

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

DUSA PHARMACEUTICALS INC
Form 10-Q
November 13, 2003

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, 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 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 of common stock, as of the latest practicable date.

13,965,247 shares as of November 10, 2003

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

PART I.

ITEM 1. FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

| | SEPTEMBER 30, 2003 (UNAUDITED) | D |
|---|--------------------------------------|-------|
| | ----- | ----- |
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$ 3,643,546 | \$ |
| United States government securities available for sale | 37,968,316 | |
| Accrued interest receivable | 434,905 | |
| Accounts receivable | 95,386 | |
| Inventory | 953,161 | |
| Prepays and other current assets | 566,956 | |
| | ----- | |
| TOTAL CURRENT ASSETS | 43,662,270 | |
| Property and equipment, net | 4,552,267 | |
| | ----- | |
| TOTAL ASSETS | \$ 48,214,537 | \$ |
| | ===== | ===== |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable | \$ 529,766 | \$ |
| Accrued payroll | 478,407 | |
| Other accrued expenses | 1,165,868 | |
| Current maturities of long-term debt | 270,000 | |
| Deferred revenue | 53,040 | |
| | ----- | |
| TOTAL CURRENT LIABILITIES | 2,497,081 | |
| Long-term debt, net of current maturities | 1,315,000 | |
| | ----- | |
| TOTAL LIABILITIES | 3,812,081 | |
| | ----- | |
| COMMITMENTS AND CONTINGENCIES (NOTE 11) | | |
| 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: | | |
| 13,965,247 (2002: 13,887,612) shares of common stock, no par. | 95,666,684 | |
| Additional paid-in capital | 2,015,586 | |
| Accumulated deficit | (55,139,874) | |
| Accumulated other comprehensive income | 1,860,060 | |
| | ----- | |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

| | |
|--|---------------|
| TOTAL SHAREHOLDERS' EQUITY | 44,402,456 |
| | ----- |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | \$ 48,214,537 |
| | ===== |

See the accompanying Notes to the Condensed Consolidated Financial Statements.

2

DUSA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | THREE MONTHS ENDED | |
|---|--------------------|---------------|
| | SEPTEMBER 30, | |
| | (UNAUDITED) | |
| | 2003 | 2002 |
| | ----- | ----- |
| REVENUES | | |
| Product sales and rental income | \$ 163,155 | \$ 51,185 |
| Research grant and milestone revenue | - | 21,320,830 |
| Research revenue earned under collaborative agreements | - | 1,193,739 |
| | ----- | ----- |
| TOTAL REVENUES | 163,155 | 22,565,754 |
| | ----- | ----- |
| OPERATING COSTS | | |
| Cost of product sales and royalties | 887,336 | 3,240,793 |
| Research and development | 1,202,130 | 2,848,295 |
| Marketing and sales | 535,114 | - |
| General and administrative | 1,627,364 | 1,411,494 |
| | ----- | ----- |
| TOTAL OPERATING COSTS | 4,251,944 | 7,500,582 |
| | ----- | ----- |
| INCOME (LOSS) FROM OPERATIONS | (4,088,789) | 15,065,172 |
| OTHER INCOME | | |
| Interest income, net | 408,931 | 695,701 |
| | ----- | ----- |
| NET INCOME (LOSS) | \$ (3,679,858) | \$ 15,760,873 |
| | ===== | ===== |
| BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE | \$ (.26) | \$ 1.13 |
| | ===== | ===== |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | 13,954,450 | 13,887,612 |
| | ===== | ===== |

See the accompanying Notes to the Condensed Consolidated Financial Statements.

