DUSA PHARMACEUTICALS INC
Form 10-Q
August 03, 2005

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

(Mark One)

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

For the quarterly period ended June 30, 2005

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 incorporation or organization) | (I.R.S. Employer Identification No.) |

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

(978) 657-7500
(Registrant's telephone number, including area code)

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

Yes [X] No [_]

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 13 or 15(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:

16,923,697 shares as of August 1, 2005

PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS.

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

| | JUNE 30 2005 (UNAUDITE |
|---|---|
| ASSETS | |
| CURRENT ASSETS | |
| Cash and cash equivalents | $ 1,443 |
| Marketable securities | 37,217 |
| Accrued interest receivable | 505 |
| Accounts receivable, net | 630 |
| Inventory, net | 2,384 |
| Prepaids and other current assets | 1,141 |
| TOTAL CURRENT ASSETS | 43,323 |
| Restricted cash | 140 |
| Property, plant and equipment, net | 3,374 |
| Deferred charges and other assets | 252 |
| TOTAL ASSETS | $ 47,092 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | |
| CURRENT LIABILITIES | |
| Accounts payable | $ 602 |
| Accrued compensation | 884 |
| Other accrued expenses | 1,747 |
| Deferred revenue | 352 |
| TOTAL CURRENT LIABILITIES | 3,586 |
| Other liabilities | 198 |
| TOTAL LIABILITIES | 3,785 |
| COMMITMENTS AND CONTINGENCIES (NOTE 9) | |
| 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: | |

| | |
|---|---|
| 16,923,697 and 16,876,822 shares of common stock, no par, at June 30, 2005 and December 31, 2004, respectively | 124,882 |
| Additional paid-in capital | 2,035 |
| Accumulated deficit | (83,696 |
| Accumulated other comprehensive income | 84 |
| TOTAL SHAREHOLDERS' EQUITY | 43,306 |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | $ 47,092 |

See the accompanying Notes to the Condensed Consolidated Financial Statements.



DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | THREE MONTHS ENDED JUNE 30, (UNAUDITED) | | |
|---|---|---|---|
| | 2005 | 2004 | |
| REVENUES | | | |
| Kerastick (R) Product Revenues, net | $ 1,766,029 | $ 1,303,833 | $ |
| BLU-U (R) Product Revenues, net | 462,087 | 872,195 | |
| PRODUCT REVENUES, NET | $ 2,228,116 | $ 2,176,028 | $ |
| KERASTICK (R) COST OF PRODUCT REVENUES AND ROYALTIES | 846,285 | 489,241 | |
| BLU-U (R) COST OF PRODUCT REVENUES | 624,243 | 579,470 | |
| COST OF PRODUCT REVENUES AND ROYALTIES | 1,470,528 | 1,068,711 | |
| TOTAL MARGIN | 757,588 | 1,107,317 | |
| OPERATING COSTS | | | |
| Research and development | 1,799,149 | 1,577,294 | |
| Marketing and sales | 2,295,914 | 1,699,145 | |
| General and administrative | 1,841,239 | 2,402,546 | |
| TOTAL OPERATING COSTS | 5,936,302 | 5,678,985 | |
| LOSS FROM OPERATIONS | (5,178,714) | (4,571,668) | |
| OTHER INCOME | | | |
| Interest income, net | 352,596 | 375,581 | |
| NET LOSS | $ (4,826,118) | $ (4,196,087) | $ |

| | | | |
|---|---|---|---|
| BASIC AND DILUTED NET LOSS PER COMMON SHARE | $ (0.29) | $ (0.25) | $ |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | 16,921,318 | 16,727,111 | |

See the accompanying Notes to the Condensed Consolidated Financial Statements.



DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | SIX 2005 (UNAUDI |
|---|---|
| CASH FLOWS FROM OPERATING ACTIVITIES | |
| Net loss | $ (9,15 |
| Adjustments to reconcile net loss to net cash used in operating activities: | |
| Amortization of premiums and accretion of discounts on marketable securities available-for-sale, net | 30 |
| Realized gain on sale of marketable securities available-for-sale | ( |
| Depreciation and amortization expense | 52 |
| Issuance of stock options to consultants | |
| Stock-based compensation | 1 |
| Changes in other assets and liabilities impacting cash flows from operations: | |
| Accrued interest receivable | 13 |
| Accounts receivable | 8 |
| Inventory | (96 |
| Prepaids and other current assets | (31 |
| Accounts payable | (25 |
| Accrued compensation and other accrued expenses | (23 |
| Deferred revenue | 12 |
| Other liabilities-non current | |
| CASH USED IN OPERATING ACTIVITIES | (9,73 |
| CASH FLOWS FROM INVESTING ACTIVITIES | |
| Purchases of marketable securities | (24,09 |
| Proceeds from maturities and sales of marketable securities | 32,55 |
| Restricted cash | |
| Purchases of property, plant and equipment | (39 |
| CASH PROVIDED BY INVESTING ACTIVITIES | 8,06 |
| CASH FLOWS FROM FINANCING ACTIVITIES | |
| Issuance of common stock (net of stock offering costs of $200,202) | |

| | |
|---|---|
| Proceeds from exercise of options | 18 |
| Payments of long-term debt | |
| CASH PROVIDED BY FINANCING ACTIVITIES | 18 |
| INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | (1,48 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 2,92 |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | $ 1,44 |

On March 2, 2004, the Company issued 135,000 shares of its common stock in a private placement at $11.00 per share as commission and non-refundable retainer to the placement agent, and an additional 20,250 shares on April 14, 2004 with respect to the exercise of the additional investment rights, for a total value of $1,707,750.

See the accompanying Notes to the Condensed Consolidated Financial Statements.



DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheets as of June 30, 2005 and December 31, 2004, Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2005 and 2004, and Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2005 and 2004 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, 2004 audited consolidated financial statements and notes thereto. Certain amounts for 2004 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) MARKETABLE SECURITIES

The Company's marketable securities consist of securities of the United States government and its agencies and corporate bonds, all classified as available-for-sale. As of June 30, 2005, current yields range from 2.53% to 7.60% and maturity dates range from July 15, 2005 to June 15, 2008. The estimated fair value and cost of marketable securities at June 30, 2005 and December 31, 2004 are as follows:

| | JUNE 30, 2005 (UNAUDITED) | | |
|---|---|---|---|
| | AMORTIZED COST | GROSS UNREALIZED GAINS | GROSS UNREALIZED LOSSES |
| United States government securities | $ 22,002,290 | $ 132,685 | $ (23,288 |
| Corporate securities | $ 15,130,094 | $ 9,894 | $ (34,519 |
| Total marketable securities available-for-sale | $ 37,132,384 | $ 142,579 | $ (57,807 |



DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

| | DECEMBER 31, 2004 | | |
|---|---|---|---|
| | AMORTIZED COST | GROSS UNREALIZED GAINS | GROSS UNREALIZED LOSSES |
| United States government securities | $ 27,266,271 | $ 389,585 | $ (15,315 |
| Corporate securities | 18,625,317 | 504 | (43,393 |
| Total marketable securities available-for-sale | $ 45,891,588 | $ 390,089 | $ (58,708 |

The change in net unrealized gains and losses on such securities for the three and six months ended June 30, 2005 were $(18,793) and $(246,609), respectively, as compared to $(568,750) and $(716,409) for the three and six months ended June 30, 2004. These amounts have been recorded in accumulated other comprehensive income, which is reported as part of shareholder's equity in the Condensed Consolidated Balance Sheets.

3) CONCENTRATION OF CREDIT RISK

The Company is exposed to concentration of credit risk related to accounts receivable that are generated from its distributors and other customers. To manage credit risk, the Company performs regular credit evaluations of its customers' financial condition and provides allowances for potential credit losses, when applicable. Concentrations of credit risk in the Company's total revenues for the three and six months ended June 30, 2005 and 2004, and accounts receivable as of June 30, 2005 and December 31, 2004 are as follows:

| | % OF REVENUE | | % OF REVENUE | | % OF ACCOUNTS |
|---|---|---|---|---|---|
| | THREE-MONTHS ENDED (UNAUDITED) | | SIX-MONTHS ENDED (UNAUDITED) | | AS OF |
| | JUNE 30, 2005 | JUNE 30, 2004 | JUNE 30, 2005 | JUNE 30, 2004 | JUNE 30, 2005 (UNAUDITED) |
| Third-party distributor A | 19% | 25% | 16% | 30% | 8% |
| Third-party distributor B | - | 19% | - | 23% | - |
| Third-party distributor C | 17% | 12% | 15% | 8% | 44% |



DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

4) INVENTORY

Inventory consisted of the following:

| | JUNE 30, 2005 (UNAUDITED) | DECEMBER 31, 2004 |
|---|---|---|
| Finished goods | $ 1,686,690 | $ 1,226,071 |
| Work in process | 284,654 | 85,910 |
| Raw materials | 413,231 | 105,179 |
| | $ 2,384,575 | $ 1,417,160 |

5) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

| | JUNE 30, 2005 (UNAUDITED) | DECEMBER 31, 2004 |
|---|---|---|
| Research and development costs | $ 501,475 | $ 778,926 |
| Marketing and sales costs | 198,246 | 153,167 |
| Product related costs | 295,443 | 261,444 |
| Legal and other professional fees | 363,343 | 374,142 |
| Employee benefits | 290,891 | 229,304 |
| Other expenses | 97,645 | 104,858 |

| | |
|---|---|
| $ 1,747,043 | $ 1,901,841 |

6) ACCOUNTING FOR STOCK-BASED COMPENSATION

SFAS No. 123, as amended by SFAS No. 148, 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, as amended by SFAS No. 148. Under the intrinsic value method, compensation expense, if any, is recognized for the difference between the exercise price of the option and the fair value of the underlying common stock as of a measurement date. The measurement date is the time when both the number of shares and the exercise price is known. 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, as amended by SFAS No. 148, and EITF No. 96-18, 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 measurement date, which is generally the grant date. The resulting compensation cost is recognized and charged to operations over the service period, which is generally the vesting period.





In March 2005, the vesting period for 18,875 options to purchase shares of common stock was extended beyond the original terms and the vesting of 1,250 options was accelerated upon an employee's termination. As a result of this stock option modification, the Company recorded compensation expense of approximately $19,000 during the six months ending June 30, 2005. The compensation expense was calculated using the intrinsic value method, which compares the common stock option exercise price to the fair market value of the underlying common stock on the date of modification. The stock compensation expense was recorded as part of general and administrative costs in the Condensed Consolidated Statement of Operations.

As described above, the Company uses the intrinsic value method to measure compensation expense associated with grants of stock options to employees. Had the Company used the fair value method to measure compensation, the Company's pro forma net loss, and pro forma net loss per share for the three and six months ending June 30, 2005 and 2004 would have been as follows:

| | THREE MONTHS ENDED JUNE 30, (UNAUDITED) | |
|---|---|---|
| | 2005 | 2004 |

| | | | |
|---|---|---|---|
| NET LOSS | | | |
| As reported | $ (4,826,118) | $ (4,196,087) | $ |
| Effect on net loss if fair value method had been used | (758,427) | (779,453) | |
| Pro forma | $ (5,584,545) | $ (4,975,540) | $ |
| BASIC AND DILUTED NET LOSS PER COMMON SHARE | | | |
| As reported | $ (0.29) | $ (0.25) | $ |
| Effect on net loss per common share if fair value method had been used | (0.04) | (0.05) | |
| Pro forma | $ (0.33) | $ (0.30) | $ |

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS Statement No. 123(R), "Share-Based Payment," ("123(R)") a revision of SFAS Statement No. 123, which will impact the accounting for employee stock options and other equity-based compensation. The standard requires companies to measure and recognize compensation expense for all stock-based payments at fair value. The adoption of SFAS No. 123(R) will not affect the Company's cash flows, but it will affect the Company's net income (loss) and net income (loss) per share. In accordance with SFAS Statement No.123(R) and the Securities and Exchange Commission's recent ruling that defers the required effective date of adoption, the Company will recognize the expense attributable to stock awards that are granted or vest in periods subsequent





to December 31, 2005. As noted above, had the Company expensed its employee stock options under SFAS No. 123 for the three and six months ended June 30, 2005, net loss and net loss per share would have increased by approximately $758,000, or $0.04 per share and $1,081,000, or $0.07 per share, respectively. As stock award grants are determined throughout each year, the increase or decrease in stock compensation expense as a result of adoption of SFAS No. 123(R) cannot be predicted with certainty.

7) BASIC AND DILUTED NET LOSS PER COMMON SHARE

Basic net loss per common share is based on the weighted-average number of shares outstanding during each period. For the periods ended June 30, 2005, and 2004, stock options, warrants and rights totaling approximately 3,490,000 and 3,083,000 shares, respectively, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive.

