DUSA PHARMACEUTICALS INC Form 10-Q May 13, 2003

FORM 10-Q SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2003

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 0-19777

DUSA Pharmaceuticals, Inc. (Exact name of registrant as specified in its charter)

New Jersey
(State or other jurisdiction of incorporation or organization)

22-3103129 (I.R.S. Employer Identification No.)

25 Upton Drive
Wilmington, Massachusetts 01887
(Address of principal executive offices)
(Zip Code)

(978) 657-7500

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 month (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes [X] No []

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 13 or $15\,\mathrm{(d)}$ of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes [] No []

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

13,943,581 shares as of May 9, 2003

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PART 1.
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Item 1. FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS

CURRENT ASSETS

Cash and cash equivalents
United States government securities
Accrued interest receivable
Accounts receivable
Inventory
Prepaids and other current assets

Total current assets
Property and equipment, net

TOTAL ASSETS

LIABILITIES AND SHAREHOLDERS' EQUITY
CURRENT LIABILITIES
 Accounts payable
 Accrued payroll
 Other accrued expenses
 Current maturities of long-term debt
 Deferred revenue

Total current liabilities
Long-term debt, net of current

TOTAL LIABILITIES

COMMITMENTS AND CONTINGENCIES (NOTE 12) SHAREHOLDERS' EQUITY

Capital Stock

Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding: 13,910,831 (2002: 13,887,612) shares of common stock, no par

Additional paid-in capital

Accumulated deficit

Accumulated other comprehensive income

TOTAL SHAREHOLDERS' EQUITY

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months En
	2003 (Unaudited)
REVENUES	
Product sales and rental income	\$ 143,370
Research grant and milestone revenue	
Research revenue earned under collaborative agreement	
TOTAL REVENUES	143,370
OPERATING COSTS	
Cost of product sales and royalties	753,304
Research and development	1,516,391
Marketing and sales	530,512
General and administrative	1,475,271
TOTAL OPERATING COSTS	4,275,478
LOSS FROM OPERATIONS	(4,132,108)
OTHER INCOME	
Interest income	566,135
NET LOSS	\$ (3,565,973)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (0.26)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	13,892,514
	=========

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	(Unaudited
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES	\$(3,565 , 97
Net loss Adjustments to reconcile net loss to net cash used in operating activities	۶ (۵, ۵۵۵, ۶ ۱
Amortization of premiums and accretion of discounts on U.S. government securities available for sale, net	18,09
Depreciation and amortization expense	300,70
Amortization of deferred revenue	=
Changes in other assets and liabilities impacting cash flows from operations:	
Accrued interest receivable	139,38
Accounts receivable	(18,39
Receivable under co-development program	_
Inventory	54,31
Deferred charges	=
Prepaids and other current assets	193,14
Accounts payable	(335,81
Accrued payroll and other accrued expenses	(1,057,15
Deferred revenue	14,70
Net cash used in operating activities	(4,256,98
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES	
Purchases of United States government securities	-
Proceeds from maturing United States government securities	3,000,00
Purchases of property and equipment	(33,22
Net cash provided by (used in) investing activities	2,966,77
CASH FLOWS USED IN FINANCING ACTIVITIES	
Payments of long-term debt	(67,50
Net cash used in financing activities	(67,50
NEW DECREAGE IN GROW AND GROW BOUTURE DIMEG	
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,357,70
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	7,064,59
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 5,706,89

See the accompanying Notes to the Condensed Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC. NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

BASIS OF PRESENTATION 1)

The Condensed Consolidated Balance Sheet as of March 31, 2003, Condensed

Three Mo

2003

Consolidated Statements of Operations for the three months ended March 31, 2003 and 2002, and Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2003 and 2002 of DUSA Pharmaceuticals, Inc. (the "Company") have been prepared in accordance with accounting principles generally accepted in the United States of America. These condensed consolidated financial statements are unaudited but include all normal recurring adjustments, which management of the Company believes to be necessary for fair presentation of the periods presented. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full year.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. Certain amounts for 2002 have been reclassified to conform to the current year presentation. Such reclassifications had no impact on the net loss or shareholders' equity for any period presented. These condensed consolidated financial statements should be read in conjunction with the Company's December 31, 2002 audited consolidated financial statements and notes thereto.

The Company believes that it has sufficient capital resources to proceed with its current research, development, manufacturing and marketing programs for Levulan(R) PDT, and to fund operations and capital expenditures for the foreseeable future. The Company has invested its funds in liquid investments, so that it will have ready access to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis. DUSA may seek to expand or enhance its business by using its resources to acquire by license, purchase or other arrangements, businesses, new technologies, or products, especially in PDT-related areas. However, at this time, the Company intends to focus primarily on increasing the sales of its dermatology products, and on seeking a partner to help develop and market Levulan(R) PDT for the treatment of dysplasia in patients with Barrett's esophagus.

