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DUSA PHARMACEUTICALS INC  
Form 10-Q  
May 09, 2005

FORM 10-Q  
UNITED STATES  
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 March 31, 2005  
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OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-19777

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

New Jersey 22-3103129  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

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

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

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

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

Yes  No   
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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.

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16,920,697 shares as of May 5, 2005

PART 1.

ITEM 1. FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS

CURRENT ASSETS

Cash and cash equivalents  
Marketable securities  
Accrued interest receivable  
Accounts receivable, net  
Inventory, net  
Prepays and other current assets

TOTAL CURRENT ASSETS

Restricted cash  
Property, plant and equipment, net  
Deferred charges and other assets

TOTAL ASSETS

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES

Accounts payable  
Accrued compensation  
Other accrued expenses  
Deferred revenue

TOTAL CURRENT LIABILITIES

Other liabilities

TOTAL LIABILITIES

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: 16,919,447 and 16,876,822 shares of common stock, no par, at March 31,

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2005 and December 31, 2004, respectively.

Additional paid-in capital	
Accumulated deficit	
Accumulated other comprehensive income	
<b>TOTAL SHAREHOLDERS' EQUITY</b>	---
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<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	===

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	THREE MONTHS 2005 (UNAUDITED)
	-----
Kerastick(R) Product Sales, net	\$2,510,0
BLU-U(R) Product Sales, net	858,5
	-----
<b>PRODUCT SALES, NET</b>	<b>3,368,6</b>
Kerastick(R) Cost of Product Sales and Royalties	979,2
BLU-U(R) Cost of Product Sales	1,024,3
	-----
<b>COST OF PRODUCT SALES AND ROYALTIES</b>	<b>2,003,6</b>
	-----
<b>TOTAL GROSS MARGIN</b>	<b>1,364,9</b>
	-----
<b>OPERATING COSTS</b>	
Research and development	1,595,7
Marketing and sales	2,785,4
General and administrative	1,682,4
	-----
<b>TOTAL OPERATING COSTS</b>	<b>6,063,5</b>
	-----
<b>LOSS FROM OPERATIONS</b>	<b>(4,698,61</b>
	-----
<b>OTHER INCOME</b>	
Interest income, net	366,9

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NET LOSS	\$ (4,331,615)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (0.26)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED	16,908,300

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	THREE MONTHS ENDED 2005 (UNAUDITED)
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES	
Net loss	\$ (4,331,615)
Adjustments to reconcile net loss to net cash used in operating activities:	
Amortization of premiums and accretion of discounts marketable securities available for sale, net	157,611
Depreciation and amortization	271,089
Issuance of options to consultants	-
Stock-based compensation	19,444
Changes in other assets and liabilities impacting cash flows from operations:	
Accrued interest receivable	13,906
Accounts receivable	(104,926)
Inventory	(573,091)
Prepays and other current assets	(3,468)
Restricted cash	(225)
Deferred charges and other assets	11,934
Accounts payable	(386,982)
Accrued compensation and other accrued expenses	(222,208)
Deferred revenue	84,923
Other liabilities	4,089
NET CASH USED IN OPERATING ACTIVITIES	(5,059,519)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES	
Purchases of marketable securities	(11,578,287)

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Proceeds from maturing and sales of marketable securities	14,452,149
Purchases of property, plant and equipment	(202,309)
	2,671,553
NET CASH PROVIDED BY INVESTING ACTIVITIES	2,671,553
CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES	
Issuance of common stock (net of stock offering costs of \$214,402)	-
Proceeds from exercise of options	172,660
Payments of long-term debt	-
	172,660
NET CASH PROVIDED BY FINANCING ACTIVITIES	172,660
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,215,306)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,928,143
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 712,837

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 for a total value of \$1,485,000.

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of March 31, 2005, and the Condensed Consolidated Statements of Operations and Cash Flows for the three months ended March 31, 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.

