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DUSA PHARMACEUTICALS INC
Form 10-Q
November 12, 2002

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

(Mark One)

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

For the quarterly period ended September 30, 2002

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 | 22-3103129 |
| (State or other jurisdiction of | (I.R.S. Employer |
| incorporation or organization) | 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(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

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of common stock, as of the latest practicable date.

13,887,612 shares as of November 11, 2002

PART 1.

ITEM 1. FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

| | SEPTEMBER 30, 2002 (UNAUDITED) |
|---|--------------------------------------|
| ----- | |
| ASSETS | |
| CURRENT ASSETS | |
| Cash and cash equivalents | \$2,793,848 |
| United States government securities | 53,285,304 |
| Accrued interest receivable | 710,919 |
| Accounts receivable | 67,164 |
| Receivable under co-development program | 650,000 |
| Inventory | 598,347 |
| Other current assets | 1,418,024 |
| | ----- |
| TOTAL CURRENT ASSETS | 59,523,606 |
| Property and equipment, net | 4,841,921 |
| Deferred charges | 233,330 |
| Deferred royalty | -- |
| | ----- |
| TOTAL ASSETS | \$64,598,857 |
| | ===== |
| LIABILITIES AND SHAREHOLDERS' EQUITY | |
| CURRENT LIABILITIES | |
| Accounts payable | \$64,013 |
| Accrued payroll | 521,419 |
| Other accrued expenses | 1,614,986 |
| Current maturities of long-term debt | 270,000 |
| Deferred revenue | 16,830 |
| Due to licensor | 31,447 |
| | ----- |
| TOTAL CURRENT LIABILITIES | 2,518,695 |
| Long-term debt, net of current | 1,585,000 |
| Deferred revenue | -- |
| Other deferred reimbursement | 166,660 |
| | ----- |
| TOTAL LIABILITIES | 4,270,355 |
| | ----- |
| COMMITMENTS AND CONTINGENCIES (NOTE 13) | |
| SHAREHOLDERS' EQUITY | |

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| | |
|---|--------------|
| Capital Stock | |
| Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, 60,000,000 shares issuable in series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding: 13,887,612 (2001: 13,865,390) shares of common stock, no par. | 95,490,561 |
| Additional paid-in capital | 2,015,586 |
| Accumulated deficit | (40,389,689) |
| Accumulated other comprehensive income | 3,212,044 |
| | ----- |
| TOTAL SHAREHOLDERS' EQUITY | 60,328,502 |
| | ----- |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | \$64,598,857 |
| | ===== |

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED) | | SEP |
|--|---|----------------|-------|
| | 2002 | 2001 | |
| | ----- | ----- | ----- |
| REVENUES | | | |
| Product sales and rental income | \$51,185 | \$58,837 | \$1 |
| Research grant and milestone revenue | 21,320,830 | 495,834 | 22,3 |
| Research revenue earned under collaborative agreements | 1,193,739 | 881,895 | 2,8 |
| | ----- | ----- | ----- |
| TOTAL REVENUES | 22,565,754 | 1,436,566 | 25,3 |
| | ----- | ----- | ----- |
| OPERATING COSTS | | | |
| Cost of product sales and royalties | 3,240,793 | 441,979 | 4,6 |
| Research and development | 2,848,295 | 2,805,803 | 9,3 |
| General and administrative | 1,411,494 | 984,745 | 4,1 |
| | ----- | ----- | ----- |
| TOTAL OPERATING COSTS | 7,500,582 | 4,232,527 | 18,1 |
| | ----- | ----- | ----- |
| INCOME (LOSS) FROM OPERATIONS | 15,065,172 | (2,795,961) | 7,2 |
| OTHER INCOME | | | |
| Interest income | 695,701 | 978,932 | 2,2 |
| | ----- | ----- | ----- |
| NET INCOME (LOSS) | \$15,760,873 | \$ (1,817,029) | \$9,4 |
| | ===== | ===== | ===== |
| BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE | \$1.13 | \$ (0.13) | |
| | ===== | ===== | ===== |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | 13,887,612 | 13,796,004 | 13,8 |

=====

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | NINE MONTHS SEPTEMBER 30, |
|---|------------------------------|
| | 2002 |
| CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES | |
| Net income (loss) | \$9,455,756 |
| Adjustments to reconcile net income (loss) to net cash used in operating activities | |
| Amortization of premiums and accretion of discounts on U.S. government securities available for sale, net | (8,207) |
| Depreciation and amortization expense | 2,488,764 |
| Amortization of deferred revenue | (22,312,498) |
| Issue of shares of common shares to non-employee | 50,000 |
| Changes in other assets and liabilities impacting cash flows from operations: | |
| Accrued interest receivable | 212,540 |
| Accounts receivable | 54,116 |
| Receivable under co-development program | 214,534 |
| Inventory | 1,734,733 |
| Other current assets | (163,074) |
| Deferred charges | (100,000) |
| Accounts payable | (250,876) |
| Accrued payroll and other accrued expenses | (263,078) |
| Due to licensor | (31,345) |
| Deferred revenue | (256,528) |
| NET CASH USED IN OPERATING ACTIVITIES | (9,175,163) |
| INVESTING ACTIVITIES: | |
| Purchases of United States government securities | (6,131,356) |
| Proceeds from maturing United States government securities | 10,983,593 |
| Purchases of property and equipment | (2,306,726) |
| Deposits on equipment | -- |
| NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES | 2,545,511 |
| FINANCING ACTIVITIES: | |
| Proceeds from exercise of options and warrants | -- |
| Proceeds from long-term debt | 1,900,000 |

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| | |
|--|--------------|
| Payments of long-term debt | (45,000) |
| | ----- |
| NET CASH PROVIDED BY FINANCING ACTIVITIES | 1,855,000 |
| | ----- |
| NET DECREASE IN CASH AND CASH EQUIVALENTS | (4,774,652) |
| | ----- |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 7,568,500 |
| | ----- |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | \$ 2,793,848 |
| | ===== |

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of September 30, 2002, Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2002 and 2001, and Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2002 and 2001 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 DUSA Pharmaceuticals, Inc. ("DUSA" or the "Company") believes to be necessary for fair presentation of the periods presented.

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 2001 have been reclassified to conform to the current year presentation. Such reclassifications had no impact on the net income (loss) or shareholders' equity for any period presented. These condensed consolidated financial statements should be read in conjunction with the Company's December 31, 2001 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 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) SCHERING AG COLLABORATION TERMINATION

On September 1, 2002, DUSA and Schering AG, the Company's former marketing and development partner for Levulan(R) PDT in the field of dermatology,

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terminated the parties' Marketing Development and Supply Agreement, dated November 22, 1999. As a result of this termination, DUSA reacquired all rights it granted to Schering AG under the agreement. In addition, Schering AG agreed to continue its financial support for the dermatology R&D program for the remainder of 2002, including payments totaling \$2,050,000, by December 31, 2002, of which \$1,400,000 has been received as of September 30, 2002. Schering AG will also complete several on-going clinical studies for DUSA's benefit and transfer all of its interest in the regulatory filings it made in Austria, South Africa and Brazil. However, as DUSA has determined that it should concentrate solely on the US market at this time, DUSA has authorized Schering AG to withdraw

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

the application for regulatory approval of Levulan(R) PDT in Australia, and intends to follow the same course for the applications in Austria and South Africa. The regulatory approvals for Canada (held by Draxis Health, Inc.) and Brazil will not be affected. (See section entitled "Overview - Schering AG Collaboration Termination.")