2) UNITED STATES GOVERNMENT SECURITIES AVAILABLE FOR SALE

The Company's United States government securities available for sale consist of securities of the United States government and its agencies, with current yields, as of March 31, 2003, ranging from 3.96% to 7.32% and maturity dates ranging from April 30, 2003 to February 17, 2007.

Accumulated other comprehensive income consists of net unrealized gains or losses on United States government securities available for sale, which is reported as part of shareholders' equity in the Condensed Consolidated Balance Sheets.

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DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

3) INVENTORY

Inventory consisted of the following:

March 31, 2003 December 31, (Unaudited) 2002

	========	========
	\$1,134,346	\$1,188,659
Raw materials	174,626	140,718
Finished goods	\$ 959 , 720	\$1,047,941

4) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	March 31, 2003 (Unaudited)	December 31, 2002
Accrued research and development costs	\$ 293,504	\$ 473,543
Accrued marketing and sales costs	255,907	
Accrued product related costs	78,925	463,340
Accrued license milestone		500,000
Accrued legal and other professional fees	304,192	297,966
Accrued employee benefits	242,682	207,833
Other accrued expenses	112,104	127,468
	\$1,287,314	\$2,070,150
	=======	=======

5) LONG-TERM DEBT

Long-term debt consisted of the following:

	March 31, 2003	December 31,
	(Unaudited)	2002
Secured term loan promissory note Less: Current maturities	\$ 1,720,000 (270,000)	\$ 1,787,500 (270,000)
	\$ 1,450,000	\$ 1,517,500
	========	========

In May 2002, DUSA entered into a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility and borrowed \$1,900,000. The Note currently bears interest at a 360-day LIBOR-based rate of 4%. Prior to expiration of the 360-day LIBOR-based rate for each year of the loan, DUSA can either continue to choose a LIBOR-based rate at that time, execute a one-time conversion to a fixed rate

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

loan, or repay the loan balance. Approximately \$3,000,000 of the Company's United States government securities are pledged as collateral to secure the loan.

6) SHAREHOLDERS' EQUITY

On March 13, 2003, the Company issued 23,219 shares of restricted common stock at a closing price of \$1.599 per share to its Chief Executive Officer, reflecting payment of the after-tax portion of his 2002 bonus compensation.

7) MARKETING AND SALES

In 2003, as a result of the 2002 termination of the Company's marketing and development collaboration with its former marketing partner, the Company commenced certain marketing and sales initiatives associated with having full rights and responsibilities of its product. In addition, the Company has reassigned resources that were previously functioning in research and development roles to its marketing and sales function. Prior to the Company's termination of its marketing and development collaboration, all rights and activities associated with marketing and sales of its products were solely the responsibility of its former partner. Activities included in marketing and sales expense for 2003 consist of trade show expenses, advertising, resources assigned to marketing and sales activities, and other marketing and promotional activities. All such costs are expensed as incurred.

8) ACCOUNTING FOR STOCK BASED COMPENSATION

SFAS No. 123, "Accounting for Stock-Based Compensation," addresses the financial accounting and reporting standards for stock or other equity-based compensation arrangements. The Company has elected to continue to use the intrinsic value-based method to account for employee stock option awards under the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and to provide disclosures based on the fair value method in the Notes to the Consolidated Financial Statements as permitted by SFAS No. 123. Stock or other equity-based compensation for non-employees must be accounted for under the fair value-based method as required by SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and other related interpretations. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost is recognized and charged to operations over the service period, which is generally the vesting period.

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DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Had the Company used the fair value method to measure compensation, the Company's pro forma net loss, and pro forma net loss per share for the three months ending March 31, would have been as follows:

2003 (Unaudited)

As reported Effect on net loss if fair value method had been used	\$ (3,565,973) (587,209)
Proforma	(\$ ====	4,153,182)
BASIC AND DILUTED NET LOSS PER COMMON SHARE As reported	\$	(0.26)
Effect on net loss per common share if fair value method had been used		(0.04)
Proforma	\$	(0.30)

9) 401(k) PROFIT SHARING PLAN

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Effective January 1, 1996, the Company adopted a tax-qualified employee savings and retirement 401(k) Profit Sharing Plan (the "401(k) Plan"), covering all qualified employees. Participants may elect a salary deferral of at least 1% as a contribution to the 401(k) Plan, up to the statutorily prescribed annual limit for tax-deferred contributions. Effective February 1, 2003, the Company will match a participant's contribution up to 1.25% of a participant's salary (the "Match"), subject to certain limitations of the 401(k) Plan. Participants will vest in the Match at a rate of 25% for each year of service to the Company. The Match is not expected to have a material impact on the Company's financial position or results of operations.

10) BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per common share is based on the weighted average number of shares outstanding during each period. Stock options and warrants are not included in the computation of the weighted average number of shares outstanding for dilutive net loss per common share during each of the periods presented in the Statements of Operations, as the effect would be antidilutive. For the three months ended March 31, 2003, and 2002, stock options and warrants totaling approximately 2,661,000 and 2,486,000 shares, respectively, have been excluded from the computation of diluted net loss per share.