3

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

DUSA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | NINE MONTH 2003 (UNAUDITED) |
|--|-----------------------------------|
| <hr/> | |
| CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES | |
| Net income (loss) | \$(11,056, |
| Adjustments to reconcile net loss to net cash used in operating activities | |
| Amortization of premiums and accretion of discounts on United States government securities available for sale, net | 72, |
| Depreciation and amortization expense | 1,077, |
| Amortization of deferred revenue | |
| Issuance of common stock to consultants | 110, |
| Changes in other assets and liabilities impacting cash flows from operations: | |
| Accrued interest receivable | 264, |
| Accounts receivable | (58, |
| Receivable under co-development program | |
| Inventory | 235, |
| Prepays and other current assets | 348, |
| Deferred charges | |
| Accounts payable | (23, |
| Accrued payroll and other accrued expenses | (865, |
| Deferred revenue | 47, |
| | <hr/> |
| NET CASH USED IN OPERATING ACTIVITIES | (9,847, |
| | <hr/> |
| CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES | |
| Purchases of United States government securities | (4,000, |
| Proceeds from maturing United States government securities | 11,000, |
| Purchases of property and equipment | (399, |
| | <hr/> |
| NET CASH PROVIDED BY INVESTING ACTIVITIES | 6,600, |
| | <hr/> |
| CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES | |
| Proceeds from long-term debt | |
| Payments of long-term debt | (202, |
| Proceeds from issuance of options | 29, |
| | <hr/> |
| NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES | (173, |
| | <hr/> |
| NET DECREASE IN CASH AND CASH EQUIVALENTS | (3,421, |
| | <hr/> |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 7,064, |
| | <hr/> |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | \$ 3,643, |
| | <hr/> <hr/> |

See the accompanying Notes to the Condensed Consolidated Financial Statements.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

4

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

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of September 30, 2003, Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2003 and 2002, and Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2003 and 2002 of DUSA Pharmaceuticals, Inc. (the "Company" or "DUSA") 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. These condensed consolidated financial statements should be read in conjunction with the Company's December 31, 2002 audited consolidated financial statements and notes thereto. 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.

2) 2002 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 a result of this termination, DUSA reacquired all rights it granted to Schering AG under the agreement.

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. These items included unamortized deferred revenue related to non-refundable milestone payments previously received under the agreement with Schering AG, and assets including the Company's 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:

5

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

REVENUE
RECOGNITION/

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

| STATEMENT OF OPERATIONS ITEM ----- | BALANCE SHEET ITEM ----- | ASSET IMPAIRMENT ----- |
|---------------------------------------|---|------------------------------|
| Revenues: | | |
| Research grant and milestone revenue | Deferred revenue | \$ 20,990,000 ----- |
| Operating Costs: | | |
| Cost of product sales | Deferred charges (1) Inventory | \$ 543,000 1,705,000 |
| Total cost of product sales | Commercial light sources under lease or rental (2) | 390,000 ----- |
| Research and development costs | Deferred royalty (1) | 639,000 ----- |
| Total operating cost impairment | | \$ 3,277,000 ----- |

1) Deferred charges and deferred royalty were charged to expense in 2002, and are not currently items in the Condensed Consolidated Balance Sheets.

2) Commercial light sources under lease or rental are included in prepaids and other current assets in the Condensed Consolidated Balance Sheets.

3) 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 September 30, 2003, ranging from 3.62% to 7.25% and maturity dates ranging from November 14, 2003 to September 22, 2008.

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.

6

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

4) INVENTORY

Inventory consisted of the following:

| SEPTEMBER 30, 2003 (UNAUDITED) ----- | DECEMBER 31, 2002 ----- |
|---|-------------------------------|
|---|-------------------------------|

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

| | | |
|----------------|------------|--------------|
| Finished goods | \$ 769,448 | \$ 1,047,941 |
| Raw materials | 183,713 | 140,718 |
| | ----- | ----- |
| | \$ 953,161 | \$ 1,188,659 |
| | ===== | ===== |

5) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

| | SEPTEMBER 30, 2003 (UNAUDITED) | DECEMBER 31, 2002 |
|-----------------------------------|--------------------------------------|----------------------|
| | ----- | ----- |
| Research and development costs | \$ 213,131 | \$ 473,543 |
| Marketing and sales costs | 114,353 | - |
| Product related costs | 91,701 | 463,340 |
| License milestone | - | 500,000 |
| Legal and other professional fees | 417,419 | 297,966 |
| Employee benefits | 199,565 | 207,833 |
| Other | 129,699 | 127,468 |
| | ----- | ----- |
| | \$1,165,868 | \$2,070,150 |
| | ===== | ===== |

6) SHAREHOLDERS' EQUITY

On June 15, 2003, the Company granted compensation, accrued in the second quarter of 2003, of \$50,000 to Therapeutics, Inc., a clinical research organization, pursuant to an agreement for services. This compensation was issued in July 2003 and was comprised of 11,666 shares of common stock valued at \$35,000 and \$15,000 of cash. The Company recorded the total value of the compensation in the second quarter of 2003 as part of research and development costs in the Condensed Consolidated Statements of Operations.

