

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

DUSA PHARMACEUTICALS INC  
Form 10-Q  
November 08, 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 September 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  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

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

Yes    X    No  
-----    -----

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 at the Exchange Act).

Yes    X    No  
-----    -----

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 at the Exchange Act).

Yes            No    X

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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:

16,937,697 shares as of November 4, 2005

PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS.

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	SEPTEMBER 30, 2005 (UNAUDITED)	D
	-----	-----
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 2,001,402	\$
Marketable securities	33,262,314	
Accrued interest receivable	421,627	
Accounts receivable, net	703,863	
Inventory, net	2,068,738	
Prepays and other current assets	1,442,233	
	-----	
TOTAL CURRENT ASSETS	39,900,177	
Restricted cash	143,353	
Property, plant and equipment, net	3,168,314	
Deferred charges and other assets	240,454	
	-----	
TOTAL ASSETS	\$ 43,452,298	\$
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 565,614	\$
Accrued compensation	850,221	
Other accrued expenses	1,835,182	
Deferred revenue	419,415	
	-----	
TOTAL CURRENT LIABILITIES	3,670,432	
Other liabilities	202,706	
	-----	
TOTAL LIABILITIES	3,873,138	
	-----	
COMMITMENTS AND CONTINGENCIES (NOTE 10)		
SHAREHOLDERS' EQUITY		
Capital Stock		

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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: 16,936,697 and 16,876,822 shares of common stock, no par, at September 30, 2005 and December 31, 2004, respectively.

Additional paid-in capital	124,930,094
Accumulated deficit	2,035,783
Accumulated other comprehensive (loss) income	(87,304,775)
	(81,942)
	-----
TOTAL SHAREHOLDERS' EQUITY	39,579,160
	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 43,452,298
	=====

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)		NINE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)	
	2005	2004	2005	2004
	-----	-----	-----	-----
REVENUES				
Kerastick(R) Product Revenues, net	\$ 1,806,135	\$ 1,498,514	\$ 6,081,938	\$ 3,697,611
BLU-U(R) Product Revenues, net	586,109	512,105	1,907,036	1,744,722
	-----	-----	-----	-----
PRODUCT REVENUES, NET	\$ 2,392,244	\$ 2,010,619	\$ 7,988,974	\$ 5,442,333
Kerastick(R) Cost of Product Revenues and Royalties	816,182	303,091	2,641,710	1,222,966
BLU-U(R) Cost of Product Revenues	491,251	415,077	2,139,879	1,389,922
	-----	-----	-----	-----
COST OF PRODUCT REVENUES AND ROYALTIES	1,307,433	718,168	4,781,589	2,612,888
TOTAL MARGIN	\$ 1,084,811	\$ 1,292,451	\$ 3,207,385	\$ 2,829,445
OPERATING COSTS				
Research and development	1,414,428	1,585,099	4,809,294	4,850,155
Marketing and sales	1,804,439	1,835,210	6,885,755	4,901,811
General and administrative	1,663,697	1,197,707	5,187,415	5,775,500
Restructuring	150,917	--	150,917	-
	-----	-----	-----	-----
TOTAL OPERATING COSTS	5,033,481	4,618,016	17,033,381	15,527,476
	-----	-----	-----	-----
LOSS FROM OPERATIONS	(3,948,670)	(3,325,565)	(13,825,996)	(12,698,021)
OTHER INCOME				
Interest income, net	340,389	350,573	1,059,982	1,125,299
	-----	-----	-----	-----
NET LOSS	\$ (3,608,281)	\$ (2,974,992)	\$ (12,766,014)	\$ (11,572,722)
	=====	=====	=====	=====
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (0.21)	\$ (0.18)	\$ (0.75)	\$ (0.75)

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WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	=====	=====	=====	=====
	16,930,746	16,855,504	16,920,220	16,131,01
	=====	=====	=====	=====