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DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

11) COMPREHENSIVE LOSS

For the three months ended March 31, 2003 and 2002, comprehensive loss consisted of the following:

Three Months Ended March 31, (Unaudited)

	2003	2002
NET LOSS Net unrealized losses on United States	\$(3,565,973)	\$(2,867,551)
securities available for sale	(246,998)	(795 , 761)
COMPREHENSIVE LOSS	\$(3,812,971) =======	\$(3,663,312)

12) COMMITMENTS AND CONTINGENCIES

Legal Matters - On April 12, 2002, the Company received notice that one of the patents licensed to the Company by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario is being challenged by PhotoCure ASA. PhotoCure ASA has filed a lawsuit in Australia alleging that Australian Patent No. 624985, which is one of the patents relating to the Company's 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University has assigned the Australian patent to the Company so that DUSA may participate directly in this litigation. The Company has filed an answer setting forth its defenses and a related countersuit alleging that PhotoCure's activities infringe the patent. The case is in its earliest stages so the Company is unable to predict the outcome at this time.

In March 2003, the Company received notice that its Dutch patent is being formally challenged by an anonymous agent. DUSA has filed a formal response to the opposition. At this point in time, it is too early to assess the merits of the allegations. The potential impact in The Netherlands is minimal; however, the Company does plan to defend its patent at this time.

13) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect on the method used on reported results. The Company

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DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

has determined that it will continue to account for stock-based compensation to employees using the intrinsic value method under the provisions of APB Opinion No. 25 and will make all required disclosures in its financial reports to comply with SFAS 148.

In December 2002, the EITF reached conclusion on EITF Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." This consensus provides guidance in determining when a revenue arrangement with multiple deliverables should be divided into separate units of accounting, and, if separation is appropriate, how the arrangement consideration should be allocated to the identified accounting units. The provisions of EITF No. 00-21 are

effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company will evaluate multiple element arrangements in accordance with this EITF upon its effective date for new arrangements into which it enters.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

OVERVIEW

DUSA is a pharmaceutical company engaged primarily in the research, development, and marketing of a drug named 5-aminolevulinic acid, or ALA, used in combination with appropriate light devices in order to detect or treat a variety of medical conditions. The trademark for our brand of ALA is Levulan(R). When Levulan(R) is used and followed with exposure to light to produce a therapeutic effect, the technology is called photodynamic therapy, or PDT. When Levulan(R) is used and followed with exposure to light to detect medical conditions, the technology is called photodetection, or PD. Our first products, which were launched in September 2000 in the United States, are Levulan(R) 20% topical solution using our Kerastick(R) brand applicator, and our BLU-U(R) brand light unit. Our products are used together to provide PDT for the treatment of non-hyperkeratotic actinic keratoses, or AKS, of the face or scalp.

We have primarily devoted our resources to funding research and development in order to advance the Levulan(R) PDT/PD technology platform and, as a result, we have experienced significant operating losses. As of March 31, 2003, we had an accumulated deficit of approximately \$47,649,000. Achieving our goal of becoming a profitable operating company is dependent upon the market penetration of our products, acceptance of our therapy by the medical and consumer constituencies, and our ability to develop new products. We believe that as doctors become more familiar with the benefits of Levulan(R) PDT, and if improved reimbursement for physicians is attained, more widespread adoption of our technology should occur over time.

We expect to continue to incur operating losses until the successful market penetration of our first products occurs. As a result of the termination of our former dermatology collaboration arrangement in 2002, we reevaluated our expenses and are minimizing research and development and related general and administrative expenditures that are not directly related to our core objectives for 2003. At this time, we intend to focus primarily on increasing the sales of our dermatology products, formulating our own development program, which could lead to a broader AK indication, and on seeking a partner to help develop and market Levulan(R) PDT for the treatment of dysplasia in patients with Barrett's esophagus. As of March 31, 2003, our staff included 42 full-time employees as compared to 43 at the end of 2002, in support of all activities including marketing, production, maintenance, customer support, and financial operations for our products, as well as the research and development programs for dermatology and internal indications. We expect to slightly increase our staff in 2003 as we focus on marketing activities and customer support associated with our AK products, and research and development programs for dermatology and internal indications. While our financial position is strong, we cannot predict when product sales along with interest and/or other income may offset the cost of these efforts.

LICENSE AND SUPPLY AGREEMENTS - In December 2002, we entered into a license and development agreement with Photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a

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German pharmaceutical company, and a supply agreement for the licensed formulation with medac. These agreements provide for the licensing to us of Photonamic's proprietary technology related to ALA for systemic dosing in the field of brain cancer. The technology provides us with access to a systemic formulation of ALA, and a significant amount of pre-clinical data, both of which could also be useful and are licensed to us for certain other indications. Photonamic is currently conducting a European Phase III clinical trial in which ALA-induced fluorescence is used to guide surgical tumor resection in patients suffering from the most aggressive form of adult brain tumor, glioblastoma multiforme. This clinical trial is expected to continue through late 2004, at a minimum. Our license covers both this primary clinical indication as well as other brain cancers. In January 2003, based on the license agreement, DUSA paid Photonamic a non-refundable \$500,000 milestone payment. This amount was charged to research and development costs in 2002, when the obligation was incurred.