On May 2, 2003, the Company granted a total of 32,750 shares of unregistered common stock, without par value, accrued in the second quarter of 2003, to two outside consultants as compensation for services. These shares were valued at approximately \$75,000 and were recorded in the second quarter of 2003 as part of research and development costs in the Condensed Consolidated Statements of Operations.

7

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

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. This amount had been accrued in the December 31, 2002 financial statements.

7) MARKETING AND SALES

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

As a result of the termination of the Company's marketing and development collaboration with its former marketing partner in September 2002, the Company commenced certain marketing and sales initiatives in 2003 associated with having full rights and responsibilities for 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, personnel and other 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

Statement of Financial Accounting Standards ("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.

8

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 income (loss) and pro forma net income (loss) per common share for the three and nine months ending September 30, 2003 and 2002 would have been as follows:

| | THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED) | | NI |
|--|--|---------------|-----------|
| | 2003 | 2002 | 2003 |
| NET INCOME (LOSS) | | | |
| As reported | \$ (3,679,858) | \$ 15,760,873 | \$ (11,05 |
| Effect on net loss if fair value method had been used | (482,455) | (970,058) | (1,61 |
| Proforma | \$ (4,162,313) | \$ 14,790,815 | \$ (12,67 |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

| | ===== | ===== | ===== |
|--|-----------|---------|-------|
| BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE | | | |
| As reported | \$ (0.26) | \$ 1.13 | \$ |
| Effect on net loss per common share if fair value method had been used | (0.04) | (0.06) | |
| Proforma | \$ (0.30) | \$ 1.07 | \$ |
| | ===== | ===== | ===== |

9) BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE

Basic and diluted net income (loss) per common share are 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 Condensed Consolidated Statements of Operations, as the effect would be antidilutive. For the periods ended September 30, 2003 and 2002, such potentially dilutive securities totaling approximately 2,711,000 and 2,672,000 shares, respectively, have been excluded from the computation of diluted net income (loss) per common share.

9

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

10) COMPREHENSIVE INCOME (LOSS)

For the three and nine months ended September 30, 2003 and 2002, comprehensive loss consisted of the following:

| | THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED) | | NINE MONTHS ENDED SEPTEMBER 30, (UNAUDITED) | |
|--|--|---------------|---|----------|
| | 2003 | 2002 | 2003 | 2002 |
| | ----- | ----- | ----- | ----- |
| NET INCOME (LOSS) | \$ (3,679,858) | \$ 15,760,873 | \$ (11,056,947) | \$ 9,45 |
| Net change in unrealized gains (losses) on United States securities available for sale | (407,119) | 945,511 | (774,450) | 98 |
| COMPREHENSIVE INCOME (LOSS) | \$ (4,086,977) | \$ 16,706,384 | \$ (11,831,397) | \$ 10,44 |
| | ===== | ===== | ===== | ===== |

11) 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 was challenged by PhotoCure ASA. PhotoCure ASA has filed a lawsuit in Australia alleging that Australian Patent No. 624985, which is one of the

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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 a response setting forth its defenses, in addition to a related countersuit alleging that certain activities of PhotoCure and its marketing partner, Galderma S.A., infringe the patent. The case is ongoing and the Company is unable to predict the outcome at this time. The Company believes that the final hearing in the Federal Court of Australia will occur in 2004.

In March 2003, the Company received notice that its Dutch patent was being formally challenged by an anonymous agent, and DUSA filed a formal response to the opposition. The Dutch patent office has informed the Company's that its amended patent claim is valid; however, the opposing party has the right to appeal the decision.

12) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

10

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

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 any new multiple element arrangements into which it enters in accordance with this EITF.

13) MANUFACTURING FACILITY APPROVAL

In March 2003, DUSA completed the facility qualification, process validation, and drug product stability testing, and submitted an NDA supplement to the FDA with respect to its manufacturing facility in Wilmington, Massachusetts. The FDA completed its inspection of the facility in May 2003 and, on July 14, 2003, DUSA received approval from the FDA to manufacture the Levulan(R) Kerastick(R) at our Wilmington facility. Accordingly, the Company began to depreciate its manufacturing facility and related manufacturing equipment, with a total cost of \$2,204,000 and \$461,000, respectively, over their useful lives.