8) COMPREHENSIVE LOSS

For the three and six months ended June 30, 2005 and 2004, comprehensive loss consisted of the following:

| | THREE MONTHS ENDED | SIX |
|---|---|---|

| | JUNE 30, (UNAUDITED) | | (U |
|---|---|---|---|
| | 2005 | 2004 | 2005 |
| NET LOSS | $ (4,826,118) | $ (4,196,087) | $ (9,157,7 |
| Change in net unrealized gains and losses on marketable securities available-for-sale | (18,793) | (568,750) | (246,6 |
| COMPREHENSIVE LOSS | $ (4,844,911) | $ (4,764,837) | $ (9,404,3 |

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

9) 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 being challenged by PhotoCure ASA. PhotoCure ASA filed a lawsuit in Australia alleging that Australian Patent No. 624985, which is one of the patents relating to the Company's 5-aminolevulinic acid technology, is





invalid. As a consequence of this action, Queen's University assigned the Australian patent to the Company so that DUSA could participate directly in this litigation. The Company filed a response setting forth its defenses, and a related countersuit alleging that certain activities of PhotoCure and its marketing partner, Galderma S.A., infringed the patent. The final hearing in the Federal Court of Australia was held in April 2004. On April 6, 2005, the Federal Court of Australia ruled that the Australian patent is valid and remains in full force and effect. However, the Court also ruled that PhotoCure's product, Metvix, does not infringe the claims in the Australian patent. Since these claims are unique to the Australian patent and Australian law differs from patent law in other jurisdictions, the Company does not expect this ruling to be determinative of the validity of any other patents licensed by DUSA from Queen's University or of whether PhotoCure's product infringes claims in such other patents, including the United States patent. As DUSA does not have an active drug application in Australia, DUSA believes that this ruling will have no operational impact on the Company. None of the parties have appealed the decision and the date to do so has expired. The parties signed a Mediation Agreement in August 2004 to attempt to settle their disputes and those discussions are ongoing.

In December 2004, the Company filed a lawsuit against New England Compounding Pharmacy, Inc. of Framingham, Massachusetts alleging violations of U.S. patent law in the United States District Court in Boston, Massachusetts. On March 17, 2005, New England Compounding Pharmacy filed an answer against us, including a defense that our patents are invalid and several counterclaims against us, and we filed our response on April 5, 2005. The parties are now in

the discovery stage of this litigation and we are unable to predict the outcome of this lawsuit at this time. A tentative trial date has been set by the Court for January 2007. We are seeking injunctive relief, monetary damages and costs. In January 2005, the Company filed a lawsuit against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement, and of U.S. patent law in the U.S. District Court for the District of Arizona. A motion for default judgment was granted on July 25, 2005 in our favor for failure of The Cosmetic Pharmacy of Tucson to appear, together with injunctive relief and attorney fees and costs in the amount of approximately $20,000. While we also believe that certain actions of these pharmacies go beyond the activities which are permitted under the Food, Drug and Cosmetic Act and have advised the FDA and local health authorities of our concerns, we cannot be certain that our lawsuits will be successful in curbing the practices of these pharmacies or that regulatory authorities will intervene to stop their activities which we believe may be having a negative impact on our business.

The Company has not accrued any amounts for these contingencies as of June 30, 2005 as these amounts are neither probable nor estimable.

10) SUBSEQUENT EVENTS

On July 29, 2005, the Company signed an amendment to its existing supply agreement with Sochinaz S.A, the bulk supplier of the active ingredient in Levulan(R). This amendment





extends the agreement through December 31, 2009, with an option to extend for an additional one year, and amends certain pricing and purchasing terms.

As a consequence of slower revenue growth than previously anticipated, the Company reduced its corporate staff, across all departments, by 14 persons and consolidated two sales territories, effective July 29, 2005.



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, which is used in combination with appropriate light devices in order to detect or treat a variety of medical conditions. The trademark for our brand of ALA is Levulan(R). When Levulan(R) is used and followed with exposure to light to produce a therapeutic effect, the technology is called photodynamic therapy, or PDT. When Levulan(R) is used and followed with exposure to light to detect medical conditions, the technology is called photodetection, or PD. Our products are Levulan(R) 20% topical solution using our Kerastick(R) brand applicator, and our BLU-U(R) brand light unit. Our products are used together to provide PDT for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp. In addition, the BLU-U(R) is used without Levulan(R) for the treatment of

moderate inflammatory acne vulgaris and general dermatological conditions. Both products have received approval or market clearance as required from the United States Food and Drug Administration ("FDA") and regulatory approval from Health Canada. We are currently conducting clinical trials to test whether our products can be used to treat both photodamaged skin and acne with Levulan(R) PDT.

Since the October 2003 launch of our sales force, sales and revenues of our products have increased substantially, although sales for the three months ended June 30, 2005 were disappointing as compared to the preceding quarter ended March 31, 2005 for reasons described below. Kerastick(R) unit sales to end-users were 20,172 and 48,876 for the three and six-month periods ended June 30, 2005, respectively, including 3,666 and 7,470, respectively, sold by Coherent-AMT, our Canadian marketing and distribution partner. This represents an increase from 17,910 and 29,964 Kerastick(R) units sold in the three and six-month periods ended June 30, 2004, respectively, including 1,908 sold by Coherent-AMT all sold in the second quarter of 2004.

The net number of BLU-U(R) units placed in doctors' offices during the three months ended June 30, 2005 was 72, including 24 placed in Canada. As of June 30, 2005 there were 1,117 units in doctor's offices, consisting of 961 in the United States and 156 in Canada. There were 914 BLU-U(R) units in doctors' offices at December 31, 2004, consisting of 813 in the United States and 101 in Canada.

We have continued our efforts to penetrate the market by implementing targeted sales efforts in key geographic locations. As of June 30, 2005, our direct sales force consisted of 31 employees, including representatives and management, compared to 22 at the end of 2004. See section entitled "Results of Operations - Marketing and Sales Costs." Despite our disappointment with sales volumes for the quarter ended June 30, 2005, we are encouraged by both the increases in sales on a year-to-date basis and the positive feedback we continue to receive from doctors across the country that believe Levulan PDT should become a routine part



of standard dermatological practice. During the quarter ended June 30, 2005, 738 customers in the United States ordered Kerastick(R) units, of which approximately 70% were existing customers and 30% were new customers, as compared to approximately 1,600 customers in the United States who ordered product during all of 2004. However, due to various factors, including, but not limited to a price increase which had been announced prior to its November 2004 effective date and certain volume discount programs which had been in place for much of 2004, we believe that physicians ordered more Kerastick(R) units than their usage necessitated at that time. We also experienced a disruption of the sales force related to the addition of 11 new sales employees during the first 4 months of 2005 and the implementation of a more focused sales strategy from a more opportunistic approach to selling. In addition, efforts by compounding pharmacies may be having a negative impact on our sales. We believe that as a result of these conditions approximately 45% of our top 114 volume customers from 2004 have not yet reordered Kerastick(R) units in 2005, and, in some cases, may still be working down their supplies through the remainder of the year.