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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 March 31, 2005, current yields range from 2.54% to 7.84% and maturity dates range from April 1, 2005 to June 15, 2008. The estimated fair value and cost of marketable securities at March 31, 2005 and December 31, 2004 are as follows:

	MARCH 31, 2005		
	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES
United States government securities	\$23,199,574	\$197,745	(\$34,600)
Corporate securities	19,660,541	1,185	(60,600)
Total marketable securities available for sale	\$42,860,115	\$198,930	(\$95,200)

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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	(\$15,300)
Corporate securities	18,625,317	504	(43,300)
Total marketable securities available for sale	\$45,891,588	\$390,089	(\$58,600)

The change in net unrealized gains and losses on such securities for the three months ending March 31, 2005 and December 31, 2004 was (\$227,816) and (\$277,088), respectively, and has been recorded in accumulated other

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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 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-months ended March 31, 2005 and 2004, and accounts receivable as of March 31, 2005 and December 31, 2004 are as follows:

	% OF REVENUE		
	THREE-MONTHS ENDED		% OF ACCO
	MARCH 31, 2005	MARCH 31, 2004	MARCH 31, 2005
Third-party distributor A	15%	39%	8%
Third-party distributor B	-	29%	-
Third-party distributor C	13%	-	47%
Direct customer distribution	72%	32%	45%
Total	100%	100%	100%

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

### 4) INVENTORY

Inventory consisted of the following:

	MARCH 31, 2005 (UNAUDITED)
Finished goods	\$1,409,511
Work in process	333,621
Raw materials	247,119
	-----
	\$1,990,251
	=====

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5) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	MARCH 31, 2005 (UNAUDITED)
	-----
Research and development costs	\$511,737
Marketing and sales costs	174,560
Product related costs	612,423
Legal and other professional fees	400,682
Employee benefits	239,978
Other expenses	83,037
	-----
	\$2,022,417
	=====

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 strike 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 strike 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

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

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



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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 three months ending March 31, 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 months ending March 31, 2005 and 2004 would have been as follows:

	MARCH 31, 2005 (UNAUDITED)
	-----
Net loss: as reported	\$ (4,331,615)
Deduct: effect on net loss if fair value method had been used	(322,173)
	-----
Net loss: proforma	\$ (4,653,788)
	=====
Basic and diluted net loss per common share: as reported	\$ (0.26)
	-----
Basic and diluted net loss per common share: proforma	\$ (0.28)
	=====

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS Statement No. 123(R), "Share-Based Payment," 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 flow or financial position, but it will affect the Company's net income (loss) and earnings (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, the Company will recognize the expense attributable to stock options 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 months ended March 31, 2005, net loss and net loss per share

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would have increased by approximately \$322,000, or \$0.02 per share, respectively. As stock option 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 SHARE

Basic net loss per common share is based on the weighted-average number of shares outstanding during each period. For the three months ended March 31, 2005, and 2004, stock options, warrants and rights totaling approximately 3,386,000 and 3,396,000 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 months ended March 31, 2005 and 2004, comprehensive loss consisted of the following:

	MARCH 31, 2005 (UNAUDITED)	MAR 2 (UNA
	-----	-----
NET LOSS	\$ (4,331,615)	\$ (4
Change in net unrealized gains and losses on marketable securities available for sale	(227,816)	
	-----	-----
COMPREHENSIVE LOSS	\$ (4,559,431)	\$ (4
	=====	=====

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. None of the parties filed an appeal and the time period for doing so has expired. Since these claims are unique to the Australian patent, 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 Metvix 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.

In December 2004, we 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 counterclaims, and we filed our response on April 5, 2005. 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 default was entered on May 2, 2005 since no answer was filed. We are seeking injunctive relief, monetary damages and costs in both lawsuits. These cases are in their early stages and the Company is unable to predict the outcomes at this time.