We will also be obligated to pay certain regulatory milestones and royalties on net sales of a brain cancer product under the terms of the license and development agreement and will purchase product under the supply agreement for mutually agreed upon indications. Should Photonamic's clinical study be successful, we will be obligated to proceed with development of the product in the United States in order to retain the license for the use of the technology to treat brain cancer. We are unable to determine at this time whether these obligations will mature.

401(K) PROFIT SHARING PLAN - Effective January 1, 1996, we adopted a tax-qualified employee savings and retirement 401(k) Profit Sharing Plan (the "401(k) Plan"), covering all qualified employees. Participants may elect a salary deferral of at least 1% as a contribution to the 401(k) Plan, up to the statutorily prescribed annual limit for tax-deferred contributions. Effective February 1, 2003, DUSA will match a participant's contribution up to 1.25% of a participant's salary (the "Match"), subject to certain limitations of the 401(k) Plan. Participants will vest in the Match at a rate of 25% for each year of service to DUSA. The Match is not expected to have a material impact on our financial position or results of operations.

CRITICAL ACCOUNTING POLICIES

Our accounting policies are disclosed in Note 2 to the Notes to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2002. Since all of these accounting policies do not require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting policies with our audit committee. We consider the following policies and estimates to be critical to our financial statements.

REVENUE RECOGNITION - Revenues on product sales of the Kerastick(R) are recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred, and there is reasonableness of collection. Research revenue earned under collaborative agreements consisted of non-refundable research and development funding from our former dermatology

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collaboration partner. Research revenue generally compensated us for a portion of agreed-upon research and development expenses and is recognized as revenue at

the time the research and development activities are performed under the terms of the related agreements and when no future performance obligations existed. Milestone or other up-front payments are typically recorded as deferred revenue upon receipt and recognized as income on a straight-line basis over the term of an agreement. Although we make every effort to assure the reasonableness of our estimates, significant unanticipated changes in our estimates due to business, economic, or industry events could have a material impact on our results of operations.

INVENTORY - Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method. Inventories are continually reviewed for slow moving, obsolete and excess items. Inventory items identified as slow-moving are evaluated to determine if an adjustment is required. Additionally, our industry is characterized by regular technological developments that could result in obsolete inventory. Although we make every effort to assure the reasonableness of our estimates, any significant unanticipated changes in demand, technological development, or significant changes to our business model could have a significant impact on the value of our inventory and our results of operations. We use sales projections to estimate the appropriate level of inventory that should remain on the Consolidated Balance Sheet. Management believes that the level of remaining inventory is reasonable in light of our current sales forecasts and uncertainties relating to the timing of FDA approval of our manufacturing facility. Should we be unable to achieve the forecasted sales, additional adjustments may be recorded to cost of goods sold.

VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS - We review long-lived and intangible assets, comprised of property, plant and equipment for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Factors considered important which could trigger an impairment review include significant changes relative to: (i) projected future operating results; (ii) the use of the assets or the strategy for the overall business; (iii) business collaborations; and (iv) industry, business, or economic trends and developments. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. When it is determined that the carrying value of long-lived or intangible assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, the asset is written down to its estimated fair value on a discounted cash flow basis. In 2002 and again as of March 31, 2003, we concluded that the termination of our former dermatology collaboration arrangement in September 2002 and current business events have not caused any impairment to our manufacturing facility under construction. At March 31, 2003, our total property, plant and equipment had a carrying value of \$4,962,000, including \$2,642,000 associated with our manufacturing facility, and we had no intangible assets recorded as of that date.

STOCK-BASED COMPENSATION - We have elected to continue to use the intrinsic value-based method to account for employee stock option awards under the provisions of Accounting Principles Board Opinion No. 25, and to provide disclosures based on the fair value method in the Notes to the Consolidated Financial Statements as permitted by Statement of Financial Accounting Standards ("SFAS") No. 123. Stock or other equity-based compensation for non-employees is accounted for

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under the fair value-based method as required by SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and other related interpretations. Under this

method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost is recognized and charged to operations over the service period, which, in the case of stock options, is generally the vesting period. As we utilize stock and stock options as one means of compensating employees, consultants, and others, a change in accounting for stock-based compensation would, under certain circumstances, result in a material effect on our results of operations, but would not affect cash flow based on our current stock option plan.