Historically, we have primarily devoted our resources to fund research and development efforts in order to advance the Levulan(R) PDT/PD technology platform and, as a result, we have experienced significant operating losses. As of June 30, 2005, we had an accumulated deficit of approximately $83,700,000. We expect to continue to incur operating losses until sales of our products increase substantially. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our therapy by the medical and consumer constituencies, and our ability to develop and/or acquire new

profitable products.

We believe that issues related to reimbursement have negatively impacted the economic competitiveness of our therapy with other AK therapies and have hindered its adoption in the past. Effective January 1, 2005, the CMS average national reimbursement for the use of Levulan(R) PDT for AKs was increased, reflecting the cost of additional medical supplies that were not included in the original application. However, a change in 2005 to the way the drug is reimbursed, which is now based on the average selling price (ASP) rather than the average wholesale price (AWP), caused a decrease in the amount reimbursed for the Kerastick(R). Reimbursement for the Kerastick(R) will vary from quarter to quarter, calculated as 106% of the ASP to the end-user during a prior quarter, including all discounts. As we have decreased our Kerastick(R) volume discount programs, reimbursement is expected to increase in future quarters. While we believe that 2005 reimbursement changes related to treatment of AK are positive overall for doctors using our therapy, some physicians still believe that even the new reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices. We continue to support ongoing efforts that might lead to further increases in reimbursement and intend to support efforts to seek reimbursement for our FDA-cleared use of the BLU-U(R) alone in the treatment of mild to moderate inflammatory acne.

In addition, we continue to work to educate private insurance carriers so that they will approve our therapy for coverage. Several of the major private insurers have approved coverage for our AK therapy. We believe that due to these efforts, along with our education and marketing programs, a more widespread adoption of our therapy should occur over time.



We have been encouraged by the positive response from many physicians and patients who have used our therapy, but we recognize that we have to continue to demonstrate the clinical value of our unique therapy, and the related product benefits as compared to other well-established conventional therapies, in order for the medical community to accept our products on a large scale. While our financial position is strong, we cannot predict when product sales may offset the costs associated with these efforts. We are aware that physicians have been using Levulan(R) with the BLU-U(R), and with light devices manufactured by other companies, for uses other than our FDA-approved use. While we are not permitted to market our products for so-called `off-label' uses, we estimate, based on limited in-house survey data, that these activities are positively affecting the sales of our products and may represent a greater percentage of our total sales than the usage of our products for treatment of AKs.

We are also aware that some compounding pharmacies may be exceeding the legal limits for their activities, including manufacturing and/or selling quantities of ALA in circumstances which may be inducing purchasers to infringe our intellectual property. These activities may be negatively impacting our sales growth. Therefore in December, 2004 and in January, 2005, we filed lawsuits against two compounding pharmacies. See "Part II, Item 1, Litigation."

As of June 30, 2005, our staff included 84 full-time employees and 4 part-time employees as compared to 65 full-time employees and 4 part-time employees at the end of 2004. These include marketing and sales, production, maintenance, customer support, and financial operations personnel, as well as those who support research and development programs for dermatology and internal indications. During the six-month period ended June 30, 2005, we increased the size of our sales force to 31 from 22 at the end of 2004. As a consequence of slower revenue growth than previously anticipated, we reduced our corporate staff, across all departments, by 14 persons and consolidated two sales territories, effective July 29, 2005. As a result of these actions, we expect

that we will reduce operating costs by $1.4 million on an annualized basis. We may add and/or replace employees during the balance of 2005 as business circumstances deem necessary.

We believe that DUSA is now much better positioned to take advantage of the market opportunities for Levulan(R) PDT in dermatology and other fields. With our strengthened management team, increased sales force, and a variety of educational and marketing initiatives, we anticipate continued year-over-year increases in sales going forward, although variability in quarterly growth rates at this early stage of the adoption curve is still to be expected. Now that we have a specialty dermatology sales force, we are also actively working on in-licensing and/or developing additional dermatology products; while continuing to work on out-licensing Levulan(R) PDT for dermatology in territories outside of North America.

During the quarter, we also received the Notice of Final Determination under the Hatch-Waxman Patent Term Extension Act, which will extend the term of our patent claims in United States Patent No. 5,079,262 with respect to actinic keratoses from July 2009 to September 2013.



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, 2004. Since all of these accounting policies do not require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting policies with our audit committee. We consider the following policies and estimates to be critical to our financial statements.

REVENUE RECOGNITION - Revenues on product sales are recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and collection is probable. Product sales made through distributors who have a general right of return of product have been recorded as deferred revenue until the product is sold by our distributors to the end user. Although we make every effort to assure the reasonableness of our estimates, significant unanticipated changes in our estimates due to business, economic, or industry events could have a material impact on our results of operations.

INVENTORY - Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method. Inventories are continually reviewed for slow moving, obsolete and excess items. Inventory items identified as slow-moving are evaluated to determine if an adjustment is required. Additionally, our industry is characterized by regular technological developments that could result in obsolete inventory. Although we make every effort to assure the reasonableness of our estimates, any significant unanticipated changes in demand, technological development, or significant changes to our business model could have a significant impact on the value of our inventory and our results of operations. We use sales projections to estimate the appropriate level of inventory reserves necessary at each balance sheet date.

VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS - We review long-lived assets 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 that we consider 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. At June 30, 2005, our total property, plant and equipment had a carrying value of $3,375,000, including $2,500,000 associated with our manufacturing facility. As of June 30, 2005, we had intangible assets totaling $174,000 recorded in deferred charges and other assets relating to the unamortized balance of payments made in 2004 to National Biological Corporation to amend our agreement to develop and manufacture



light sources, and to Draxis Health, Inc., our former parent, to reacquire our product rights in Canada.

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, "Accounting for Stock Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure". 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.