The Company has not accrued any amounts for settlement as of March 31, 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

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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. Kerastick(R) unit sales to end-users were 28,704 for the three months ended March 31, 2005, consisting of 24,900 sold in the United States, and 3,804 sold by Coherent-AMT, our Canadian marketing and distribution partner. This represents an increase of 107% in the United States and an overall increase of 138% when compared to the 12,054 Kerastick(R) units sold solely in the United States during the three months ended March 31, 2004, prior to the Canadian launch.

The net number of BLU-U(R) units placed in doctors' offices during the three months ended March 31, 2005 was 131, including 31 placed in Canada. As of March 31, 2005 there were 1,045 units in doctor's offices, consisting of 913 in the United States and 132 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 expanding our sales coverage in key geographic locations. As of March 31, 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". To date, we are

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encouraged with the quarterly increases in sales and the positive trends we are seeing in such key metrics as number of reordering customers and new customers, although the costs related to the expansion of our sales force and related marketing activities are significant as compared to the revenue generated from the increased sales volumes. During this quarter, approximately 1,000 customers ordered Kerastick(R) units, of which approximately two-thirds were existing customers and one-third were new customers, as compared to approximately 1,600 customers 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 may have necessitated at that time. As a result, approximately 60% of our top 100 customers did not order Kerastick(R) units in this quarter and, in some cases, may still be working down their supplies through the second quarter.

Historically, we have primarily devoted our resources to fund research and development in order to advance the Levulan(R) PDT/PD technology platform and, as a result, we have experienced significant operating losses. As of March 31, 2005, we had an accumulated deficit of approximately \$78,870,000. 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

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the average wholesale price (AWP), caused a decrease in the amount reimbursed for the Kerastick(R). Going forward, 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 DUSA has already started to decrease its Kerastick(R) volume discount programs, reimbursement is expected to increase in future quarters. Overall, we believe that 2005 reimbursement changes related to treatment of AK are positive for doctors using our therapy. However, we are aware that 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. DUSA believes that the reimbursement codes which apply to Levulan(R) PDT will be reexamined within a five-year review cycle. It is difficult to predict the effect of the 2005 changes at this time. DUSA continues to support ongoing efforts that might lead to further increases in reimbursement and intends 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

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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 the 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."

During the quarter, we increased the size of our sales force to 31 from 22 at the end of 2004. As of March 31, 2005, our staff included 80 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. We may add and/or replace employees throughout 2005 as business circumstances deem necessary.

On January 4, 2005, we announced the appointment by DUSA's Board of Directors of Mr. Robert F. Doman as our President and Chief Operating Officer effective January 3, 2005. As a result of Mr. Doman joining DUSA, Dr. D. Geoffrey Shulman resigned his position as President of the Company and Mr. Jay

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Haft resigned as Chairman of the Board of Directors also effective January 3, 2005. Dr. Shulman remains as DUSA's Chief Executive Officer and has been re-appointed to the position of Chairman of the Board of Directors. Mr. Haft retains his position as Lead Director and has been appointed to the position of Vice Chairman of the Board of Directors. During the quarter we also announced the hiring of Mr. Gary Talarico as Vice President, Sales, and the promotion of Mr. Richard Christopher to Vice President, Finance and Chief Financial Officer.

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 significant 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.

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### 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 final, 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. Management believes that the recorded value of inventory as of March 31, 2005 is reasonable in light of our current sales forecasts.

**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

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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

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fair value on a discounted cash flow basis. At March 31, 2005, our total property, plant and equipment had a carrying value of \$3,413,000, including \$1,925,000 associated with our manufacturing facility. As of March 31, 2005, we had intangible assets totaling \$264,000 recorded in deferred charges and other assets relating to the unamortized balance of payments incurred 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 or financial position, but it will affect our net income (loss) and earnings (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 months ended March 31, 2005, net loss and net loss per share would have increased by approximately \$322,000, or \$0.02 per share, respectively. As stock option 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.