11

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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. Levulan(R) is used with the BLU-U(R) to provide PDT for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp. In addition, the BLU-U(R) has received market clearance as a stand alone device for the treatment of moderate inflammatory acne vulgaris.

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 September 30, 2003, we had an accumulated deficit of approximately \$55,140,000. 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 and/or acquire new products. We expect that with the addition of our new sales force, doctors will become more familiar with the benefits of Levulan(R) PDT for actinic keratoses. (See section entitled "Results of Operations - Marketing and Sales Costs") We continue to support efforts to improve reimbursement levels to physicians, and are working to educate the major private insurance carriers to reimburse our therapy so they will approve our therapy for coverage. In addition, these efforts include working with the Centers for Medicare and Medicaid Services (CMS) to reverse the bundling of the drug cost from the procedure fee which occurred, effective March 1, 2003. In November 2003, CMS agreed to reinstate the code for physicians to bill the drug cost separate from the procedure fee, effective January 1, 2004. We believe that due to these efforts, more widespread adoption of our therapy should occur over time. In addition, we are aware that some physicians have been using Levulan(R) with light devices manufactured by other companies and for uses other than our FDA-approved use. While we are not permitted to market our products for so-called "off-label" uses, these activities could also positively affect adoption of our products and increase sales.

We expect to continue to incur operating losses until our first products successfully penetrate the market. However, as a result of the 2002 termination of our former dermatology collaboration arrangement, we reported positive operating income in the 2002 period, which included the one-time recognition of certain items resulting in an increase to operating income of approximately \$17,713,000. Also as a result of this collaboration termination, we reevaluated our expenses in 2003 and increased the level of marketing and sales activities due to reacquiring our marketing and product rights, while minimizing expenditures that are not directly related to our core objectives for

12

2003. At this time, we are focusing primarily on increasing the sales of our approved products, on implementing our development program, 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 September 30, 2003, we had a staff of 41 full-time employees, as compared to 43 at the end of 2002, who support all of our activities, including marketing and sales, production, maintenance, customer support, and financial operations for our products, as well as the research and development programs for dermatology and internal indications. In October, 2003 we increased our staff by hiring an initial regional sales force as we focus on increasing sales, marketing, and customer support activities associated with our AK products. With success, DUSA plans to further expand the sales force in 2004. (See section entitled "Results of Operations - Marketing and Sales Costs") While our financial position is strong, we cannot predict when product sales may offset the cost of these efforts.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

2002 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 a result of this termination, DUSA reacquired all rights it granted to Schering AG under the agreement.

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. These items included unamortized deferred revenue related to non-refundable milestone payments previously received under the agreement with Schering AG, and assets including the Company's 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 | \$20,990,000 |
| Operating Costs: | | |
| Cost of product sales | Deferred charges (1) | \$ 543,000 |
| | Inventory | 1,705,000 |
| | Commercial light sources under lease or rental (2) | 390,000 |
| Total cost of product sales | | \$ 2,638,000 |
| Research and development costs | Deferred royalty (1) | 639,000 |
| Total operating cost impairment | | \$ 3,277,000 |

13

- 1) Deferred charges and deferred royalty were charged to expense in 2002, and are not currently items in the Condensed Consolidated Balance Sheets.
- 2) Commercial light sources under lease or rental are included in prepaids and other current assets in the Condensed Consolidated Balance Sheets.

MANUFACTURING FACILITY APPROVAL - On July 14, 2003, DUSA received approval from the FDA to manufacture the Levulan(R) Kerastick(R) at our Wilmington facility. We expect to manufacture Kerastick(R) units at our approved facility in 2004 assuming market demand for our products increases significantly. As of September 30, 2003, we had 39,756 Kerastick(R) units in inventory. This inventory, which includes physician samples, was produced in

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

2002 by our former third-party manufacturer to meet product demand during the execution of our project to complete and gain FDA approval of our new manufacturing facility. In 2004, manufacturing levels will be dependent on sales levels. We plan to maintain a reasonable level of Kerastick(R) inventory based on sales projections. The facility will also be utilized in 2004 to produce clinical supplies for our planned DUSA-sponsored studies in addition to investigator studies which DUSA plans to support.