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R), "Share-Based Payment," a revision of SFAS No. 123, which will impact the accounting for employee stock options and other equity-based compensation. The standard requires companies to measure and recognize compensation expense for all stock-based payments at fair value. The adoption of SFAS No. 123(R) will not affect our cash flow, but it will affect our net income (loss) and net income (loss) per share. In accordance with the revised statement and the Securities and Exchange Commission's recent ruling that defers the required effective date of adoption, we will recognize the expense attributable to stock options that are granted or vest in periods subsequent to December 31, 2005. As described in Note 6 to the Notes to the Condensed Consolidated Financial Statements, had the Company expensed its employee stock options under SFAS No. 123 for the three and six months ended June 30, 2005, net loss and net loss per share would have increased by approximately $758,000, or $0.04 per share and $1,081,000, or $0.07 per share, respectively. As stock award grants are determined throughout each year, the increase or decrease in stock compensation expense as a result of the adoption of SFAS No. 123(R) cannot be predicted with certainty.



RESULTS OF OPERATIONS

REVENUES - Total revenues for the three and six-month periods ended June

30, 2005 were $2,228,000 and $5,597,000, respectively, as compared to $2,176,000 and $3,432,000 in the comparable periods in 2004, and were comprised of the following:

| | THREE MONTHS ENDED JUNE 30, (UNAUDITED) | | | |
|---|---|---|---|---|
| | 2005 | 2004 | INCREASE/ (DECREASE) | 2005 |
| KERASTICK(R) REVENUES | | | | |
| United States | $ 1,510,000 | $ 1,204,000 | $ 306,000 | $ 3,759,000 |
| Canada | 256,000 | 100,000 | 156,000 | 517,000 |
| Total | 1,766,000 | 1,304,000 | 462,000 | 4,276,000 |
| BLU-U(R) REVENUES | | | | |
| United States | $ 340,000 | $ 720,000 | $ (380,000) | $ 1,026,000 |
| Canada | 122,000 | 152,000 | (30,000) | 295,000 |
| Total | 462,000 | 872,000 | (410,000) | 1,321,000 |
| Total Revenues | $ 2,228,000 | $ 2,176,000 | $ 52,000 | $ 5,597,000 |

The increase in 2005 Kerastick(R) revenues was driven mainly by increased sales volumes. Kerastick(R) unit sales to end-users were 20,172 and 48,876 for the three and six-month periods ended June 30, 2005, respectively, including 3,666 and 7,470, respectively, sold by Coherent-AMT, our Canadian marketing and distribution partner. This represents an increase from 17,910 and 29,964 Kerastick(R) units sold in the three and six-month periods ended June 30, 2004, respectively, including 1,908 sold by Coherent-AMT all sold in the second quarter of 2004. The increase in revenues in 2005 is also attributable to our decision to increase our average unit selling price during the fourth quarter of 2004, increased levels of our direct distribution to customers by eliminating one of our distributors, and a reduction in our overall sales volume discount programs. In fact, our average net selling price for the Kerastick(R) increased to $87.48 for the first six months of 2005 from $73.39 for the first six months of 2004.

The increase in 2005 BLU-U(R) revenue on a year-to-date basis was driven by an increase in our average selling price to $6,187 for the six-month period ended June 30, 2005 from $3,747 for the six-month period ended June 30, 2004. In the three and six-month periods ended June 30, 2005, there were 69 and 212 units sold, respectively, versus 220 units and 329 units in the comparable 2004 periods. The 2005 total consists of 159 units sold in the United States and 53 sold in Canada by Coherent-AMT. The 2004 total consists of 281 sold in the United States and



48 sold in Canada. The decrease in BLU-U(R) units sold in the three and six-month periods ended June 30, 2005 compared to the same periods in 2004 is

due primarily to the implementation of a more focused sales strategy aimed at increasing Kerastick(R) sales volumes in existing accounts; as well as, a decrease in BLU-U(R) discounting programs.

The increase of both Kerastick(R) and BLU-U(R) revenues during 2005 is a result of the efforts of our sales force and related marketing and sales activities. With respect to United States Kerastick(R) sales, we increased the selling price in November 2004 and will continue to evaluate the market during the year. We have increased our direct selling and distribution efforts, while still maintaining the services of one external distributor, and we have reduced our overall sales volume discount programs, all of which have had a positive impact on our average selling prices during 2005. We also believe, however, that due to various factors mentioned above, during 2004 physicians ordered more Kerastick(R) units then their usage necessitated at that time. As a result, approximately 45% of our top 114 volume customers from 2004 have not ordered Kerastick(R) units during the first half of 2005 and, in some cases, may still be working down their supplies through the remainder of the year. We also experienced a disruption of the sales force related to the addition of 11 new sales employees during the first 4 months of 2005 and the implementation of a more focused sales strategy from a more opportunistic approach to selling. Although the level of Kerastick(R) sales to end-users for 2005 is higher than that in the prior year, sales volumes for three month period ended June 30, 2005 of 20,172 is lower than sales volumes for the preceding three month period ended March 31, 2005 of 28,704. Sales must increase significantly from these levels in order for us to become profitable. We remain confident that we are in a good position to exploit our therapy and that with a more focused sales strategy we will begin to deliver increasing revenue as we approach year end. For the balance of 2005, we have retained the services of a specialty device firm, on a commission basis, in order to increase sales of our products, in addition to the other strategic decisions described above.

COST OF PRODUCT REVENUES AND ROYALTIES - Cost of product revenues and royalties for the three and six-month periods ended June 30, 2005 were $1,471,000 and $3,474,000, respectively, as compared to $1,069,000 and $1,895,000 in the comparable periods in 2004. A summary of the components of cost of product revenues and royalties is provided below:

| | THREE MONTHS ENDE (UNAUDITE | |
|---|---|---|
| KERASTICK(R) COST OF PRODUCT REVENUES AND ROYALTIES | 2005 | 2004 |
| Direct Kerastick(R) Product costs | $ 389,000 | $ 346,0 |
| Other Kerastick(R) Product costs including internal costs assigned to support products | 359,000 | 79,0 |
| Royalty and supply fees (1) | 98,000 | 64,0 |
| Total Kerastick(R) cost of product revenues and royalties | $ 846,000 | $ 489,0 |



| | 2005 | 2004 |
|---|---|---|

| | | |
|---|---|---|
| BLU-U(R) COST OF PRODUCT REVENUES | | |
| Direct BLU-U(R) Product costs (2) | $ 238,000 | $ |
| Other BLU-U(R) Product costs including internal costs assigned to support products; as well as costs incurred to ship, install and service the BLU-U(R) in physicians offices | 387,000 | 580,0 |
| Total BLU-U(R) cost of product revenues | 625,000 | 580,0 |
| TOTAL COST OF PRODUCT REVENUES AND ROYALTIES | $ 1,471,000 | $ 1,069,0 |