RESULTS OF OPERATIONS - THREE MONTHS ENDING MARCH 31, 2003 VERSUS MARCH 31, 2002

REVENUES - Total revenues for the three months ended March 31, 2003 were \$143,000 as compared to \$1,325,000 in 2002. Revenues for 2003 were totally comprised of product sales reflecting direct Kerastick(R) sales from our distributor, Moore Medical Corporation, to physicians, as compared to product sales of \$51,000 in 2002, primarily reflecting rental income on the BLU-U(R) and royalties from our former marketing partner on direct Kerastick(R) sales to end-user sales. The increase in 2003 product sales reflects 100% of revenues on Kerastick(R) sales to end-users as compared to approximately 30% that we received as a royalty under our former collaboration agreement. In 2002, revenues also included research grant and milestone revenues of \$496,000, and research and development reimbursement of \$779,000 that we earned based on our collaboration agreement with our former marketing and development partner.

Excluding BLU-U(R) units installed at clinical trial sites or sold to our former partner, 324 BLU-U(R) units were in place, as of March 31, 2003, down slightly from the 329 units at December 31, 2002, as BLU-U(R) units placed during the current quarter were 13 as compared to returns of 18. Kerastick(R) sales to end-users were 1,842 for the three months ended March 31, 2003 as compared to 1,722 in the comparable 2002 period.

As of March 1, 2003, a new national reimbursement code for Medicare and other third-party payors for the BLU-U(R) application procedure, and for the costs of the Levulan(R) Kerastick(R), became effective. Doctors can also bill for any applicable visit fees. With implementation of the new code, the charge for our drug product was bundled into the new code. Some physicians have suggested that the new reimbursement levels still do not fully reflect the required efforts to routinely execute our therapy in their practices. In addition, others have reported problems prior to March 1, 2003 of getting reimbursed at the former level indicated, or at all. These issues have affected the economic competitiveness of our products with other AK therapies and hence have hindered the adoption of our therapy in many cases. Accordingly, we are continuing to support efforts to improve reimbursement levels to physicians, work with the major private insurance carriers to reimburse our therapy, and to resolve related billing and payment issues, which we believe could significantly improve physician adoption. We are hopeful that the recent changes to reimbursement, plus future improvements, along with our education and marketing programs, will help make Levulan(R) PDT a

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common therapy for AKs over time. However, if reimbursement levels do not adequately reimburse physicians based on their level of cost and service to administer our unique therapy, we believe that adoption of our therapy may continue to suffer.

COST OF PRODUCT SALES AND ROYALTIES - Cost of product sales and royalties for the three months ended March 31, 2003 were \$753,000 as compared to \$679,000 in 2002. A summary of the components of cost of product sales and royalties is provided below:

	(UNAUDITED)		
COST OF PRODUCT SALES AND ROYALTIES	2003	2002	INCREASE (DECREASE)
Product costs including internal manufacturing costs (e.g. customer service, quality assurance, purchasing, and other product support operations)			
assigned to products Costs incurred to ship, install and service the BLU-U(R) in physicians	\$ 563,000	\$ 304,000	\$ 259,000
offices including depreciation	173,000	210,000	(37,000)
Royalty and supply fees (1)	17,000	16,000	1,000
Net underutilization costs (2)	· 	92,000	(92 , 000)
Amortization of deferred charges (3)		57,000	(57,000)
Total cost of product sales and royalties	\$ 753 , 000	\$ 679,000	\$ 74,000
	=======	=======	=======

THREE MONTHS ENDED MARCH 31.

- Royalty and supply fees are paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario.
- 2) Underutilization costs commenced in 2001 and were fully amortized as of December 31, 2002 based on agreements with our thirty-party manufacturers due to orders falling below certain previously anticipated levels.
- 3) Amortization of deferred charges reflects consideration paid by us in 2000 to amend our Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan(R). Such deferred charges were fully amortized in 2002.

Prior to September 2002, inventory costs related to the BLU-U(R) units under rental or lease were deferred until the BLU-U(R) was no longer returnable to us by the physician, which was one year under our initial marketing program. As of March 31, 2003 and December 31, 2002, BLU-U(R) units have been included in property, plant and equipment amounted to approximately \$387,000\$ and \$473,000, net of depreciation of \$541,000 and \$473,000, respectively.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs for the three months ended March 31, 2003 were \$1,516,000 as compared to \$3,282,000 for 2002, of which \$779,000 was reimbursed to us by our former marketing partner. The reduction in research and development costs for 2003 as compared to 2002 reflects the absence of certain costs incurred in 2002 for co-sponsored projects, including Phase I/II studies using Levulan(R) PDT in the treatment of persistent plantar warts and onychomycosis (nail fungus), that were being developed in collaboration with our former marketing and development partner. Such projects have been delayed as we concentrate on

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formulating our own development program, which may include a broad area actinic keratoses (BAAK) treatment. The currently approved Levulan(R) Kerastick(R) only allows application of Levulan(R) to individual lesions using the Kerastick(R),

but we are considering a revised protocol that will apply Levulan(R) to the entire face and/or scalp in a BAAK treatment. We are developing the protocol for our treatment allowing the use of the $BLU-U\left(R\right)$ for the BAAK indication after a much shorter drug incubation time. With regards to BAAK indication, we met with the FDA during the guarter to discuss AK-related Phase III clinical trials that, if successful, would make the therapy more practical, and expand the medical indications for use. We believe that, should development of this indication be successful, the market penetration of the therapy could be significantly enhanced. Our near-term development program also includes completing an FDA-mandated Phase IV long-term AK tracking study, which should be completed in 2003, and funding of various investigator studies involving the Kerastick(R) in support of formulating our development program. This strategy should keep us in a strong financial position as we continue to implement activities to increase revenues from the current product. Under our former marketing and dermatology development agreement, \$779,000 of the agreed upon dermatology research and development expenses were reimbursed to us for the three months ended March 31, 2002.