510(K) FDA FILING - On September 9, 2003, DUSA received market clearance from the FDA to market the BLU-U(R) as a stand alone device for the treatment of moderate inflammatory acne vulgaris. We plan to initiate marketing of the BLU-U(R) for this indication in the fourth quarter of 2003. The impact that selling the BLU-U(R) as a stand alone device for the treatment of acne will have on product sales is uncertain at this time.

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 not all of these accounting policies 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 previously earned under our collaborative agreement consisted of non-refundable research and development funding from our former dermatology collaboration partner. Research revenue generally compensated us for a portion of our agreed-upon research and development expenses and was recognized as revenue at the time the research and development activities were 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 earned, generally 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.

14

INVENTORY - Inventories are stated at the lower of cost or market value. 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 recorded inventory value is reasonable in light of our current sales forecasts. Should we be unable to achieve the forecasted sales, additional adjustments may be recorded to cost of goods sold.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS - We review long-lived 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. If 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 in 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. At September 30, 2003, total property, plant and equipment had a carrying value of \$4,552,000, including our manufacturing facility which received FDA approval on July 14, 2003. We had no intangible assets recorded as of September 30, 2003 or December 31, 2002.

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 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,

15

under certain circumstances, result in an adverse material effect on our results of operations, but would not affect cash flows.

RESULTS OF OPERATIONS

REVENUES - Total revenues for the three and nine months ended September 30, 2003 were \$163,000 and \$454,000, as compared to \$22,566,000 and \$25,321,000 during the comparable 2002 periods. Revenues for 2003 were comprised entirely of direct Kerastick(R) product sales to physicians as compared to \$51,000 and \$157,000 of product sales and rental income in the three and nine months ended September 30, 2002. The increase in 2003 product sales revenue is due in part to DUSA's receipt of 100% of revenues on Kerastick(R) units sold to end-users primarily through our distributor, Moore Medical Corporation, as compared to approximately 30% of the net sales that we received as a royalty under our former collaboration agreement during 2002. Total revenues for the three and nine month periods in 2002 also included research grant and milestone revenues of \$21,321,000 and \$22,312,000, and research and development reimbursement of \$1,194,000 and \$2,851,000 that we earned under our collaboration agreement with our former marketing and development partner. As discussed above, research grant

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

and milestone revenue for the three and nine-month periods ended September 30, 2002 includes \$20,990,000 as a result of the termination of the Schering AG collaboration.

As of September 30, 2003, 360 BLU-U(R) units were in place in physicians offices, up from 323 units at June 30, 2003 and 329 units at December 31, 2002. Kerastick(R) sales to end-users were 1,938 and 5,694 for the three and nine months ended September 30, 2003, as compared to 1,392 and 5,394 for the comparable 2002 periods. Although the level of Kerastick(R) sales to end-users for the current periods are higher than those in the prior year periods, Kerastick(R) sales continue to be at insignificant levels as we continue to develop an infrastructure to support marketing and sales activities and implement our own marketing strategy. See "Marketing and Sales Costs."

16

COST OF PRODUCT SALES AND ROYALTIES - Cost of product sales and royalties for the three and nine months ended September 30, 2003 were \$887,000 and \$2,465,000, respectively, as compared to \$3,241,000 and \$4,696,000 in 2002. A summary of the components of cost of product sales and royalties is provided below:

| THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED) (DOLLARS IN 000's) | | | | NINE MONTHS ENDED SEPTEMBER 30, (UNAUDITED) (DOLLARS IN 000's) | | |
|---|---------|------------------------|--|--|----------|------------------------|
| 2003 | 2002 | INCREASE (DECREASE) | | 2003 | 2002 | INCREASE (DECREASE) |
| ----- | ----- | ----- | | ----- | ----- | ----- |
| | | | Product costs including internal costs (e.g. customer service, quality assurance, purchasing, and other product support operations) assigned to support products (1) | \$ 1,905 | \$ 992 | \$ 913 |
| \$ 722 | \$ 357 | \$ 365 | | | | |
| 96 | 66 | 30 | Depreciation on BLU-U(R) units | 337 | 266 | 71 |
| | | | Costs incurred to ship, install and service the BLU-U(R) in physicians offices | 169 | 345 | (176) |
| 51 | 53 | (2) | | | | |
| 18 | 16 | 2 | Royalty and supply fees (2) | 54 | 48 | 6 |
| - | 84 | (84) | Net underutilization costs (3) | - | 267 | (267) |
| - | 27 | (27) | Deferred charges amortization (4) | - | 140 | (140) |
| | | | Inventory and deferred charge adjustments resulting from collaboration termination | - | 2,638 | (2,638) |
| - | 2,638 | (2,638) | | | | |
| ----- | ----- | ----- | | ----- | ----- | ----- |
| \$ 887 | \$3,241 | \$ (2,354) | Total cost of product sales and royalties | \$ 2,465 | \$ 4,696 | \$ (2,231) |
| ===== | ===== | ===== | | ===== | ===== | ===== |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

- 1) 2003 includes costs to support DUSA's manufacturing facility including submission of the FDA supplement and depreciation.
- 2) Royalty and supply fees are paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario.
- 3) Underutilization costs commenced in 2001 and were fully amortized as of December 31, 2002 based on agreements with our third-party manufacturers due to orders falling below certain previously anticipated levels.
- 4) Deferred charges amortization 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.

As discussed above, cost of product sales and royalties for the three and nine months ended September 30, 2002 included \$2,638,000 as a result of the termination of the Schering AG collaboration.

17

RESEARCH AND DEVELOPMENT COSTS - Research and development costs for the three and nine month periods ended September 30, 2003 were \$1,202,000 and \$4,167,000, as compared to \$2,848,000 and \$9,320,000 in the comparable 2002 periods. The research and development costs for 2002 include the write-off of \$639,000 of previously deferred royalty costs as a result of the termination of the Schering AG collaboration. The overall lower level of research and development costs in 2003 is also attributable to the absence of costs for co-sponsored projects that were developed in collaboration in 2002 and previously reimbursed to us by our former marketing partner. Co-sponsored projects included Phase I/II studies using Levulan(R) PDT in the treatment of persistent plantar warts and onychomycosis (nail fungus). These projects have been delayed as we concentrate on increasing sales, and implementing a new dermatology development program focused on indications that use our approved Kerastick(R). Based on market research that was completed earlier in 2003, we decided to move forward with Phase II studies for use of Levulan(R) PDT in photo-damaged skin and acne rather than pursuing a broad area actinic keratoses (BAAK) treatment, as we do not believe this indication would have a major impact on sales. We have also received market clearance from the FDA on a Section 510(k) premarket notification application for use of the BLU-U(R) without Levulan(R) PDT, to treat moderate inflammatory acne. The development program also includes completing an FDA-mandated Phase IV long-term AK tracking study, which should be completed by the end of 2003, and funding of various investigator studies involving the Kerastick(R).

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 twelve months of follow-up data in four patients, and six months in one patient, showed a continued complete ablation of high-grade dysplasia. The treatment has been well tolerated, with no occurrence of strictures (circumferential scarring), and no signs of mucosal overgrowth. In addition, in preparation for a Phase II clinical trial, we are planning to carry out a small single-center pilot Phase II clinical trial using DUSA's new proprietary light delivery device for the treatment of high grade dysplasia. However, currently, we do not plan to fund other Phase II or III clinical trials for this indication. While our original

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

goal had been to complete a partnership agreement during 2003, it does not appear that we will have a signed partnership in place by the end of 2003. 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 and nine month periods ended September 30, 2003 were \$535,000 and \$1,599,000, respectively. In the prior year, there were no marketing and sales expenses incurred directly by us as all rights and activities associated with marketing and sales of our products were the sole responsibility of our 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 our products. In addition, as of January 1, 2003, we reassigned resources that were functioning in research and development roles to our marketing and sales function. In August 2003, DUSA hired an Associate Vice President of Sales, and in October 2003 we hired, trained, and deployed a regional sales force designed to focus on most of our key geographic markets in the United States. This sales organization is initially comprised of six direct representatives, five independent representatives, and

18

an independent sales distributor with seven representatives. With success, DUSA plans to further expand these sales channels in 2004.