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### RESULTS OF OPERATIONS - THREE MONTHS ENDING MARCH 31, 2005 VERSUS MARCH 31, 2004

REVENUES - Total revenues for the three months ended March 31, 2005 were \$3,369,000 as compared to \$1,256,000 in 2004, and were comprised of the following:

	THREE MONTHS ENDED MARCH 31, 2005 (UNAUDITED)	
	2005	2004
KERASTICK(R) PRODUCT REVENUES		
United States	\$2,249,000	\$896,000
Canada	261,000	-
Total	2,510,000	896,000
BLU-U(R) PRODUCT REVENUES		
United States	686,000	360,000
Canada	173,000	-
Total	859,000	360,000
Total product revenues	\$3,369,000	\$1,256,000

The increase in 2005 Kerastick(R) revenues was driven mainly by increased sales volumes. Kerastick(R) sales to end-users for the three months ended March 31, 2005 totaled 28,704 units versus 12,054 units in the comparable 2004 period. The 2005 total consists of 24,900 sold in the United States and 3,804 sold by Coherent-AMT, our Canadian marketing and distribution partner. All first quarter 2004 units were all sold in the United States, as the Canadian launch had not yet occurred. The increase in revenues is also attributable to our decision to increase our average unit selling price as of November 2004, increased levels of our direct distribution to customers, and a reduction in our overall sales volume discount programs. In fact, our average net selling price for the Kerastick(R) increased to \$87.44 in the first quarter of 2005 from \$74.27 in the first quarter of 2004.

The increase in 2005 BLU-U(R) revenue was driven by both increased sales volumes and an increase in our average selling price. There were 143 units sold for the three months ended March 31, 2005 versus 109 units sold in the comparable 2004 period. The 2005 total consists of 112 units sold in the United States and 31 sold in Canada by Coherent-AMT. The 109 units from 2004 were all sold in the United States. During the quarter, we received a new supply of BLU-U(R) units, and are now in a positive inventory position.

' The increase of both Kerastick(R) and BLU-U(R) revenues is a result of the



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efforts of our sales force and related marketing and sales activities including our participation at the American Academy of Dermatology ("AAD") annual meeting in February 2005, which is the largest and most important dermatology conference each year in the United States. With respect to United States Kerastick(R) sales, we increased the price last November 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 we believe have had a positive impact on sales this quarter. We also believe, however, that due to the various factors mentioned above, physicians may have ordered more Kerastick(R) units than their usage necessitated at that time. As a result, approximately 60% of our top 100 customers from 2004 did not order Kerastick(R) units in this quarter and, in some cases, may be working down their supplies through the second quarter. We expect to continue to increase our internal distribution capabilities in order to increase our gross revenue and net profit per unit. However, our costs will also increase to support this function. Although the level of Kerastick(R) sales to end-users for 2005 is higher than those in the prior year, Kerastick(R) sales must continue to increase significantly in order for us to become profitable.

COST OF PRODUCT SALES AND ROYALTIES - Cost of product sales and royalties for the three months ended March 31, 2005 were \$2,004,000 as compared to \$826,000 in 2004. A summary of the components of cost of product sales and royalties is provided below:

	THREE MONTHS ENDED MARCH 31, 2005 (UNAUDITED)	
	2005	2004
KERASTICK(R) COST OF PRODUCT SALES AND ROYALTIES		
Direct Kerastick(R) Product costs	\$580,000	\$233,000
Other Kerastick(R) Product costs including internal costs assigned to support products	272,000	162,000
Royalty and supply fees (1)	128,000	36,000
Total Kerastick(R) cost of product sales and royalties	\$980,000	\$431,000
BLU-U(R) COST OF PRODUCT SALES		
Direct BLU-U(R) Product costs (2)	\$476,000	\$-
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	548,000	395,000

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Total BLU-U(R) cost of product sales	\$1,024,000	\$395,000
TOTAL COST OF PRODUCT SALES AND ROYALTIES	\$2,004,000	\$826,000

- 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

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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 sales 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.