We have also been conducting Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett's esophagus. Results of the high-grade dysplasia (HGD) study as of January 2003, with 12 months of follow up in 4 patients, and 6 months in 1 patient, showed a continued absence of dysplasia (i.e. complete ablation), no strictures, and no signs of mucosal overgrowth. While limited studies in the high-grade dysplasia indication are still being funded, we do not expect to fund full Phase II or III clinical trials for this indication on our own. Therefore, we have begun soliciting potential partners for this indication, with the goal of completing a partnership during 2003; however, there can be no assurance that we will be able to consummate any collaboration, or whether we will be able to obtain terms acceptable to us.

MARKETING AND SALES COSTS - Marketing and sales costs for the three months ended March 31, 2003 were \$531,000. In the prior year period ended March 31, 2002, there were no marketing and sales expenses incurred by us as all rights and activities associated with marketing and sales of its products were the sole responsibility of its former partner. In late 2002, following the termination of our collaboration with our former marketing partner, we commenced marketing initiatives associated with having full rights and responsibilities for its products. In addition, as of January 1, 2003, we reassigned resources that were functioning in research and development roles to its marketing and sales function

DUSA is considering limited regional test marketing during the second half of 2003. If such a program is implemented and successful, our goal would be to develop a small, dedicated Levulan(R) PDT sales team in 2004.

GENERAL AND ADMINISTRATIVE COSTS - General and administrative costs for the three months ended March 31, 2003 increased to \$1,475,000 as compared to \$1,007,000 for 2002. This increase is mainly attributable to higher legal expenses of \$684,000 incurred in 2003 as compared to

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\$356,000 in 2002, due primarily to patent defense costs. It is expected that legal expenses will remain at elevated levels as long as the patent dispute continues. In April 2002, we received a copy of a notice issued by PhotoCure ASA to Queen's University at Kingston, Ontario, alleging that Australian Patent No. 624985, which is one of the patents licensed by PARTEQ to us, relating to 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University has assigned the Australian patent to us so that we may participate directly in this litigation. We have filed an answer setting forth

our defenses and a related countersuit alleging that PhotoCure's activities infringe the patent. The case is in its earliest stages so we are unable to predict the outcome at this time.

In March 2003, we received notice that our Dutch patent is being formally challenged by an anonymous agent. We filed a formal response to the opposition. At this point in time, it is too early to assess the merits of the allegations. Although we believe that the potential impact in The Netherlands would be minimal regardless of the outcome of the case, we plan to defend our patent at this time.

INTEREST INCOME - Interest income for the three months ended March 31, 2003 decreased to \$566,000, as compared to \$774,000 in 2002. This decrease was attributable to a decrease in investable cash balances as we used cash to support our operating activities, and lower yields. Interest income will continue to decline as our investable cash balances are reduced to support our operating activities. During the three months ended March 31, 2003, we incurred interest expense of \$17,000 on borrowings associated with the construction of our new Kerastick(R) manufacturing facility, which has been capitalized in property and equipment in the Condensed Consolidated Balance Sheet as of March 31, 2003. There was no interest incurred in the comparable period in 2002.

NET LOSSES - The Company incurred a net loss of \$3,566,000, or \$0.26 per share, for the three months ended March 31, 2003, as compared to a net loss of \$2,868,000 or \$0.21 per share for the comparable period in 2002. This increase is due in part to the loss of revenue from our former collaborative partner, offset by savings realized through cost reductions. These losses were within management's expectations, and are expected to continue unless market penetration of our first products increases significantly.

LIQUIDITY AND CAPITAL RESOURCES

We are in a strong cash position to continue to fund our current research and development activities for our Levulan(R) PDT/PD dermatology platform. Our total assets were \$55,691,000 as of March 31, 2003 compared to \$60,950,000 as of December 31, 2002. This decrease is attributable to the funding of operating activities during 2003.

As of March 31, 2003 we had inventory of \$1,134,000, representing finished goods and raw materials, as compared to \$1,189,000 as of December 31, 2002. Also, as of March 31, 2003, we had net property, plant and equipment of \$4,962,000, as compared to \$5,230,000 as of December 31,

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2003, representing construction costs associated with our manufacturing facility, commercial light units in the field, and other property, plant and equipment.

As of March 31, 2003, we had accounts receivable of \$55,000 as compared to \$37,000 as of December 31, 2003, representing net sales associated with Kerastick(R) product sales.