| | SIX MONTHS ENDED (UNAUDITED | |
|---|---|---|
| | 2005 | 2004 |
| KERASTICK(R) COST OF PRODUCT REVENUES AND ROYALTIES | | |
| Direct Kerastick(R) Product costs | $ 969,000 | $ 579,0 |
| Other Kerastick(R) Product costs including internal costs assigned to support products | 630,000 | 241,0 |
| Royalty and supply fees (1) | 226,000 | 100,0 |
| Total Kerastick(R) cost of product revenues and royalties | $ 1,825,000 | $ 920,0 |

| | 2005 | 2004 |
|---|---|---|
| BLU-U(R) COST OF PRODUCT REVENUES | | |
| Direct BLU-U(R) Product costs (2) | $ 714,000 | $ |
| Other BLU-U(R) Product costs including internal costs assigned to support products; as well as costs incurred to ship, install and service the BLU-U(R) in physicians offices | 935,000 | 975,0 |
| Total BLU-U(R) cost of product revenues | 1,649,000 | 975,0 |
| TOTAL COST OF PRODUCT REVENUES AND ROYALTIES | $ 3,474,000 | $ 1,895,0 |

1) Royalty and supply fees reflect amounts paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, and amortization of an upfront fee and ongoing royalties paid to Draxis, DUSA's former parent, on sales of the Levulan(R) Kerastick(R) in Canada.

2) Although there were direct BLU-U(R) product revenues in 2004, there were no related direct BLU-U(R) product costs as these units had a zero book value due to inventory impairment charges recorded during 2002.



MARGIN - Total product margins for the three and six-month periods ended June 30, 2005 were $758,000 and $2,123,000, respectively, as compared to $1,107,000 and $1,537,000 in the comparable periods in 2004, as shown below:

| | THREE MONTHS ENDED JUNE 30, (UNAUDITED) | | | | |
|---|---|---|---|---|---|
| | 2005 | | 2004 | | INCREASE/ (DECREASE) |
| Kerastick(R) | $ 920,000 | 52% | $ 814,000 | 62% | $ 106,000 |
| BLU-U(R) | (162,000) | (35)% | 293,000 | 34% | (455,000) |
| Total Margin | $ 758,000 | 34% | $1,107,000 | 51% | $ (349,000) |

| | SIX MONTHS ENDED JUNE 30, (UNAUDITED) | | | | |
|---|---|---|---|---|---|
| | 2005 | | 2004 | | INCREASE/ (DECREASE) |
| Kerastick(R) | $2,451,000 | 57% | $1,279,000 | 58% | $1,172,000 |
| BLU-U(R) | (328,000) | (25)% | 258,000 | 21% | (586,000) |
| Total Margin | $2,123,000 | 38% | $1,537,000 | 45% | $ 586,000 |

Kerastick(R) margins for the three and six months ended June 30, 2005 were 52% and 57%, respectively, versus 62% and 58% for the comparable 2004 periods. We have been operating our Kerastick(R) manufacturing plant well below capacity, resulting in underutilization charges, which have negatively impacted margins. Due to this situation, we are realizing expected fluctuations in our margins as a result of both the timing of production and unabsorbed expenses. This has been somewhat offset by an increase in the overall selling price per unit. Our long-term goal is to achieve much higher margins on Kerastick(R) sales which will be significantly dependent on increased volume.

BLU-U(R) margins for the three and six months ended June 30, 2005 were (35%) and (25%), respectively, versus 34% and 21% for the comparable 2004 periods. The erosion on margin is directly attributable to the fact that in the first half of 2005 we sold newly purchased units with an associated production cost, whereas during the comparable 2004 period, we sold units which had a zero net book value due to inventory impairment charges recorded during 2002 following termination of an agreement with a marketing partner. The margin erosion is somewhat offset by an increase in the overall selling price per unit.

Our short-term strategy is to approach breakeven on device sales in an effort to drive Kerastick(R) sales volumes. However, our longer term goal is to move towards a reasonable profit margin on all device sales.



RESEARCH AND DEVELOPMENT COSTS -

Research and development costs for the three and six-month periods ended June 30, 2005 were $1,799,000 and $3,395,000, respectively, as compared to $1,577,000 and $3,265,000 in the comparable periods in 2004. We have commenced the efficacy phase of our Phase II photodamaged skin study and completed enrollment in the second of three cohorts of the Phase II multi-center acne study. We anticipate that we will have preliminary efficacy and safety data for both of the Phase II studies around year end 2005. As our Phase II clinical trials proceed, and especially at such time as we may commence Phase III trials in these indications, research and development expenses are expected to increase significantly. We have retained the services of a regulatory consultant to assist us with seeking foreign marketing approvals for our products, which could cause research and development expenses to increase.

We have also been following patients who completed Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett's esophagus. On September 27, 2004, DUSA signed a clinical trial agreement with the National Cancer Institute, Division of Cancer Prevention, or NCI DCP, for the clinical development of Levulan(R) PDT for the treatment of high-grade dysplasia within Barrett's Esophagus. In addition, to further our objectives concerning treatment of internal indications using Levulan(R) photodynamic therapy ("PDT"), on November 4, 2004 we signed an additional clinical trial agreement with the NCI DCP for the treatment of oral cavity dysplasia. DUSA and the NCI DCP are working together to prepare overall clinical development plans for Levulan(R) PDT in these indications, starting with Phase II trials, and continuing through Phase III studies, if appropriate. The immediate plan is for the NCI DCP to solicit clinical protocols from its extramural expert clinical investigator consortium, after which time DUSA and the NCI DCP will finalize the clinical trial designs. The NCI DCP will use its resources to file its own Investigational New Drug applications with the FDA. We will provide Levulan(R), device(s) and the necessary training for the investigators involved in the studies. We will maintain full ownership of our existing intellectual property, have options on new intellectual property and, subject to successful Phase II and III clinical trial results, intend to seek FDA approvals in due course. In preparation for new Phase II clinical trials for the treatment of high-grade dysplasia associated Barrett's esophagus, we are carrying out a small single-center pilot Phase II clinical trial using our new proprietary endoscopic light delivery device.