In the quarter ended September 30, 2002, DUSA evaluated certain items on its Condensed Consolidated Balance Sheet for the timing of revenue recognition and potential impairment due to the Schering AG agreement termination. These items included unamortized deferred revenue related to non-refundable milestone payments previously received under the Schering AG agreement, and assets, which at June 30, 2002 totaled approximately \$6,950,000, including the Company's nearly completed manufacturing facility, raw material and finished goods inventories, commercial light units, and deferred charges and royalties. As a result of this analysis, in addition to normal amortization recorded prior to the termination of the Schering AG agreement, the Company recorded the following items in its Condensed Consolidated Statements of Operations during the three months ended September 30, 2002:

| STATEMENT OF OPERATIONS ITEM | BALANCE SHEET ITEM | REVENUE RECOGNITION/ ASSET IMPAIRMENT |
|--------------------------------------|--------------------------|--|
| Revenues: | | |
| Research grant and milestone revenue | Deferred Revenue | \$20,990,274 |
| Operating Costs: | | |
| Cost of product sales | Deferred Charges | \$542,766 |
| | Inventory | 1,705,364 |
| | Commercial Light Sources | |
| | Under Lease or Rental | 389,647 |
| Research and development costs | Deferred Royalty | 639,051 |
| Total Operating Cost Impairment | | \$3,276,828 |

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The Company also concluded that the carrying value of its nearly completed manufacturing facility as of September 30, 2002 is more likely than not fully recoverable after considering the effects of the change in business circumstances caused by the Schering AG agreement termination. Therefore, no impairment charges were recorded during the current periods; however, the Company will continue to periodically review the carrying value of the facility.

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

3) THIRD-PARTY DISTRIBUTION AGREEMENT

As of September 1, 2002, DUSA engaged Moore Medical Corporation, a national distributor and marketer of medical and surgical supplies, to be its exclusive distributor of the Kerastick(R) in the United States. The agreement has a one-year term, which can be automatically renewed for additional one-year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. In addition, either party may terminate the agreement earlier, on certain terms, or in the event that the other party shall have materially breached any of its obligations in the agreement. Moore has a right to return its inventory of Kerastick(R) units for full credit for a period of time prior to and after the expiration date of the agreement. Accordingly, DUSA recognizes product sales when Moore sells the Kerastick(R) to the end-user, as the price is fixed and final to Moore at that point.

4) UNITED STATES GOVERNMENT SECURITIES AVAILABLE FOR SALE

The Company's United States government securities available for sale consist of obligations of the United States government and its agencies, with current yields, as of September 30, 2002, ranging from 3.94% to 7.11% and maturity dates ranging from October 31, 2002 to February 15, 2007. Certain of the Company's United States government securities are pledged as collateral to secure a manufacturing construction loan. (See "Note 9 to the Notes to the Condensed Consolidated Financial Statements - Long-term Debt.")

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

5) INVENTORY

DUSA had built up significant inventory levels to support the September 2000 product launch by its former marketing and development partner, Schering AG. However, in September 2002, the Company recorded lower of cost or market adjustments for excess BLU-U(R) inventory of \$1,594,000, and \$111,000 for bulk Levulan(R). Such write-downs were based on the termination of the Schering AG agreement, limited product sales since the product launch, and the Company's expectation of no significant near-term increases in Kerastick(R) sales levels and/or BLU-U(R) placements. The inventory charges were recorded in cost of product sales in the Condensed Consolidated Statements of Operations during the three months ended September 30, 2002. (See "Note 2 to the Notes to the

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Condensed Consolidated Financial Statements - Schering AG Collaboration Termination.")

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Inventory consisted of the following:

| | SEPTEMBER 30, 2002 (UNAUDITED) | DECEMBER 31, 2001 |
|----------------|--------------------------------------|----------------------|
| | ----- | ----- |
| Finished goods | \$419,112 | \$2,013,799 |
| Raw materials | 179,235 | 319,281 |
| | ----- | ----- |
| | \$598,347 | \$2,333,080 |
| | ===== | ===== |

6) OTHER CURRENT ASSETS

In September 2002, the Company shortened the useful life of its BLU-U(R) units that are under lease, rental, or trial arrangements to reflect a three-year asset life, and recorded an additional \$390,000 of depreciation. This accelerated depreciation policy is attributed to the low level of BLU-U(R) placements to date, the termination of the Schering AG agreement, including the decision not to launch the BLU-U(R) in non-US markets, except possibly Canada, at this time, and expectations that near-term placements will be limited. The additional depreciation reserve was recorded in cost of product sales in the Condensed Consolidated Statements of Operations during the three months ended September 30, 2002. (See "Note 2 to the Notes to the Condensed Consolidated Financial Statements - Schering AG Collaboration Termination.")

| | SEPTEMBER 30, 2002 (UNAUDITED) | DECEMBER 31, 2001 |
|--|--------------------------------------|----------------------|
| | ----- | ----- |
| Prepaid expenses and deposits | \$830,855 | \$447,520 |
| Commercial light units under lease, rental, or trial arrangements (net of depreciation of \$411,308 and \$21,743) | 575,831 | 764,025 |
| Other current assets | 11,338 | 43,405 |
| | ----- | ----- |
| | \$1,418,024 | \$1,254,950 |
| | ===== | ===== |

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7) DEFERRED CHARGES AND ROYALTIES

In September 2002, as a result of the termination of the Schering AG agreement, the Company charged \$509,000 to cost of product sales for deferred charges associated with its amended Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan(R), \$33,000 to cost of product sales for deferred charges associated with underutilization costs paid to National Biological Corporation ("NBC"), the manufacturer of our BLU-U(R), and \$639,000 to research and development costs for deferred royalties associated with payments to PARTEQ, the Company's licensor. These charges, in addition to normal amortization recorded prior to the termination of the Schering AG agreement, were recorded in the Condensed Consolidated Statements of Operations during the three months ended September 30, 2002. (See "Note 2 to the

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Notes to the Condensed Consolidated Financial Statements - Schering AG Collaboration Termination.")

