our revenues are derived from outside the United States; primarily from Mexico. We anticipate that revenues from international customers will continue to represent a substantial portion of our revenues for the foreseeable future. Because we generate revenues in foreign currencies, we are subject to the effects of exchange rate fluctuations. The functional currency of our Mexican subsidiary is the Mexican Peso, and the functional currency of our 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.

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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 a member of our Board of Directors and Robert Northey, our Director of Research and Development. The efforts of these people will be critical to us as we continue to develop our products and attempt to commercialize products in the 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.***

Our success depends, in part, upon our ability to stay at the forefront of technological change and maintain a competitive position.

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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 conduct 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. If we need third party assistance in identifying and negotiating one or more acceptable arrangements, it might be costly. Also, we may not have products that are desirable to other parties, or we may be unwilling to license a potential product because the party interested in it is a competitor. The terms of any arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position or for scientific, commercial or other reasons. If we are not able to establish collaborative agreements, we may not be able to develop and commercialize new products, which would adversely affect our business and our revenues.

In order for any of these collaboration or license arrangements to be successful, we must first identify potential collaborators or licensees whose capabilities complement and integrate well with ours. We may rely on these arrangements for, not only financial resources, but also for expertise or economies of scale that we expect to need in the future relating to clinical trials, manufacturing, sales and marketing, and for licenses to technology rights. However, it is likely that we will not be able to control the amount and timing 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 current stockholders' 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.

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To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute current stockholders' 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 previously had agreements to pay compensation to our advisory board members and physicians who conduct clinical trials or provide other services for us. Currently, these agreements have been terminated. 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.

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***We must implement additional and expensive finance and accounting systems, procedures and controls to accommodate growth of 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 are 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 for the reporting period ending March 31, 2008. 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. Our current independent auditors recommended certain changes in our internal controls, which we are in the process of implementing. We have upgraded 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 in entering 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, indicated that we need to better plan for complex transactions and the application of complex accounting principles relating to those transactions and to better identify potentially improper practices. As a result of these agreements, we were required to consolidate QP's operations with our financial results for a portion of our year ended March 31, 2006. 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 in Mexico prior to the execution of the agreements between our company and QP, and we did not discover these facts prior to our execution of these agreements or for several months thereafter. 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 second 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. Also, if we are unable to implement and maintain adequate internal controls, we could be subject to fines and penalties. For example, 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 action for fraud, is five years from March 31, 2006.

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

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

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

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

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

- demand by physicians, other medical staff and patients for our Microcyn products;
- reimbursement decisions by third-party payors and announcements of those decisions;



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- 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;
- costs associated with collaborations and new product candidates;
- introduction of technological innovations or new commercial products by us or our competitors;
- litigation or public concern about the safety of our product candidates or products;
- changes in recommendations of securities analysts or lack of analyst coverage;
- failure to meet analyst expectations regarding our operating results;
- additions or departures of key personnel; and
- general market conditions.

Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, the Nasdaq 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 price you paid for it.***

Prior to our initial public offering, there was no public market for our common stock. Although we listed our common stock on the Nasdaq Global Market, an active and liquid trading market for our common stock has not yet and may not ever develop or be sustained. You may not be able to sell your shares quickly or at or above the price you paid for our stock if trading in our stock is not active.

***We do not expect to pay dividends in the foreseeable future.***

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our Board of Directors. In addition, under two of our secured loans, we will not pay any dividends without our secured lenders' prior written consent for as long as we have any outstanding obligations to the secured lenders. 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.

***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:

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- the ability of our Board of Directors to issue and designate the rights of, without stockholder approval, up to 5,000,000 shares of convertible preferred stock, which rights could be senior to those of common stock;
- limitations on persons authorized to call a special meeting of stockholders; and
- advance notice procedures required for stockholders to make nominations of candidates for election as directors or to bring matters before an annual meeting of stockholders.