MARKETING AND SALES COSTS -

Marketing and sales costs for the three and six-month periods ended June 30, 2005 were $2,296,000 and $5,081,000, respectively, as compared to $1,699,000 and $3,067,000 in the comparable periods in 2004. These costs consist primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling $1,853,000 and $3,690,000 for the three and six-month periods ended June 30, 2005, compared to $1,277,000 and $2,292,000 in the comparable periods in 2004. These increases were mainly attributable to the expansion of our sales force from 16 employees as of June 30, 2004 to 31 employees as of June 30, 2005, including sales

management. The remaining expenses consist of tradeshows, miscellaneous marketing and outside consultants totaling $443,000 and $1,391,000 for the three and six-month periods ended June 30, 2005, compared to $422,000 and $775,000 for the comparable periods in 2004. We expect that our marketing and sales costs for the remainder of 2005 will continue to show an increase over comparable 2004 periods, reflecting the expansion of our sales capacity year over year, offset in part, by the resignation of our Vice President of Sales who we will not replace at this time.

GENERAL AND ADMINISTRATIVE COSTS -

General and administrative costs for the three and six-month periods ended June 30, 2005 were $1,841,000 and $3,524,000, respectively, as compared to $2,403,000 and $4,578,000 in the comparable periods in 2004. This decrease is mainly attributable to lower legal expenses of $619,000 and $1,038,000 incurred for the three and six-month periods ended June 30, 2005 as compared to $1,331,000 and $2,530,000 in the comparable periods in 2004, due to the absence of patent litigation costs in Australia as the final hearing in the PhotoCure litigation described below was held in April 2004. The savings related to the Australian litigation is partially offset by the on-going negotiations with PhotoCure and Galderma to try and settle remaining patent issues and litigation costs against two compounding pharmacies also described below, as well as higher levels of general corporate expenses to support our expanding business, including an increase in personnel related costs.

On April 12, 2002, we received notice that one of the patents licensed to DUSA by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario was being challenged by PhotoCure ASA. PhotoCure ASA filed a lawsuit in Australia alleging that Australian Patent No. 624985, which is one of the patents relating to our 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University assigned the Australian patent to us so that we could participate directly in this litigation. We filed a response 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 final hearing in the Federal Court of Australia was held in April 2004. On April 6, 2005, the Federal Court of Australia ruled that our Australian patent is valid and so it remains in full force and effect. However, the Court also ruled that PhotoCure's product, Metvix, does not infringe the claims in the Australian patent. None of the parties filed an appeal and the time period for doing so has now expired. Since these claims are unique to the Australian patent and Australian law differs from patent law in other jurisdictions, the Company does not expect this ruling to be determinative of the validity of any other patents licensed by DUSA from Queen's University or of whether PhotoCure's product infringes claims in such other patents, including the United States patent. As DUSA does not have an active drug application in Australia, we believe that this ruling will have no operational impact. We continue to negotiate with PhotoCure and Galderma under the terms of a Mediation Agreement signed by the parties in August 2004 in order to try to facilitate a settlement of our differences with respect to certain of our other patents licensed from PARTEQ.



In December 2004, we filed a lawsuit against New England Compounding Pharmacy, Inc. of Framingham, Massachusetts alleging violations of United States patent law in the U.S. District Court in Boston, Massachusetts. On March 17, 2005, New England Compounding Pharmacy filed an answer against us, including a defense that our patents are invalid and counterclaims, and we filed our response on April 5, 2005. The parties are now in the discovery stage of this litigation and we are unable to predict the outcome of this lawsuit at this

time. A tentative trial date has been set by the court for January 2007. We are seeking injunctive relief, monetary damages and costs. In January 2005, we filed a lawsuit against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement, and of U.S. patent law in the U.S. District Court for the District of Arizona. A motion for default judgment was granted on July 25, 2005 in our favor for failure of The Cosmetic Pharmacy of Tucson to appear, together with injunctive relief and attorney fees and costs in the amount of approximately $20,000. While we also believe that certain actions of these pharmacies go beyond the activities which are permitted under the Food, Drug and Cosmetic Act and have advised the FDA and local health authorities of our concerns, we cannot be certain that our lawsuits will be successful in curbing the practices of these pharmacies or that regulatory authorities will intervene to stop their activities which we believe are having a negative impact on our business.

OTHER INCOME, NET -

Other income for the three and six-month periods ended June 30, 2005 were $353,000 and $720,000, respectively, as compared to $376,000 and $775,000 in the comparable periods in 2004. This decrease was attributable to a reduction in our average investment balances as we used cash to support our operating activities.

NET LOSSES -

For the three and six months ended June 30, 2005, we incurred net losses of $(4,826,000), or $(0.29) per share, and $(9,158,000), or $(0.54) per share, respectively, as compared to net losses of $(4,196,000), or $(0.25) per share, and $(8,598,000), or $(0.55) per share, for the comparable periods in 2004. Net losses are expected to continue until end-user sales offset the cost of launching our sales force and marketing initiatives, and the costs for other business support functions.

LIQUIDITY AND CAPITAL RESOURCES

DUSA is in a strong liquidity position. At June 30, 2005, we had approximately $38,661,000 of total liquid resources comprised of $1,444,000 of cash and cash equivalents and marketable securities available-for-sale totaling $37,217,000. As of June 30, 2005, these available-for-sale securities had current yields ranging from 2.53% to 7.60% and maturity dates ranging from July 15, 2005 to June 15, 2008.



As of June 30, 2005, working capital (total current assets minus total current liabilities) was $39,737,000 as compared to $48,799,000 as of December 31, 2004. Total current assets and total current liabilities decreased by $9,428,000 and $367,000, respectively, during the six months ended June 30, 2005 due primarily to cash used in operating activities of $9,737,000, offset in part by cash provided by investing activities of $8,068,000.

We believe that based on current sales volumes and related expenses we have sufficient resources to continue to fund our current programs for Levulan(R) PDT and our operations and capital expenditures for approximately two years. We have invested our funds in liquid investments, so that we will have ready access to these investments, as needed, for the funding of development plans on a short-term and long-term basis.

We anticipate that marketing and sales expenses will level off for the remainder of 2005 as we seek to focus our current sales force in key territories and concentrate on potential high volume users. We are actively seeking to expand or enhance our business by using resources to acquire by license,

purchase or other arrangements, businesses, new technologies, or products. For 2005, we are focusing primarily on increasing the sales of the Levulan(R) Kerastick(R) and the BLU-U(R), and advancing our Phase II studies for use of Levulan(R) PDT in photodamaged skin and acne.

DUSA has no off-balance sheet financing arrangements other than its operating leases.

CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS -

On July 29, 2005, the Company signed an amendment to its existing supply agreement with Sochinaz S.A, the bulk supplier of the active ingredient in Levulan(R). This amendment extends the agreement through December 31, 2009, with an option to extend for an additional one year, and amends certain pricing and purchasing terms.