Deferred charges, which include costs paid in advance to third parties under various agreements were being amortized on a straight-line basis over the initial expected terms (1 - 4 1/2 years), were as follows:

| | SEPTEMBER 30, 2002 (UNAUDITED) | DECEMBER 31, 2001 |
|-----------------------------------|--------------------------------------|----------------------|
| | ----- | ----- |
| Facilities underutilization costs | \$233,330 | \$933,333 |
| Facilities reimbursement costs | -- | 660,375 |
| | ----- | ----- |
| | \$233,330 | \$1,593,708 |
| | ===== | ===== |

Outstanding deferred charges as of September 30, 2002, related to facilities underutilization costs to our Kerastick(R) manufacturing supplier, will be fully amortized at December 31, 2002 when its obligation to manufacture Kerastick(R) units is completed.

8) DEFERRED REVENUE

In September 2002, based on the termination of the Schering AG agreement, the Company recorded \$20,990,000 of unamortized research grant and milestone revenue, in addition to normal amortization recorded prior to the termination of the Schering AG agreement, in the Condensed Consolidated Statements of Operations. (See "Note 2 to the Notes to the Condensed Consolidated Financial Statements - Schering AG Collaboration Termination.")

SEPTEMBER 30, DECEMBER 31,

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| | 2002 (UNAUDITED) | 2001 |
|---|---------------------|--------------|
| | ----- | ----- |
| Milestone and unrestricted grant payments | \$ -- | \$22,312,498 |
| Sale of BLU-U(R) units | -- | 273,358 |
| Sale of Levulan(R) Kerastick(R) units | 16,830 | -- |
| | ----- | ----- |
| | \$16,830 | \$22,585,856 |
| | ===== | ===== |

As of September 1, 2002, DUSA engaged a third-party distributor to be its exclusive distributor of the Levulan(R) Kerastick(R) in the United States. The Company has recorded \$16,830 of deferred revenue for Kerastick(R) units placed with the distributor as the price was not fixed and final, since the distributor has a right of return on Kerastick(R) units. (See "Note 3 to the Notes to the Condensed Consolidated Financial Statements - Third-Party Distribution Agreement".)

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

During the first half of 2002, deferred revenue of \$273,000 related to the sale of BLU-U(R) units was reclassified to other accrued expenses, of which \$130,000 remains outstanding as of September 30, 2002.

9) LONG-TERM DEBT

Long-term debt consisted of the following:

| | SEPTEMBER 30, 2002 (UNAUDITED) | DECEMBER 31, 2001 |
|---------------------------------|--------------------------------------|----------------------|
| | ----- | ----- |
| Manufacturing construction loan | \$1,855,000 | \$ -- |
| Less: Current maturities | (270,000) | -- |
| | ----- | ----- |
| | \$1,585,000 | \$ -- |
| | ===== | ===== |

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 of a \$2,700,000 commitment. The remaining amount of the commitment lapsed on June 30, 2002. DUSA paid interest only at the prime rate through July 1, 2002, and on August 1, 2002 commenced monthly loan payments with fixed monthly principal payments of \$22,500 plus interest which are scheduled to continue through June 30, 2009. Based on the terms of the Note, the Company had an option to select a fixed rate or a rate at the LIBOR interest rate plus 1.75%, for varying LIBOR periods. The Company

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selected a 360-day LIBOR-based rate that resulted in a 4% interest rate for the initial year of the Note. 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, or can execute a one-time conversion to a fixed rate loan. Approximately \$3,000,000 of the Company's United States government securities are pledged as collateral to secure the loan.

10) SHAREHOLDERS' RIGHTS PLAN

On September 27, 2002, the Company adopted a shareholder rights plan (the "Plan") at a special meeting of the Board of Directors on Friday. The Plan provides for the distribution of one right as a dividend for each outstanding share of common stock (the "Common Stock") of the Company to holders of record as of October 10, 2002. Each right entitles the registered holder to purchase one one-thousandths of a share of preferred stock at an exercise price of \$37.00 per right. The rights will be exercisable subsequent to the date that a person or group either has acquired, obtained the right to acquire, or commences or discloses an intention to commence a tender offer to acquire, 15% or more of the Company's outstanding common stock (or 20% of the outstanding common stock in the case of a shareholder or group who beneficially hold in excess of 15% at the record date), or if a person or group is declared an Adverse Person, as such term is defined in the Plan. The rights may be redeemed by the Company at a redemption price of one one-hundredth of

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

a cent per right until ten days following the date the person or group acquires, or discloses an intention to acquire, 15% or 20% or more, as the case may be, of the Company, or until such later date as may be determined by the Board.

Under the Plan, if a person or group acquires the threshold amount of the Common Stock, all holders of rights (other than the acquiring shareholder) may, upon payment of the purchase price then in effect, purchase shares of Common Stock having a value of twice the purchase price. In the event that the Company is involved in a merger or other similar transaction where it is not the surviving corporation, all holders of rights (other than the acquiring shareholder) shall be entitled, upon payment of the purchase price then in effect, to purchase common stock of the surviving corporation having a value of twice the purchase price. The rights will expire on October 10, 2012, unless previously redeemed. Also, the Board adopted certain amendments to the Company's Certificate of Incorporation consistent with the terms of the Plan.

11) BASIC AND DILUTED NET INCOME (LOSS) PER SHARE

Basic net income (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 income (loss) per common share during each of the periods presented in the Condensed Consolidated Statements of Operations, as the effect would be antidilutive. For the periods ended September 30, 2002 and 2001, total outstanding stock options and warrants of approximately 2,672,000, and 2,546,000 shares, respectively, have been excluded from consideration in the

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computation of diluted net income (loss) per share.

12) COMPREHENSIVE INCOME (LOSS)

For the three and nine months ended September 30, 2002 and 2001, comprehensive income (loss) consisted of the following:

| | THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED) | | NIN SEPTEMB |
|--|---|----------------|----------------|
| | 2002 | 2001 | 2 |
| NET INCOME (LOSS) | \$15,760,873 | \$ (1,817,029) | \$9,455, |
| Net unrealized gains on United States securities available for sale | 945,511 | 1,445,831 | 988, |
| COMPREHENSIVE INCOME (LOSS) | \$16,706,384 | \$ (371,198) | \$10,443, |
| | ===== | ===== | ===== |

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

13) COMMITMENTS AND CONTINGENCIES

KERASTICK(R) MANUFACTURING LINE - In late 2001, because of the Company's commitment under the Schering AG agreement, and because the Company's current Kerastick(R) manufacturing arrangement was scheduled to expire on December 31, 2002, the Company decided to construct a Kerastick(R) manufacturing facility at its Wilmington, Massachusetts location. Construction started in January 2002, and is expected to be completed during 2002, and then will be followed by facility qualification, process validation, drug product stability testing, and FDA review. As of September 30, 2002, the Company has incurred \$2,434,000 for certain equipment, pre-construction, construction, validation, and testing activities, which have been classified in property and equipment in the Condensed Consolidated Balance Sheet.

LEGAL MATTERS - In April 2002, the Company received a copy of a notice issued by PhotoCure ASA to PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario, alleging that Australian Patent No. 624985, which is one of the patents licensed by PARTEQ to DUSA, 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 DUSA so that DUSA may participate directly in this litigation. DUSA 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.