GENERAL AND ADMINISTRATIVE COSTS - General and administrative costs for the three and nine month periods ended September 30, 2003 were \$1,627,000 and \$4,782,000, respectively, as compared to \$1,411,000 and \$4,105,000 in comparable 2002 periods. These increases are attributable to higher legal expenses amounting to \$814,000 and \$2,400,000 during the current three and nine month periods, as compared to \$596,000 and \$1,346,000 in the comparable 2002 periods, due primarily to patent defense costs. Such patent defense issues are discussed below. It is expected that legal expenses will remain at elevated levels as long as these patent disputes continue. These increased legal expenses were offset, slightly, by lower staffing costs in 2003, due primarily to employee separations during 2002.

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 certain activities of PhotoCure and its marketing partner, Galderma S.A, infringe the patent. The case is ongoing and we are unable to predict the outcome at this time. DUSA believes that the final hearing in the Federal Court of Australia will occur in 2004.

In March 2003, we received notice that our Dutch patent is being formally challenged by an anonymous agent, and we filed a formal response to the opposition. The Dutch patent office has informed us that our amended patent claim is valid; however, the opposing party has the right to appeal the decision.

INTEREST INCOME, NET - Interest income, net for the three and nine month periods ended September 30, 2003 was \$409,000 and \$1,502,000, respectively, as compared to \$696,000 and \$2,255,000 in the comparable 2002 periods. These decreases were attributable to lower 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 used to

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

support our operating activities. During the three and nine month periods ended September 30, 2003, interest expense associated with the construction of our Kerastick(R) manufacturing facility of \$1,000 and \$36,000 was capitalized in property, plant and equipment in the Condensed Consolidated Balance Sheet. We capitalized interest expense of \$29,000 in the three and nine-month periods ended September 30, 2002.

NET INCOME (LOSS) - For the three and nine months ended September 30, 2003, the Company incurred net losses of (\$3,680,000), or (\$0.26) per share, and (\$11,057,000), or (\$0.79) per share, respectively, as compared to net income of \$15,761,000, or \$1.13 per share, and \$9,456,000, or \$0.68 per share, respectively, for the comparable three and nine-month periods ended September 30, 2002. As a result of the termination of the Schering AG agreement, net income for both prior periods included \$17,713,000 of income from operations that was based on the one-time recognition of certain items on its Consolidated Condensed Balance Sheets. (See section entitled "Overview -

19

2002 Collaboration Termination".) This one-time recognition resulted in an increase to earnings per share of \$1.28 for both prior year three and nine-month periods. Net losses are expected to be incurred until the successful market penetration of our first products occurs. Such losses may increase until end-user sales offset the cost of launching our sales force and other marketing initiatives.

LIQUIDITY AND CAPITAL RESOURCES

We are in a strong cash position to continue to increase Levulan(R) PDT marketing expenses, and to fund our current research and development activities for our Levulan(R) PDT/PD platform. Our primary sources of working capital have been public and private equity financings, as well as research milestone and grant payments from our former marketing and development partner. At September 30, 2003, we had \$41,612,000 of available cash resources comprised of \$3,644,000 of cash and cash equivalents, and United States government securities of \$37,968,000. All of our United States government securities are classified as available for sale.

As of September 30, 2003, our working capital (total current assets minus total current liabilities) was \$41,165,000 as compared to \$52,346,000 as of December 31, 2002. Total current assets decreased \$12,058,000 as of September 30, 2003 compared to December 31, 2002 due primarily to a decline in cash, cash equivalents, and United States government securities of \$11,268,000 as we use cash to support our operating activities. Total current liabilities decreased \$878,000 as of September 30, 2003 compared to December 31, 2002 due primarily to a decline in other accrued expenses of \$904,000 as higher 2002 accruals for research and development costs, product related costs and license milestone were paid in 2003.