INFLATION -

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

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS -

There have been no recently issued accounting pronouncements that have a material impact on our financial reporting other than those presented in our Annual Report on Form 10-K for the year ended December 31, 2004, other than SFAS No. 123(R) discussed above.



ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments in our investment portfolio. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our investments consist of United States government securities and high grade corporate bonds. All investments are carried at market value, which approximates cost.

As of June 30, 2005, the weighted average rate of return on our investments was 4.82%. If market interest rates were to change immediately and uniformly by 100 basis points from levels as of June 30, 2005, the fair market value of the portfolio would change by $260,000. Declines in interest rates could, over time, reduce our interest income.

ITEM 4. CONTROLS AND PROCEDURES.

We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2005.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2005 that have materially affected, or are reasonably likely to materially affect, DUSA's internal control over financial reporting.

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, impact of the activities of compounding pharmacies on our business, expectations for continuing operating losses, expectations regarding increases in sales and adequate supply of inventory, expectations regarding internal distribution capabilities, beliefs regarding physician Kerastick(R) orders, estimates regarding the effects of so-called `off-label' use of our products, expectations for research and development expenses and expenses and regulatory requirements associated with seeking foreign marketing approvals for our products, beliefs regarding development programs with respect to photodamaged skin and acne, expectations regarding marketing and sales expenses, effects of unanticipated changes in estimates, forecasts, technological developments and our business model, beliefs regarding inventory levels, factors which could trigger impairment review, beliefs concerning the effect of increased reimbursement (or failure to achieve it), beliefs regarding our education and marketing programs and potential



market opportunities, intentions to evaluate and pursue licensing and acquisition opportunities, beliefs regarding the effects of staff reductions and the consolidation of sales territories, expectations regarding the reduction of operating costs, expectations concerning the operational impact and general effect of the ruling by the Federal Court of Australia regarding the Australian patent, requirements of cash resources, potential impact on conversion of government securities, need for additional funds for development, levels of interest income and net losses, sufficiency of our capital resources, expectations regarding accounting pronouncements, inflation, market risks and controls and procedures. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the timely development, FDA approval, and market acceptance of our products, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by third-party payors, and other risks noted in our SEC filings from time to time, including our Form 10-K for the period ending December 31, 2004, none of which can be assured.



PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

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 being challenged by PhotoCure ASA. PhotoCure ASA filed a lawsuit in Australia alleging that Australian Patent No. 624985, which is one of the patents relating to the Company's 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University assigned the Australian patent to the Company so that DUSA could participate directly in this litigation. The Company filed a response setting forth its defenses, and a related countersuit alleging that certain

activities of PhotoCure and its marketing partner, Galderma S.A., infringed the patent. The final hearing in the Federal Court of Australia was held in April 2004. On April 6, 2005, the Federal Court of Australia ruled that the Australian patent is valid and remains in full force and effect. However, the Court also ruled that PhotoCure's product, Metvix, does not infringe the claims in the Australian patent. Since these claims are unique to the Australian patent and Australian law differs from patent law in other jurisdictions, the Company does not expect this ruling to be determinative of the validity of any other patents licensed by DUSA from Queen's University or of whether PhotoCure's product infringes claims in such other patents, including the United States patent. As DUSA does not have an active drug application in Australia, DUSA believes that this ruling will have no operational impact on the Company. None of the parties have appealed the decision and the date to do so has expired. The parties signed a Mediation Agreement in August 2004 to attempt to settle their disputes and those discussions are ongoing.

In December 2004, the Company filed a lawsuit against New England Compounding Pharmacy, Inc. of Framingham, Massachusetts alleging violations of U.S. patent law in the United States District Court in Boston, Massachusetts. On March 17, 2005, New England Compounding Pharmacy filed an answer against us, including a defense that our patents are invalid and several counterclaims against us, and we filed our response on April 5, 2005. The parties are now in the discovery stage of this litigation and we are unable to predict the outcome of this lawsuit at this time. We have not reserved any funds for settlement or damages at this time. A tentative trial date has been set by the court for January 2007. We are seeking injunctive relief, monetary damages and costs. In January 2005, we filed a lawsuit against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement, and of U.S. patent law in the U.S. District Court for the District of Arizona. A motion for default judgment was granted on July 25, 2005 in our favor for failure of The Cosmetic Pharmacy of Tucson to appear, together with injunctive relief and attorney fees and costs in the amount of $20,668.12.



ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

Matters submitted to a vote of security holders of the Corporation at the Annual Meeting of Shareholders held June 16, 2005 included the election of six (6) directors, and the ratification of the selection of Deloitte & Touche LLP as the independent registered public accounting firm for the Corporation for 2005.

a) The following persons were elected to serve as directors of the Corporation:

| | Votes Cast For | Votes Cast Against | Abstained | Broker Non-votes |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| D. Geoffrey Shulman | 15,503,784 | 28,430 | -0- | -0- |
| John H. Abeles | 15,469,001 | 63,213 | -0- | -0- |
| David Bartash | 15,161,980 | 370,234 | -0- | -0- |
| Jay Haft | 15,503,734 | 28,480 | -0- | -0- |
| Richard C. Lufkin | 15,468,999 | 63,215 | -0- | -0- |
| Magnus Moliteus | 15,498,683 | 33,531 | -0- | -0- |

b) Shareholders ratified the selection of Deloitte & Touche LLP as the independent registered public accounting firm for the Corporation for 2005 as follows:

| | Votes Cast For | Votes Cast Against | Abstained | Broker Non-votes |
|---|---|---|---|---|
| Deloitte & Touche LLP | 15,510,427 | 19,304 | 2,483 | -0- |

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

a) Exhibit 10.1 Third Amendment to Supply Agreement, dated July 29, 2005, between DUSA Pharmaceuticals, Inc. and Sochinaz S.A., 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, as amended.

28

b) Exhibit 31(a) - Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer.

c) Exhibit 31(b) - Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.

d) Exhibit 32(a) - Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and

e) Exhibit 32(b) - Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

f) Exhibit 99(a) - Press Release dated August 3, 2005.

29

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
Chairman and Chief Executive Officer
(principal executive officer)

Date: August 3, 2005

By: /s/ Richard C. Christopher
---
Richard C. Christopher
Vice President, Finance and Chief Financial Officer (principal financial officer and principal accounting officer)

30

EXHIBIT INDEX

10.1 Third Amendment to Supply Agreement, dated July 29, 2005, between DUSA Pharmaceuticals, Inc. and Sochinaz S.A., 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, as amended.

31(a) Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer.

31(b) Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.

32(a) Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and

32(b) Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

99(a) Press Release dated August 3, 2005.