14) RECENT ACCOUNTING PRONOUNCEMENT

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In August 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment of Disposal of Long-lived Assets." This statement supercedes SFAS No. 121, "Accounting for the Impairment of Long-lived Assets and for Long-lived Assets to Be Disposed Of." SFAS No.144 establishes a single accounting model, based on the framework established in SFAS No. 121, for long-lived assets to be disposed of by sale, and resolves implementation issues related to SFAS No. 121. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. When the Company adopted this statement on January 1, 2002, SFAS No. 144 did not have any effect on its financial position or results of operations. During the three-month period ended September 30, 2002, the Company concluded that the termination of the Schering AG agreement on September 1, 2002 did not have any impairment effects on its nearly completed manufacturing facility, but did result in impairment adjustments to certain intangible assets as more fully discussed in Notes 2 and 7 to the Condensed Consolidated Financial Statements.

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

OVERVIEW

The following discussion should be read in conjunction with the Company's Consolidated Financial Statements and Notes to the Consolidated Financial Statements for the year ended December 31, 2001 and its Condensed Consolidated Financial Statements and Notes to the Condensed Consolidated Financial Statements for the three and nine-month periods ended September 30, 2002 and 2001. DUSA is engaged primarily in the research, development, and commercialization 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 is 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. These products are used together to provide photodynamic therapy for the treatment of non-hyperkeratotic actinic keratoses (AKs) of the face or scalp.

We have devoted substantial resources to funding research and development in order to advance our Levulan(R) PDT/PD technology platform, and as a result, have experienced significant operating losses. As of September 30, 2002, we had an accumulated deficit of approximately \$40,390,000. Achieving our goal of becoming a profitable operating company is dependent on the market penetration of our products in the United States, acceptance of our therapy by the medical and consumer constituencies, and our ability to develop and/or acquire new products. We expect to continue to incur operating losses as we invest in our current approved products, research and development opportunities, and until product sales from current or future products increase significantly. As of September 30, 2002, our staff included 50 full-time employees as compared to 55 at the end of 2001, in support of all activities including production, maintenance, customer support, and financial operations for our products, as well as the research and development programs for dermatology and internal indications. As a result of the termination of the Schering AG agreement, which is discussed below, we have reevaluated our expenses and intend to minimize

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research and development and related general and administrative expenditures that are not directly related to our core objectives for 2003. These objectives include increasing the sales of our dermatology products, and seeking a partner to help develop and market Levulan(R) PDT for the treatment of dysplasia in patients with Barrett's esophagus. Subsequent to the end of the current quarter, DUSA separated employment with an additional 5 employees, which resulted in a total reduced work force in 2002 through a combination of layoffs and attrition of approximately 20%.

SCHERING AG COLLABORATION TERMINATION - On September 1, 2002, DUSA and Schering AG, the Company's former marketing and development partner for Levulan(R) PDT in the field of dermatology, terminated the parties' Marketing Development and Supply Agreement, dated November 22, 1999, as amended. As a result of this termination, DUSA reacquired all rights it granted to Schering AG under the agreement. In addition, Schering AG agreed to continue its

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financial support for the dermatology R&D program for the remainder of 2002, including payments totaling \$2,050,000 by December 31, 2002, of which \$1,400,000 has been received as of September 30, 2002. However, the entire \$2,050,000 has been recognized during the nine months ended September 30, 2002. Schering AG has agreed to also complete several on-going clinical studies for DUSA's benefit and transfer all of its interest in the regulatory filings it made in Austria, South Africa and Brazil. However, as DUSA has determined that it should concentrate solely on the US market at this time. DUSA has authorized Schering AG to withdraw the application for regulatory approval of Levulan(R) PDT in Australia, and intends to follow the same course for the applications in Austria and South Africa. The regulatory approvals for Canada (held by Draxis Health, Inc.) and Brazil will not be affected.

In the quarter ended September 30, 2002, DUSA evaluated certain items on its Condensed Consolidated Balance Sheet for the timing of revenue recognition and potential impairment due to the Schering AG agreement termination. These items included unamortized deferred revenue related to non-refundable milestone payments previously received under the Schering AG agreement, and assets, which as of June 30, 2002 totaled approximately \$6,950,000, including the Company's nearly completed manufacturing facility, raw material and finished goods inventories, commercial light units, and deferred charges and royalties. As a result of this analysis, in addition to normal amortization recorded prior to the termination of the Schering AG agreement, the Company recorded the following items in its Condensed Consolidated Statements of Operations during the three months ended September 30, 2002:

| STATEMENT OF OPERATIONS ITEM | BALANCE SHEET ITEM | REVENUE RECOGNITION ASSET ITEM |
|--------------------------------------|--------------------|--------------------------------|
| Revenues: | | |
| Research grant and milestone revenue | Deferred Revenue | \$20,000 |
| Operating Costs: | | |
| Cost of product sales | Deferred Charges | |
| | Inventory | 1,000 |
| | Commercial Light | |

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| | |
|---------------------------------|----------------------------------|
| | Sources Under Lease or Rental |
| Research and development costs | Deferred Royalty |
| Total Operating Cost Impairment | |

\$3,

The Company also concluded that the carrying value of its nearly completed manufacturing facility as of September 30, 2002 is more likely than not to be fully recoverable after considering the effects of the change in business circumstances caused by the termination of the Schering AG agreement. Therefore, no impairment charges were recorded during the current periods; however, the Company will continue to periodically review the carrying value of the facility.

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As a result of the termination of the Schering AG agreement, DUSA has commenced implementing its own marketing, education, and development strategy, and will continue to develop and implement such strategies for the remainder of 2002 and beyond. For now, DUSA has decided not to create a nationwide sales force, or to seek a new dermatology marketing partner. Instead, the Company intends to focus on meeting the needs of dermatologists, and educating them about the benefits of our therapy, in an effort to increase product sales over time. This will be done through the support of medical education activities, participation in dermatology conferences, support of company research and development efforts and independent investigator studies, and support of efforts to improve third party reimbursement. DUSA is also planning clinical studies, which if successful, would expand the Company's current FDA approved label for treatment of AKs. We are also offering a new BLU-U(R) placement program for physicians and have introduced a Kerastick(R) sampling program to allow new doctors to become familiar with the therapy.

As a result of the termination of the Schering AG agreement, DUSA has commenced marketing its products directly and may incur significant expense. DUSA may also enter into arrangements with other third parties in the future. On September 1, 2002, DUSA entered into an exclusive distribution agreement with Moore Medical Corporation to distribute the Kerastick(R) throughout the United States. (See section entitled "Contractual Obligations and Other Commercial Commitments - Third-party Distribution Agreement.")