GROSS MARGIN - Total product margins for the three months ended March 31, 2005 were \$1,365,000 as compared to \$430,000 for the comparable 2004 period, as shown below:

	THREE MONTHS ENDED MARCH 31, (UNAUDITED)			
	2005		2004	INCREASE/ (DECREASE)
KERASTICK(R)	\$1,530,000	61%	\$465,000	52%
BLU-U(R)	(165,000)	(19%)	(35,000)	(10%)
Total Gross Margin	\$1,365,000	41%	\$430,000	34%
	\$1,065,000		(130,000)	\$935,000

Kerastick(R) gross margins for the three months ended March 31, 2005 were 61% versus 52% for the comparable 2004 period. Similar to the increase in revenues, the increase in margin is attributable to our decision to increase our average unit selling price as of November 2004, increased levels of direct distribution to customers; as well as a reduction in our overall sales volume discount programs. Our long-term goal is to achieve much higher gross margins on Kerastick(R) sales which will be significantly dependent on increased volume.

BLU-U(R) gross margins for the three months ended March 31, 2005 were negative 19% versus negative 10% for the comparable 2004 period. The erosion on

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margin is directly attributable to the fact that in the first quarter 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 erosion is somewhat offset by an increase in the overall selling price per unit. Also, this quarter we sold most of the units at a discounted price at the major medical conferences we attended, which also affected our margins. 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 months ended March 31, 2005 were \$1,596,000 as compared to \$1,688,000 in 2004. We have commenced Part B (the efficacy phase) of our Phase II photodamaged skin study, and completed

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enrollment in the first of three cohorts of the Phase II multi-center acne study, treating 24 patients with a total of 81 PDT sessions. It is anticipated that we will have primary 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 also continue to examine the costs and regulatory requirements associated with seeking foreign marketing approvals for our products, which could cause research and development expenses to increase.

DUSA has 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. DUSA will provide Levulan(R), device(s) and the necessary training for the investigators involved in the studies, and is in the process of estimating DUSA's incremental costs of this program. DUSA will maintain full ownership of its existing intellectual property, has options on new intellectual property and, subject to successful Phase II and III clinical trial results, intends 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 have initiated a small single-center pilot Phase II clinical trial using DUSA's new proprietary endoscopic light delivery device.

During the quarter, we also received the Notice of Final Determination for the Hatch-Waxman Patent Term Extension for Actinic Keratoses, which will extend our patent claims that cover AK from July 2009 to October 2013.

MARKETING AND SALES COSTS - Marketing and sales costs for the three months

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ended March 31, 2005 were \$2,785,000 as compared to \$1,367,000 for 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 \$1,837,000 for the three month period ended March 31, 2005, compared to \$1,016,000 in 2004. These increases were mainly attributable to the expansion of our sales force from 8 employees as of March 31, 2004 to 31 employees as of March 31, 2005, including sales management. The remaining

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expenses consist of tradeshows, miscellaneous marketing and outside consultants totaling \$948,000 for the three month period ended March 31, 2005, compared to \$351,000 in 2004. We expect that our overhead expenses will remain elevated reflecting the expansion of our sales capacity; however, these expenses should be somewhat offset by lower tradeshow spending for the remainder of the year, as the major conferences took place during the first quarter of 2005.

GENERAL AND ADMINISTRATIVE COSTS - General and administrative costs for the three months ended March 31, 2005 decreased to \$1,682,000 as compared to \$2,175,000 for 2004. This decrease is mainly attributable to lower legal expenses of \$419,000 incurred in 2005 as compared to \$1,199,000 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 litigation costs against two compounding pharmacies also described below and 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, we do not expect this ruling to be determinative of the validity of any other patents licensed by us from Queen's University or of whether Metvix 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. 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 the U.S. patent law in the U.S. District Court for the District of Arizona. A default was entered on May 2, 2005 since no answer was filed. We are seeking injunctive relief, monetary damages and costs in both lawsuits. We have not reserved any funds for settlement or damages at this time. These cases are in their early stages and we are unable to predict the outcomes at this time. 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 months ended March 31, 2005 decreased to \$367,000, as compared to \$399,000 during the same period in 2004. This decrease was attributable to a reduction in our average investable cash balances during 2004 and early 2005, as we used cash to support our operating activities. During the three months ended March 31, 2004, we incurred interest expense of \$11,000 on borrowings associated with the construction of our Kerastick(R) manufacturing facility.