For the nine months ended September 30, 2003, we used \$9,848,000 of cash for operating activities, purchased \$400,000 of property and equipment, and received \$7,000,000 of net proceeds from maturations and purchases of United States government securities. During the current period, we also made payments on long-term debt of \$203,000, while receiving \$29,000 in stock options proceeds. During the comparable 2002 nine-month period, we used \$9,175,000 of cash for operating activities, purchased \$2,307,000 of property and equipment primarily attributed to the construction of our manufacturing facility, and received net proceeds of \$4,852,000 from maturations and purchases of United States government securities. During June 2002, we also received a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

construction of our manufacturing facility. We made payments on this loan of \$45,000 in the 2002 period. As of September 30, 2003, the total outstanding loan balance was \$1,585,000, 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. 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. The current interest rate on the Note is 2.755% based on the annual renewal on June 30, 2003. As this rate was lower than the yield being generated by each of our United States government securities at that time, we decided not to repay the loan.

20

We believe that we have sufficient capital resources to proceed with our current 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.

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 also implementing a development program focused on dermatology indications that use our approved Kerastick(R). See "Research and Development Costs."

We anticipate that the level of marketing and sales expense will increase following the hiring of a senior sales executive in August 2003, and the initial small sales force in October 2003. We may also 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, for the balance of the year, we are focusing primarily on increasing the sales of the Levulan(R) Kerastick(R) and the BLU-U(R), planning and/or initiating Phase II studies for use of Levulan(R) PDT in photo-damaged skin and acne, 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 sales we receive.

CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

There have been no material changes to our contractual obligations and other commercial commitments from those presented in our Annual Report on Form 10-K for the year ended December 31, 2002.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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

INFLATION

21

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 United States 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 long-term instruments with maturities, 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.

We currently have exposure to interest rate risk under a secured term loan promissory note which we issued to fund the construction of our manufacturing facility. This loan currently bears interest at a LIBOR-based rate, and calls for an annual renewal on June 30th of each year through June 30, 2009 to either the applicable LIBOR-based rate or a one-time conversion to a fixed rate loan. On June 30, 2003, the loan rate was reduced to the then current 360-day LIBOR-based rate of 2.755%. Our exposure to interest rate risk due to changes in LIBOR is not expected to be material.

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 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 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.

22

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

As of September 30, 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/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 September 30, 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, improving reimbursement levels, expectations for continuing operating losses, expectations of increasing staff and our sales force, timing of Phase II photo-damaged skin and acne studies, effects of unanticipated changes in estimates, technology and forecasts, belief concerning reasonableness of inventory values, factors which could trigger impairment review, effect of an accounting change for stock-based compensation, expectations for the use of our facility to manufacture Kerasticks(R) and other clinical supplies, beliefs concerning the decrease in revenues and decision not to pursue the BAAK indication, plans to initiate marketing of the BLU-U(R) for moderate inflammatory acne vulgaris, plans to conduct additional clinical trials for high-grade dysplasia and consummation of any partnerships for high-grade dysplasia, expectations for increased marketing and sales costs and elevated levels of legal fees, beliefs regarding The Netherlands and Australian patent litigation, expectations regarding levels of interest income and net losses, requirements of cash resources, and potential impact on conversion of government securities, need for additional funds for development, evaluation of transactions under new 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 FDA approval and market acceptance of our products, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by additional 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.

23

PART II- OTHER INFORMATION

Items 1, 3-5.

None.

Item 2. Changes in Securities and Use of Proceeds.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

- i) On June 15, 2003, DUSA granted 11,666 shares of unregistered common stock, without par value, to an outside consultant for compensation of services in reliance on Section 4(2) of the Securities Act of 1933, as amended. Such shares were issued in July 2003.

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

- i) Exhibits
 - a) Exhibit 31.1 - Sarbanes-Oxley Section 302(a) Certification.
 - b) Exhibit 32.1 - Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - c) Exhibit 99.1 - Press Release dated November 13, 2003.
- ii) Form 8-K
 - a) Form 8-K dated and filed September 11, 2003 noting receipt of 510(k) marketing clearance from the United States Food and Drug Administration for the BLU-U(R) to treat dermatological indications and specifically, moderate inflammatory acne vulgaris.

24

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
(Principal Executive Officer), and Chief
Financial Officer (Principal Financial
Officer)

Date: November 13, 2003

By: /s/ Peter M. Chakoutis

Peter M. Chakoutis
Controller (Principal Accounting Officer)

EXHIBIT INDEX

- 31.1 Sarbanes-Oxley Section 302(a) Certification.
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350 as Adopted to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99.1 Press Release dated November 13, 2003.