SHAREHOLDERS' RIGHTS PLAN - In order to protect the long term interest of the Company's shareholders, the Company adopted a Shareholders Rights Plan, on September 27, 2002. (See "Note 10 to the Notes to the Condensed Consolidated Financial Statements - Shareholders' Rights Plan.") The Shareholder Rights Plan is designed to prevent an acquirer from gaining control of the Company without offering a fair price to all of the Company's shareholders. The Shareholder Rights Plan was not adopted by the Board in response to any specific offer or threat, but rather is intended to protect the interests of shareholders in the event the Company is confronted in the future with takeover tactics. Issuance of shares of Common Stock under the Shareholder Rights Plan could be used to make a change in control of the Company more difficult or costly by diluting stock ownership of persons seeking to obtain control of the Company. The Company's management is not aware of any takeover activity involving the Company. In addition, the Board of Directors adopted certain amendments to the Company's Certificate of Incorporation which are consistent with the terms of the Plan.

CRITICAL ACCOUNTING POLICIES

In May 2002, the United States Securities and Exchange Commission ("SEC") issued disclosure guidance and proposed rules for "critical accounting policies" - "Disclosure in Management's Discussion and Analysis about the Application of Critical Accounting Policies." The SEC defines "critical accounting policies" as those that require application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. DUSA's accounting policies are disclosed in Note 2 of the Company's Notes to the Consolidated Financial Statements for the year ended December 31, 2001. Since not all of these accounting policies require

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management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We consider the following policies and estimates to be critical to our financial statements.

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 developments, or significant changes to our business model could have a significant impact on the value of our inventory and our results of operations. DUSA had built up inventory levels in support of the September 2000 product launch by its former marketing and development partner, Schering AG. However, in September 2002, based on the termination of the Schering AG agreement, the Company recorded lower of cost or market adjustments of \$2,095,000 for excess inventory and commercial light units under lease, rental, or trial arrangements to cost of product sales in its Condensed Consolidated Statements of Operations during the three months ended September 30, 2002. (See section entitled "Overview - Schering AG Collaboration Termination.")

VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS - We review long-lived and intangible assets, comprised of property, plant and equipment, deferred charges, and deferred royalties 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: 1) projected future operating results; 2) the use of the assets or the strategy for the overall business; and 3) 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 intangibles 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. During the three-month period ended September 30, 2002, the Company concluded that the termination of the Schering AG agreement did not have any impairment on its manufacturing facility under construction, but did result in impairment adjustments to certain intangible assets as more fully discussed in Notes 2 and 7 to the Condensed Consolidated

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Financial Statements. (Also see section entitled "Overview - Schering AG Collaboration Termination".)

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 consists of non-refundable research and development funding from the Company's former corporate partner. Research revenue generally compensates the Company 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 exist. Milestone or other up-front payments have been recorded as deferred revenue upon receipt and are recognized as income on a straight-line basis over the term of the

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Company's agreement with our collaborator. 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 deferred revenue and our results of operations. In September 2002, based on the termination of the Schering AG agreement, the Company recorded \$20,990,000 of research grant and milestone revenue, in addition to normal amortization recorded prior to the termination of the Schering AG agreement, in its Condensed Consolidated Statements of Operations during the three months ended September 30, 2002. (See section entitled "Overview - Schering AG Collaboration Termination".)

STOCK-BASED COMPENSATION - 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, 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 is 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, 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, the accounting for stock-based compensation could, 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.

CONCENTRATION OF CREDIT RISK - We invest our cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. We are subject to credit risk through short-term investments and mitigate this risk by investing in United States government securities. If there is an adverse change, other than temporary decline in market value, in the credit risk of the financial institutions or in the entities that we invest in, we may be required to record impairment charges in the future. To date, substantially all of our revenues have been earned from a single collaborator, Schering AG. As a result of the termination of the Schering AG agreement, we may be subject to credit risk. (See section entitled "Overview - Schering AG Collaboration Termination".)

RESULTS OF OPERATIONS

REVENUES - Revenues recognized for the current three and nine-month periods ended September 30, 2002 increased to \$22,566,000 and \$25,321,000, respectively, as compared to \$1,437,000 and \$4,143,000 for the same periods in 2001. Revenues during the current periods include the one-time recognition of unamortized up-front milestone and unrestricted grant payments previously received from Schering AG totaling \$20,990,000 due to the finalization of the termination of the Schering AG agreement. (See section entitled "Overview - Schering AG Collaboration Termination".) Revenues for the current three and nine-month periods also included amortization

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of up-front milestone and unrestricted grant payments recorded prior to the termination of the Schering AG agreement of \$331,000 and \$1,322,000, and the recognition of research and development revenue totaling \$1,194,000 and \$2,851,000 as compared to \$882,000 and \$2,186,000 during the same periods in 2001.

Product sales and rental income for the current three and nine-month periods totaled \$51,000 and \$157,000, respectively, primarily due to royalty revenues of \$6,000 and \$77,000 earned by DUSA for Kerastick(R) sales by Berlex to its distributor and \$44,000 of revenue recognized during the current quarter based on direct Kerastick(R) sales to our distributor, Moore Medical Corporation, a national distributor and marketer of medical and surgical supplies. (See section entitled "Contractual Obligations and Other Commercial Commitments - Third-party Distribution Agreement.") During 2002, there were no direct sales of the Kerastick(R) to Berlex, the subsidiary of the Company's former marketing partner. Revenues from product sales and rental income for the three and nine-month periods ended September 30, 2001 were \$59,000 and \$470,000, primarily reflecting direct sales of the Kerastick(R) to Berlex, as Berlex purchased Kerastick(R) units to fill the anticipated forecasts at the time the units were ordered. During the balance of 2002 and into early 2003, the Company expects to sell a minimum level of Kerastick(R)' units to our distributor consistent with the current quarter. Due to the disappointing market acceptance since the inception of our products, the termination of the Schering AG agreement, and the historical fluctuations of end-user Kerastick(R) sales and BLU-U(R) placements up to this point, the Company does not expect any significant near-term increase in Kerastick(R) sales levels, and/or BLU-U(R) placements.

In September 2002, the Company initiated a new BLU-U(R) placement strategy as part of its new marketing initiatives. Under this plan, physicians will receive the BLU-U(R) unit in exchange for an agreement to purchase a minimum number of Kerastick(R) units each year. Previous BLU-U(R) marketing programs, which included leasing or renting the BLU-U(R) to physicians, medical institutions and academic centers, that were carried out in cooperation with Schering AG, have now been terminated. As of September 30, 2002, 360 BLU-U(R) units were in place, down slightly from the 369 units at June 30, 2002. Not including BLU-U(R) units installed at clinical trial sites or sold to our former partner, BLU-U(R) units were 338, and 347, respectively as of September 30, 2002, and June 30, 2002, respectively. Kerastick(R) sales to end-users were 1,392 and 5,394 for the current three and nine month periods ended September 30, 2002, as compared to 1,638 and 4,623 for the same periods in 2001. DUSA believes that as doctors become more familiar with the benefits of Levulan(R) PDT, and

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especially if our clinical studies support, and we receive, FDA approval for a broader label claim and improved reimbursement is achieved, more widespread adoption of our technology should occur over time.