NET LOSSES - We incurred a net loss of \$4,332,000, or \$0.26 per share, for the three months ended March 31, 2005, as compared to a net loss of \$4,402,000 or \$0.30 per share for the comparable period 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 cash position to continue to fund increased Levulan(R) PDT sales and marketing expenses and current research and development activities for our Levulan(R) PDT/PD platform. At March 31, 2005, we had approximately \$43,818,000 of total cash resources comprised of \$713,000 of cash and cash equivalents, marketable securities available for sale totaling \$42,964,000, and restricted cash of \$141,000. As of March 31, 2005, these securities had yields ranging from 2.54% to 7.84% and maturity dates ranging from April 1, 2005 to June 15, 2008.

As of March 31, 2005, working capital (total current assets minus total current liabilities) was \$44,516,000 as compared to \$48,799,000 as of December 31, 2004. Total current assets and total current liabilities decreased by \$4,807,000 and \$524,000, respectively, during the three

months ended March 31, 2005 due primarily to cash used in operating activities of \$5,059,000, offset in part by cash provided by investing activities of \$2,672,000.

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

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basis.

We anticipate that the level of marketing and sales expenses and related support functions will continue to increase in 2005 as we seek to expand our sales coverage as a result of the initial success of our sales initiatives. 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

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, 2004.

### INFLATION

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

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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consist of United States government securities and high grade corporate bonds. All investments are carried at market value, which approximates cost.

As of March 31, 2005, the weighted average rate of return on our investments was 5.21%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of March 31, 2005, the fair market value of the portfolio would decline by \$319,000. 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 March 31, 2005.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2005 that have materially affected, or are reasonably likely to materially affect, DUSA's internal control

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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 sales growth, expectations for continuing operating losses, intention to focus on increasing sales and to insure 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 costs and costs and regulatory requirements associated with seeking foreign marketing approvals for our products, plans for conducting development programs with respect to photodamaged skin and acne, expectations of increasing staff and marketing and sales expenses, effects of unanticipated changes in estimates and forecasts, belief regarding inventory levels, factors which could trigger impairment review, beliefs concerning the effect of improved reimbursement (or failure to achieve it) and beliefs regarding Levulan(R) PDT reimbursement codes, beliefs regarding our education and marketing programs, continued participation at medical conferences and potential sales activities, intentions to evaluate and pursue licensing and acquisition opportunities, beliefs regarding hiring levels and levels of legal expenses, 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

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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.

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### PART II - OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS.

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 Federal District Court in Boston, Massachusetts. On March 17, 2005, New England Compounding Pharmacy filed an answer against us, including a

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defense that our patents are invalid and counterclaims, and we filed our response on April 5, 2005. 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 the U.S. patent law in the U.S. District Court for the District of Arizona. On May 2, 2005, a default was entered for failure to file an answer to this complaint. We are seeking injunctive relief, monetary damages and costs in both lawsuits. These cases are in their early stages and we are unable to predict the outcomes at this time.

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.  
None.

ITEM 5. OTHER INFORMATION.  
None.

ITEM 6. EXHIBITS

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

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

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c) 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

d) 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.

e) Exhibit 99(a) - Press Release dated May 9, 2005

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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

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D. Geoffrey Shulman  
Director, Chairman and Chief Executive  
Officer (principal executive officer)

Date: May 9, 2005  
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By: /s/ Richard C. Christopher  
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Richard C. Christopher  
Vice President, Finance and Chief Financial  
Officer (principal financial officer)

EXHIBIT INDEX

- 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 May 9, 2005