As of March 31, 2003, we had current liabilities of \$1,959,000, as compared to \$3,375,000 as of December 31, 2002. Prior to 2002, we had no long-term debt; however, in May 2002 we entered into a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of our manufacturing facility and borrowed \$1,900,000. The Note currently bears interest at a 360-day LIBOR-based rate of 4%. Prior to expiration of the 360-day LIBOR-based rate for each year of the loan, we can either continue to choose a LIBOR-based rate at that time, execute a one-time

conversion to a fixed rate loan, or repay the loan balance. As of March 31, 2003, the total outstanding loan balance is \$1,720,000, of which \$270,000 is current. Approximately \$3,000,000 of the Company's United States government securities are pledged as collateral to secure the loan.

We invest our excess cash in United States government securities, all of which are classified as available for sale. These securities had an aggregate cost of \$40,162,000, and a current aggregate market value of \$42,550,000 as of March 31, 2003, resulting in a net unrealized gain on securities available for sale of \$2,388,000, which has been included in shareholders' equity. As of December 31, 2002, government securities had an aggregate cost of \$43,180,000 and an aggregate market value of \$45,815,000, resulting in a net unrealized gain of \$2,635,000. Due to fluctuations in interest rates and depending upon the timing of our need to convert government securities into cash to meet our working capital requirements, some gains or losses could be realized. As of March 31, 2003, these securities had interest rates ranging from 3.96% to 7.32% and maturity dates ranging from April 30, 2003 to February 17, 2007. As of December 31, 2002, these securities had interest rates and yields ranging from 3.95% to 7.21% and maturity dates ranging from January 21, 2003 to February 15, 2007.

We believe that we have sufficient capital resources to proceed with our current dermatology research, development, manufacturing, and marketing programs for Levulan(R) PDT, and to fund operations and capital expenditures for the foreseeable future, particularly with the current reduction in research and development spending. We have invested our funds in liquid investments, so that we will have ready access to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis.

As a result of the termination of our former dermatology collaboration arrangement, we have reevaluated our operations and are minimizing research and development and related general and administrative expenditures that are not directly related to our core objectives for 2003. We are concentrating on formulating our own development program, which may include a BAAK treatment. We also intend to invest in manufacturing, and marketing programs for Levulan(R) PDT that support our efforts to penetrate the marketplace with our unique Levulan(R) PDT therapy for AKs, and continue funding for various investigator studies involving the Kerastick(R). In 2003, we are

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establishing a marketing capability, which could become a significant expense. We do not anticipate the level of expense to decrease over the balance of 2003. We may seek to expand or enhance our business by using resources to acquire by license, purchase or other arrangements, businesses, new technologies, or products, especially in PDT-related areas. However, at this time, we intend to focus primarily on increasing the sales of the Levulan(R) Kerastick(R) and the BLU-U(R), and on seeking a partner to help develop and market Levulan(R) PDT for the treatment of dysplasia in patients with Barrett's esophagus.

We cannot accurately predict the level of revenues from sales of our products. In order to maintain and expand continuing research and development programs, we may need to raise additional funds through future corporate alliances, financings, or other sources, depending upon the amount of revenues we receive from our first product.

CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

Kerastick(R) Manufacturing Line - We commenced the construction of a Kerastick(R) manufacturing facility at our Wilmington, Massachusetts location in January 2002, and the initial build-out was completed in June 2002. We completed

the facility qualification, process validation, and drug product stability testing in March 2003, and submitted an NDA supplement to the FDA. FDA review and approval is expected to take approximately 6 months, with an estimated completion date in late 2003. The cost to build the facility includes all costs of construction, calibration, validation testing and equipment. As of March 31, 2003, we have capitalized \$2,642,000 for this facility, and do not expect to incur any significant additional costs. Earlier this month, the FDA inspected the facility, and we anticipate a response regarding the qualification of the facility later in 2003.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect on the method used on reported results. We have determined that we will continue to account for stock-based compensation to employees under the provisions of APB Opinion No. 25 and will make all required disclosures in our financial reports to comply with SFAS 148.

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In December 2002, the EITF reached conclusion on EITF Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." This consensus provides guidance in determining when a revenue arrangement with multiple deliverables should be divided into separate units of accounting, and, if separation is appropriate, how the arrangement consideration should be allocated to the identified accounting units. The provisions of EITF No. 00-21 are effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We will evaluate multiple element arrangements in accordance with this EITF upon its effective date for new arrangements into which it enters.

INFLATION

Although inflation rates have been comparatively low in recent years, inflation is expected to apply upward pressure on our operating costs. We have included an inflation factor in our cost estimates. However, the overall net effect of inflation on our operations is expected to be minimal.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We hold fixed income U.S. government securities that are subject to interest rate market risks. We do not believe that the risk is material at this time as we have apportioned our investments in short-term and longer-term instruments, up to five years, and we strive to match the maturity dates of these instruments to our cash flow needs. A ten percent decline in the average yield of these instruments would not have a material effect on our results of operations or cash flows. As noted above, if significant, sudden fluctuations in interest rates occur, losses could be realized. We do not hold derivative securities. Accordingly, we do not believe that there is a material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this item.