COST OF PRODUCT SALES AND ROYALTIES - Cost of product sales and royalties for the three and nine-month periods ended September 30, 2002 increased to \$3,241,000 and \$4,696,000, respectively, as compared to \$442,000 and \$1,818,000 for the comparable periods in 2001. Due to the termination of the Schering AG agreement, cost of product sales for the current periods amounted to \$2,638,000 for lower of cost or market inventory adjustments, increased depreciation taken on BLU-U(R) units, and deferred charges associated with our amended Supply Agreement with Sochinaz SA. (See section entitled "Overview - Schering AG Collaboration Termination".) Direct product costs during the current quarter were \$16,000 representing costs recognized based on direct Kerastick(R) sales since

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September 1, 2002 to our distributor, Moore Medical Corporation. (See section entitled "Contractual Obligations and Other Commercial Commitments - Third-party Distribution Agreement.") The current three and nine-month periods also included internal operations costs of \$406,000 and \$1,030,000 for resources (e.g. customer service, quality assurance, purchasing, and other product support operations) assigned to support our products, \$47,000 and \$611,000 incurred to ship, install, and maintain the BLU-U(R) in physicians offices, and \$16,000 and \$48,000 in royalty and supply fees due to DUSA's licensor. Also included in the current three-and nine-month periods are \$83,000 and \$267,000 of net underutilization costs resulting from payments made to our third-party manufacturers since our initial orders fell well below certain previously anticipated levels. The current three and nine-month period also includes \$38,000 and \$140,000 in amortization of deferred charges, recorded prior to the termination of the Schering AG agreement, which were fully amortized as of September 30, 2002 as a result of the termination of the Schering AG agreement.

Cost of product sales for the prior three and nine-month periods ended September 30, 2001 included internal operations costs of \$178,000 and \$564,000 for resources assigned to support our products, \$66,000 and \$467,000 of underutilization costs due to orders to our Kerastick(R) manufacturer falling below certain previously anticipated levels, \$56,000 and \$169,000 in amortization of deferred charges, as well as costs incurred for shipping and installing the BLU-U(R) in physicians offices. The nine month period ended September 30, 2001 also included \$358,000 in direct Kerastick(R) related product costs.

We incur certain fixed costs resulting in under-absorbed overhead, which are included in cost of product sales. We expect that the development of our own facility will enable us to better manage and control the costs of production when it is operational. However, our unit cost per Kerastick(R) will initially increase as compared to our unit cost under our agreement with our current manufacturer, until and unless, production levels increase significantly. DUSA commenced the construction of its Kerastick(R) manufacturing facility in January 2002. (See section entitled "Contractual Obligations and Other Commercial Commitments - Manufacturing Facility Construction Loan.") This new facility will serve to replace our current Kerastick(R) manufacturer, who will cease production at the end of 2002, while there will be a period of 6-12 months without an approved source of supply, until our facility receives FDA approval, assuming that there are no unusual delays in the FDA approval. DUSA expects that the approximately 45,000 Kerastick(R) units currently being manufactured by our current manufacturer, together with approximately 8,000 units currently in our

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inventory, will be sufficient to supply our customer needs for at least 2003. If this supply is unable to meet the demand for Kerastick(R) units until our manufacturing facility received FDA approval, our business would be adversely affected.

Inventory costs related to the BLU-U(R) units under rental, lease, or trial arrangements are deferred and recorded in other current assets, and are being amortized over a thirty-six month period through June 30, 2004. As of September 30, 2002 and December 31, 2001, the net book value of these units amounted to approximately \$576,000 and \$764,000, respectively.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs for the three and nine-month periods ended September 30, 2002 increased to \$2,848,000 and \$9,320,000, respectively, as compared to \$2,806,000 and \$7,068,000 for the comparable periods in 2001. The current three-

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month period was relatively unchanged as compared to the prior year as lower spending on dermatological indications in 2002 was offset by a charge of \$639,000 for deferred royalties associated with payments to PARTEQ, the Company's licensor. (See section entitled "Overview - Schering AG Collaboration Termination.") The current nine-month increase was mainly attributable to higher third-party expenditures in support of DUSA's FDA mandated Phase IV clinical study of the long-term efficacy of our marketed product, clinical feasibility studies in other dermatological indications, and DUSA's Phase I/II clinical studies on the safety and efficacy of Levulan PDT treatment of Barrett's esophagus with and without dysplasia.

DUSA intends to focus its near-term dermatology development program on expansion of the currently approved Levulan(R) Kerastick(R) product labeling. The currently approved indication only allows application of Levulan(R) to individual lesions using the Kerastick(R), so we are seeking to apply Levulan(R) to the entire face or scalp in a Broad Area Actinic Keratoses (BAAK) treatment. We are developing a revised protocol for our BLU-U(R) treatment allowing the use of the Levulan(R) Kerastick(R) for the BAAK indication after a much shorter drug incubation time. This could be as soon as one hour after the Levulan(R) application, compared with the 14-18 hours specified in the current labeling. We believe that should clinical development of this indication be successful and approved as an expansion of our current FDA approved label, the market penetration of the therapy could be significantly enhanced. The Company also intends to complete its FDA-required Phase IV long-term AK tracking study before the end of 2003.

Analysis of data obtained from DUSA's Phase I/II study on resistant plantar warts is ongoing. However, DUSA's Phase II study on onychomycosis (nail fungus) did not appear to show success in treating the disease in the majority of patients. Further Phase II development for the warts and onychomycosis indications are not being planned at this time in order to lower DUSA's total research and development spending for 2003 and beyond, as compared to the 2002 levels, during which DUSA has earned a full-year reimbursement of \$2,851,000 from Schering AG based on the parties' termination agreement. This strategy should keep the Company in a strong financial situation as it works on the BAAK indication, the long-term tracking study, and increasing revenues from the current product.

DUSA has also been conducting Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett's esophagus. There is

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currently no medical treatment for this condition and it is generally treated by surgical removal of the dysplastic portion of the esophagus. In the high-grade study, preliminary analyses have been completed and showed the removal of regions of high-grade dysplasia in five of six of the treated patients, with follow-up of these patients continuing. While limited investigator studies in the high-grade dysplasia indication will still be funded, we do not expect to fund full Phase II or III clinical trials for this indication on our own. We have completed the development of a partnering package for the use of Levulan(R) PDT in the treatment of Barrett's esophagus dysplasia, and began soliciting potential partners in September 2002. Management's goal is to complete a partnership for this indication during 2003; however there can be no assurance that we will be able to consummate any collaboration on terms acceptable to us.

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GENERAL AND ADMINISTRATIVE COSTS - General and administration costs for the three and nine-month periods ended September 30, 2002 increased to \$1,411,000 and \$4,105,000, respectively, as compared to \$985,000 and \$2,903,000 for the comparable periods in 2001. These increases were mainly attributable to an increase in legal expenses incurred during the current three and nine-month periods of \$463,000 and \$909,000, due primarily to patent defense, the Schering AG agreement termination, and strategic initiatives. It is expected that legal expenses will continue to increase as the patent dispute continues. The Company also incurred employee separation costs of \$190,000 during the current nine-month period.