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

### ***Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock.***

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

## **Item 2. Unregistered Sales of Securities and Use of Proceeds**

On August 13, 2007, we completed a private placement of 1,262,500 shares of our common stock to certain accredited investors at a price of \$8.00 per share pursuant to the terms of a Securities Purchase Agreement, dated August 7, 2007. In addition, the investors received warrants to purchase an aggregate of 416,622 additional shares of common stock at an exercise price of \$9.50 per share, subject to adjustment in certain circumstances. The warrants are exercisable 181 days after August 13, 2007, and have a term of five years. Gross proceeds from the private placement were approximately \$10.1 million and net proceeds of \$9.1 million (after deducting the placement agent's commission and other offering expenses). Pursuant to the terms of a Registration Rights Agreement, dated August 7, 2007, the shares of common stock issued to the investors in the private placement and the shares of common stock to be issued upon the exercise of the warrants issued in the private placement were registered on a Form S-1 (File No. 333-145810), which was declared effective on September 12, 2007. Through December 31, 2007 \$2.0 million of the net proceeds of this private placement had been used.

On January 24, 2007, a Registration Statement on Form S-1 (File No. 333-135584) relating to our initial public offering was declared effective by the SEC. The closing was January 30, 2007, and on February 16, 2007, our underwriters exercised their option to sell over-allotment shares. In total, the net offering proceeds to us including over-allotment shares were approximately \$21.9 million (after deducting underwriting discounts, commissions and offering expenses). Through December 31, 2007, the entirety of the net proceeds have been used, including \$8.9 million for clinical trials and related research and development, \$4.0 million for payment on the specified loan from Robert Burlingame, \$2.4 million for working capital and general corporate purposes, \$5.2 million for sales and marketing activities worldwide, and \$486,000 were used to expand facilities and laboratory operations capacity and for information systems infrastructure.

## **Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
31.1	Rule 13a-14(a) Certification of Chief Executive Officer.
31.2	Rule 13a-14(a) Certification of Chief Financial Officer.
32.1#	Statement of Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).
32.2#	Statement of Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).

# In accordance with Item 601(b)(32)(ii) of Regulation SK and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**Oculus Innovative Sciences, Inc.**

Date: February 7, 2008

By: /s/ Hojabr Alimi

Hojabr Alimi

Its: Chairman of the Board of Directors and Chief  
Executive Officer (Principal Executive Officer)

Date: February 7, 2008

By: /s/ Robert Miller

Robert Miller

Its: Chief Financial Officer (Principal Financial Officer  
and Accounting Officer)

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**Exhibit Index**

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**Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

**CERTIFICATION**

I, Hojabr Alimi, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oculus Innovative Sciences, Inc. for the period ended December 31, 2007;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's third fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Hojabr Alimi

**Hojabr Alimi**  
**Chief Executive Officer**

Date: February 7, 2008

**Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

**CERTIFICATION**

I, Robert Miller, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oculus Innovative Sciences, Inc. for the period ended December 31, 2007;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's third fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Robert Miller

**Robert Miller**  
**Chief Financial Officer**

Date: February 7, 2008

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER 18 U.S.C. § 1350**

I, Hojabr Alimi, the chief executive officer of Oculus Innovative Sciences, Inc. (the "Company"), certify for the purposes of section 1350 of chapter 63 of title 18 of the United States Code that, to the best of my knowledge,

(1) the Quarterly Report of the Company on Form 10-Q for the period ended December 31, 2007 (the "Report"), fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934, and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Hojabr Alimi

**Hojabr Alimi**

**Chief Executive Officer**

Date: February 7, 2008

**STATEMENT OF CHIEF FINANCIAL OFFICER UNDER 18 U.S.C. § 1350**

I, Robert Miller, the chief financial officer of Oculus Innovative Sciences, Inc. (the "Company"), certify for the purposes of section 1350 of chapter 63 of title 18 of the United States Code that, to the best of my knowledge,

(1) the Quarterly Report of the Company on Form 10-Q for the period ended December 31, 2007 (the "Report"), fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934, and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Robert Miller

**Robert Miller**  
**Chief Financial Officer**

Date: February 7, 2008