ITEM 4. CONTROLS AND PROCEDURES

Our management is responsible for the preparation, integrity and objectivity of the financial statements and other information presented in this report. Such financial statements have been prepared in accordance with generally accepted accounting principals and reflect certain estimates and adjustments by management. Our management maintains a system of internal accounting controls and disclosure controls and procedures which management believes provide reasonable assurance that the transactions are properly recorded and our assets are protected from loss or unauthorized use.

The integrity of the accounting and disclosure systems are based on written policies and procedures, the careful selection and training of qualified financial personnel, a program of internal controls and direct management review. Our disclosure control systems and procedures are designed to ensure timely collection and evaluation of information subject to disclosure, to ensure the selection of appropriate accounting policies and to ensure compliance with our accounting policies and procedures. The Audit Committee is composed solely of independent directors and meets

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periodically with the independent auditors and management to discuss accounting, financial reporting, auditing and internal auditing matters. The independent auditors have direct and private access to the Audit Committee.

As of March 31, 2003, an evaluation was performed under the supervision and with the participation of our management, including the Chief Executive Officer/Chief Financial Officer, regarding the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our management, including the Chief Executive Officer/Chief Financial Officer, believes that our disclosure controls and procedures are adequately designed to ensure that the information that we are required to disclose in this report has been accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding such required disclosure. There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to March 31, 2003.

FORWARD-LOOKING STATEMENTS

This report, including the Management's Discussion and Analysis, contains various "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 which represent our expectations or beliefs concerning future events, including, but not limited to statements regarding management's goal of becoming profitable, beliefs regarding adoption of our therapy, expectations for continuing operating losses, intention to focus on increasing sales, formulating a development program and seeking a partner, expectations of increasing staff, obligations regarding the Photonamic license, expectations regarding the 401(k) plan matching funds, effects of unanticipated changes in estimates and forecasts, factors which could trigger impairment review, effect of an accounting change for stock-based compensation and intentions regarding disclosures thereof, beliefs concerning the effect of improved reimbursement (or failure to achieve it) and our education and marketing programs, intentions to evaluate and pursue licensing and acquisition opportunities, intention regarding a BAAK trial and the impact if the results are successful, expectations regarding funding of Barrett's esophagus, development of a sales team, and levels of legal expenses, belief regarding The Netherlands patent litigation, requirements of cash resources, and potential impact on conversion of government securities, need for additional funds for development, levels of interest income and net losses, and sufficiency of our capital resources, expectations for incurring costs relating to the manufacturing facility and for response from the FDA regarding its inspection thereof, expectations regarding other accounting

pronouncements, inflation, market risks and controls and procedures. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the timely development, FDA approval, and market acceptance of our products, reliance on third parties for the production and manufacture of our products, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by third-party payors, and other risks noted in our SEC filings from time to time, including our Form 10-K for the period ending December 31, 2002, none of which can be assured.

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PART II- OTHER INFORMATION

Items 1, and 3 through 5.

None.

- Item 2. Changes in Securities and Use of Proceeds.
 - On March 13, 2003, DUSA issued 23,219 shares of its common stock to Dr. D. Geoffrey Shulman, the Company's President and Chief Executive Officer. These shares represent the after-tax portion of Dr. Shulman's bonus compensation for 2002. At the time of the issuance, DUSA's common stock had a fair market value of \$1.60 per share. The issuance of these shares did not involve any public offering and were issued to Dr. Shulman in reliance on Section 4(2) of the Securities Act of 1933, as amended.
- Item 6. Exhibits and Reports on Form 8-K.
 - i) Exhibits
 - a) Exhibit 99.1 Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - b) Exhibit 99.2 Press Release dated May 13, 2003
 - ii) Form 8-K
 - a) Form 8-K dated March 31, 2003 and filed April 1, 2003 noting the interest in DUSA's product, Levulan(R) Photodynamic Therapy ("PDT"), at the annual meeting of the American Academy of Dermatology.

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.

DUSA Pharmaceuticals, Inc.

By: /s/ D. Geoffrey Shulman

D. Geoffrey Shulman President, Chief Executive Officer, and Chief Financial Officer (Principal Financial Officer)

Date: May 13, 2003 By: /s/ Peter M. Chakoutis

Peter M. Chakoutis Controller (Principal Accounting Officer)

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SARBANES-OXLEY SECTION 302(a) CERTIFICATION

- I, D. Geoffrey Shulman, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of DUSA Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this quarterly 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 quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
- 4. The registrant's other signing officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures 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 quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5. The registrant's other signing officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have

identified for the registrant's auditors any material weaknesses in internal controls; and

- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other signing officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 13, 2003

/s/ D. Geoffrey Shulman

D. Geoffrey Shulman
President, Chief Executive
Officer (Principal
Executive Officer), and
Chief Financial Officer
(Principal Financial Officer)