INTEREST INCOME - Interest income for the three and nine-month periods ended September 30, 2002 decreased to \$696,000 and \$2,255,000, respectively, as compared to \$979,000 and \$3,013,000 for the comparable periods in 2001. These decreases are mainly attributable to lower investable cash balances as we used cash in support of DUSA's operating activities, and lower yields. Interest income will continue to decline as our investable cash balances are reduced to support DUSA's operating activities. During 2002, the Company has incurred interest expense associated with the development of our new Kerastick(R) manufacturing facility of approximately \$29,000, which has been capitalized in property and equipment in the Condensed Consolidated Balance Sheet.

NET INCOME (LOSSES) - The Company's net income for the three and nine-month periods ended September 30, 2002 was \$15,761,000, or \$1.13 per share and \$9,456,000, or \$0.68 per share, respectively, as compared to incurring a net loss of (\$1,817,000), or (\$0.13) per share, and (\$4,632,000), or (\$0.34) per share, for the comparable periods ended September 30, 2001. As a result of the termination of the Schering AG agreement, net income for both current periods included \$17,713,000 of income, excluding normal amortization recorded prior to termination of the Schering AG agreement, from operations that was based on the one-time recognition of certain items on its Consolidated Condensed Balance Sheets. (See section entitled "Overview - Schering AG Collaboration Termination".) This one-time recognition resulted in an increase to earnings per share of \$1.28 for both the current three and nine-month periods. However, going forward net losses are expected to be incurred until the successful market penetration of our first products occurs.

LIQUIDITY AND CAPITAL RESOURCES

We are in a strong cash position to continue our research, development, manufacturing and marketing activities for our Levulan(R) PDT/PD platform. We invest our cash in United States government securities, which are classified as

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available for sale. As of September 30, 2002, we held securities with an aggregate cost of \$50,073,000 and a current aggregate market value of \$53,285,000, resulting in a net unrealized gain on securities available for sale of \$3,212,000, which has been included in shareholders' equity. As of December 31, 2001, DUSA held securities with an aggregate cost of \$54,917,000 and a current aggregate market value of \$57,141,000 resulting in a net unrealized gain on securities available for sale of \$2,224,000. 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. These securities currently have yields ranging from 3.94% to 7.11% and maturity dates ranging from October 31, 2002 to February 15, 2007.

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As of September 30, 2002, we had inventory of \$598,000, representing finished goods and raw materials, as compared to \$2,333,000 as of December 31, 2001. (See "Note 5 to the Notes to the Condensed Consolidated Financial Statements - Inventory.") Also, at the end of the current quarter, net fixed assets increased to \$4,842,000, as compared to \$3,384,000 as of December 31, 2001, due mainly to the development of our Kerastick(R) manufacturing facility at our Wilmington, Massachusetts location. As of September 30, 2002, the Company had incurred \$2,434,000 for certain equipment, pre-construction, construction, validation and testing activities. In May 2002, we secured a seven-year term loan to finance the construction of the facility. (See section entitled "Contractual Obligations and Other Commercial Commitments - Manufacturing Facility Construction Loan" and "Notes 8 and 12 to the Notes to the Condensed Consolidated Financial Statements.") Other than remaining costs of approximately \$350,000 to validate the facility, we do not expect to incur additional significant capital expenditures to complete this facility. We have not made material capital expenditures for environmental control facilities; however, we know that environmental laws will govern our new manufacturing facility. There can be no assurance, however, that we will not be required to incur significant additional costs to comply with environmental laws and regulations in the future, or that our operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

As of September 30, 2002, we had accounts receivable of \$67,000, representing net sales associated with product sales, compared to \$121,000 at the end of 2001. In addition, based on the termination of the Schering AG agreement, a receivable of \$650,000 has been recorded during the current quarter for reimbursement of research and development costs, as compared to a co-development receivable of \$864,000 as of December 31, 2001.

As a result of the Schering AG agreement termination and the slow penetration of our products in the marketplace, we will continue to evaluate certain items on our Consolidated Balance Sheet for impairment, including inventory and property and equipment. (See section entitled "Critical Accounting Policies - Valuation of Long-lived and Intangible Assets".)

We believe that we have sufficient capital resources to proceed with our current research, development, manufacturing and marketing programs for Levulan(R) PDT, and to fund operations and capital expenditures for the foreseeable future. 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. 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 in PDT-related areas. However, at this time, we intend to focus primarily on increasing the

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sales of our 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.

While our current cash position enables us to maintain our current research program and to support the commercialization of Levulan(R) PDT for AKs, we may need to raise additional funds in the future through corporate alliances, financings, or other sources, in order to continuing research and development programs.

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CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

THIRD PARTY DISTRIBUTION AGREEMENT - As of September 1, 2002, DUSA engaged Moore Medical Corporation, a national distributor and marketer of medical and surgical supplies, to be its exclusive distributor of the Kerastick(R) in the United States. The agreement has a one-year term, which can be automatically renewed for additional one-year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. In addition, either party may terminate the agreement earlier, on certain terms, or in the event that the other party shall have materially breached any of its obligations in the agreement. Moore has a right to return its inventory of Kerastick(R) units for full credit for a period of time prior to and after the expiration date of the agreement. Accordingly, DUSA recognizes product sales when Moore sells the Kerastick(R) to the end-user as the price is fixed and final to Moore at that point.

THIRD PARTY KERASTICK(R) MANUFACTURER AGREEMENT MODIFICATION - In July 2001, we revised our agreement with our Kerastick(R) manufacturer, North Safety Products ("North"), covering the period from the execution of this amendment through December 31, 2002. In accordance with this amendment, we paid North \$1,200,000 in up-front underutilization fees during 2001, and agreed to make additional payments totaling \$200,000 in 2002, of which \$100,000 of this amount has been paid as of September 30, 2002 with the final payment to be made prior to December 31, 2002. DUSA has reported the total commitment of \$1,400,000 in deferred charges, which is being recognized in cost of product sales on a straight-line basis over the term of the amendment. In consideration for the underutilization fees, North has agreed to maintain its Kerastick(R) manufacturing capabilities in a state of readiness through December 31, 2002, with the capability of producing at least 25,000 Kerastick(R) units per month in accordance with established procedures. The term of the agreement will end on December 31, 2002 since DUSA did not exercise its option to extend the term of this agreement through June 30, 2003. During the current quarter, DUSA exercised its option to have North manufacture approximately 45,000 Kerastick(R) units, which will be available to DUSA during the fourth quarter of 2002. In September 2001, in accordance with an amendment to our former agreement with Schering AG, Schering AG reimbursed DUSA \$1,000,000 of the costs incurred to modify our manufacturing agreement with North. This amount has been reported in deferred liabilities and is being recognized as an offset to cost of product sales on a straight-line basis over the term of the agreement with North.

KERASTICK(R) MANUFACTURING LINE - DUSA commenced the construction of a Kerastick(R) manufacturing facility at our Wilmington, Massachusetts location in January 2002. The initial build-out was completed in June 2002, and the Company has commenced facility qualification, process validation, and drug product stability testing, which is expected to take approximately six months and be completed in late 2002 or early 2003. FDA review is also expected to take six

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months, with an estimated completion date in mid to late 2003, and should commence after the completion of all validation and certain stability activities, as well as the preparation and submission of an NDA supplement. The Company has estimated that the cost to build and complete testing of this facility, including equipment, is approximately \$2,700,000. This cost includes estimates to build the facility and all costs of construction, calibration, validation testing and equipment. As of September 30, 2002, the Company has incurred \$2,434,000 for certain equipment, pre-construction, construction,

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validation, and testing activities.

MANUFACTURING FACILITY CONSTRUCTION LOAN - 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 of a \$2,700,000 commitment. The remaining amount of the commitment lapsed on June 30, 2002. DUSA paid interest only at the prime rate through July 1, 2002, and on August 1, 2002 commenced monthly loan payments with fixed monthly principal payments of \$22,500 plus interest, which are scheduled to continue through June 30, 2009. Based on the terms of the Note, the Company had an option to select a fixed rate or a rate at the LIBOR interest rate plus 1.75%, for varying LIBOR periods. The Company selected a 360-day LIBOR-based rate that resulted in a 4% interest rate for the initial year of the Note. 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, or can execute a one-time conversion to a fixed rate loan. Approximately \$3,000,000 of the Company's United States government securities are pledged as collateral to secure the loan.

LEGAL MATTERS - In April 2002, DUSA received a copy of a notice issued by PhotoCure ASA to PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario, alleging that Australian Patent No. 624985, which is one of the patents licensed by PARTEQ to DUSA, 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 DUSA so that DUSA may participate directly in this litigation. DUSA 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.

RECENT ACCOUNTING PRONOUNCEMENT

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment of Disposal of Long-lived Assets." This statement supercedes SFAS No. 121, "Accounting for the Impairment of Long-lived Assets and for Long-lived Assets to Be Disposed Of." SFAS No. 144 establishes a single accounting model, based on the framework established in SFAS No. 121, for long-lived assets to be disposed of by sale, and resolves implementation issues related to SFAS No. 121. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. When DUSA adopted this statement on January 1, 2002, SFAS No. 144 did not have any effect on its financial position or results of operations. During the three-month period ended September 30, 2002, the Company concluded that the termination of the Schering AG agreement on September 1, 2002 did not have any impairment effects on its nearly completed manufacturing facility, but did result in impairment adjustments to certain intangible assets as more fully discussed in Notes 2 and 7 to the Condensed Consolidated Financial Statements.

INFLATION

Although inflation rates have been comparatively low in recent years, inflation is expected to apply upward pressure on the operating costs of the Company. We have included an inflation

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factor in its 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. The term loan used for the construction of our manufacturing facility bears interest at a fixed rate through June 30, 2003 and thereafter, is subject to change after that date. A ten percent change in the interest rate would not have a material effect on our results of operations or cash flows.

ITEM 4. CONTROLS AND PROCEDURES

The Company's 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. The Company's 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 the Company's 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. The Company's 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 the Company's accounting policies and procedures. The Audit Committee is composed solely of independent directors and meets 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 September 30, 2002, 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,

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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

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been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to September 30, 2002.

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 expectations for continuing operating losses; intention to minimize certain expenditures; intentions to withdraw certain foreign regulatory applications; intention to review the carrying value of its manufacturing facility; intention to focus on needs of dermatologists; potential significant marketing expenses and arrangements with third parties; potential credit risk; expectations for product sales and revenues; belief regarding adoption of our therapy over time; expectations for completion and FDA approval of our manufacturing facility, and costs relating thereto; replacement of our current manufacturer, and control of costs of production; sufficiency of inventory and potential adverse effect if supplies cannot meet demand; potential impact of critical accounting policies; expectation of higher Kerastick(R) costs per unit; recognition over time of BLU-U(R) inventory costs, intentions to evaluate and pursue licensing and acquisition opportunities; beliefs regarding environmental compliance; expectations regarding the clinical trials results for Phase IV long-term AK tracking study; intentions not to fund further Barrett's esophagus trials and intention to focus the dermatology development program on BAAK; beliefs regarding market penetration; requirements of cash resources for our future liquidity and potential impact on conversion of government securities; expectations for future strategic opportunities including for Barrett's esophagus and research and development programs; need for additional funds; increasing general and administrative expenses, particularly legal expenses, and anticipated decreasing research and development expenses; decreasing levels of interest income and expectations for continuing net losses; and sufficiency of our capital resources and expectations for capital expenditures; intentions to continue to evaluate assets for impairment; expectations regarding inflation and market risks; and beliefs regarding the adequacy of accounting controls and disclosure 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, the timing of the reacquisition of rights from Schering AG, the ability to establish a new marketing capability and to obtain FDA approval of our manufacturing facility, 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, manufacture, sales and marketing of our products, the securities regulatory process, the maintenance of our patent portfolio and the ability to affect a change in the levels of reimbursement by third-party payors, none of which can be assured. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors.

PART II- OTHER INFORMATION

Items 1-5.

None.

Item 6. Exhibits and Reports on Form 8-K.

(i) Exhibits

- a) Exhibit 10.1 - Wholesale Agreement dated as of September 1, 2002 between DUSA and Moore Medical Corporation, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.
- b) 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.
- c) Exhibit 99.2 - Press Release dated November 12, 2002 issued by the Company regarding quarterly results for the period ended September 30, 2002.
- d) Exhibit 99.3 - Amended Certificate of Incorporation, effective September 30, 2002.

(ii) Form 8-Ks

- a) Form 8-K dated August 27, 2002 announcing a finalized termination agreement with Schering AG, its former marketing and development partner for Levulan(R) PDT in the field of dermatology.
- b) Form 8-K dated September 27, 2002 announcing the adoption of a shareholder's rights plan.

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.

DATE: NOVEMBER 12, 2002

BY: /S/ D. GEOFFREY SHULMAN

D. GEOFFREY SHULMAN, MD, FRCPC
DIRECTOR, CHAIRMAN OF THE BOARD,
PRESIDENT, CHIEF EXECUTIVE OFFICER,

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AND CHIEF FINANCIAL OFFICER
(PRINCIPAL EXECUTIVE OFFICER AND
PRINCIPAL FINANCIAL OFFICER)

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 certifying officers 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 certifying officers 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

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- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers 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: November 12, 2002

/s/ D. Geoffrey Shulman

D. Geoffrey Shulman, MD, FRCPC, Director,
Chairman of the Board,
President, Chief Executive Officer
and Chief Financial Officer
(Principal Executive Officer
and Principal Financial Officer)