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	NINE MONTHS ENDED SEPTEMBER 30,	
	2005 (UNAUDITED)	2004 (UNAUDITED)
	-----	-----
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (12,766,014)	\$ (11,572,733)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of premiums and accretion of discounts on marketable securities, net	401,221	93,582
Realized gain on sale of marketable securities	(72,195)	
Depreciation and amortization expense	755,593	1,190,605
Stock-based compensation	19,444	240,753
Changes in other assets and liabilities impacting cash flows from operating activities:		
Accrued interest receivable	220,170	65,528
Accounts receivable	7,153	(162,250)
Inventory	(651,578)	(668,613)
Prepays and other assets	(611,338)	(718,700)
Accounts payable	(291,654)	(743,765)
Accrued compensation and other accrued expenses	(180,045)	671,224
Deferred revenue	188,700	164,532
Other liabilities-non current	12,267	
	-----	-----
CASH USED IN OPERATING ACTIVITIES	(12,968,276)	(11,439,837)
	-----	-----
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of marketable securities	(40,683,061)	(30,767,026)
Proceeds from maturities and sales of marketable securities	52,901,367	21,450,000
Restricted cash	(2,589)	(1,008)
Purchases of property, plant and equipment	(406,217)	(507,378)
	-----	-----
CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	11,809,500	(9,825,412)
	-----	-----
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock (net of stock offering costs of \$200,202)		28,262,298
Proceeds from exercise of stock options	232,035	719,319
Repayments of long-term debt		(1,517,500)

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CASH PROVIDED BY FINANCING ACTIVITIES	232,035	27,464,117
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(926,741)	6,198,868
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,928,143	4,294,482
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 2,001,402	\$ 10,493,350

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.

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

### 1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheets as of September 30, 2005 and December 31, 2004, Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2005 and 2004, and Condensed Consolidated Statements of Cash Flows for the nine months ended September 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 that 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. The reclassifications of 2004 amounts include separate presentation of the cost of product revenues and royalties for the Company's two products, the Kerastick(R) and the BLU-U(R). 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 September 30, 2005, current yields range from 2.54% to 7.25% and maturity dates range from October 6, 2005 to June 15, 2008. The estimated fair value and cost of marketable securities at September 30, 2005 and December 31, 2004 are as follows:

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	SEPTEMBER 30, 2005 (UNAUDITED)			
	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR VALUE
United States government securities	\$19,716,856	\$102,158	\$ (47,826)	\$19,771,188
Corporate securities	13,627,400	8,533	(144,807)	13,491,126
Total marketable securities available-for-sale	\$33,344,256	\$110,691	\$ (192,633)	\$33,262,314

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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	FAIR VALUE
United States government securities	\$27,266,271	\$389,585	\$ (15,315)	\$27,640,541
Corporate securities	18,625,317	504	(43,393)	18,582,428
Total marketable securities available-for-sale	\$45,891,588	\$390,089	\$ (58,708)	\$46,222,969

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 nine months ended September 30, 2005 and 2004, and accounts receivable as of September 30, 2005 and December 31, 2004 are as follows:

% OF REVENUE THREE-MONTHS ENDED SEPTEMBER 30 (UNAUDITED)	% OF REVENUE NINE-MONTHS ENDED SEPTEMBER 30 (UNAUDITED)	% OF ACCOUNTS RECEIVABLE AS OF SEPTEMBER 30, 2005
-----	-----	-----

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	2005	2004	2005	2004	(UNAUDITED)	DECEMBER 31,
	----	----	----	----	-----	-----
Third-party distributor A	17%	30%	17%	30%	6%	27%
Third-party distributor B	--	17%	--	21%	--	--
Third-party distributor C	13%	9%	14%	8%	40%	34%

4) INVENTORY

Inventory consisted of the following:

	SEPTEMBER 30, 2005 (UNAUDITED)	DECEMBER 31, 2004
	-----	-----
Finished goods	\$1,266,278	\$1,226,071
Work in process	387,719	85,910
Raw materials	414,741	105,179
	-----	-----
	\$2,068,738	\$1,417,160
	=====	=====

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

5) RESTRUCTURING CHARGE

During the quarter ended September 30, 2005, the Company eliminated 14 staff positions, representing 16% of the workforce, to align headcount more closely with management's assessment of its resource requirements at this time. These workforce reductions were made across all functions of the Company. As a result of these actions the Company recorded a restructuring charge of approximately \$150,000. As of September 30, 2005, the Company had paid an aggregate of \$136,000 and expects to pay the remainder of the charges by December 31, 2005.

A summary of the restructuring charges and related activity is as follows:

	SEPTEMBER 30, 2005		
	CHARGES	PAYMENTS	ACCRUED RESTRUCTURING BALANCE
	-----	-----	-----
Employee severance, benefits and related costs	\$150,917	\$136,093	\$14,824
	-----	-----	-----
Total	\$150,917	\$136,093	\$14,824
	=====	=====	=====

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### 6) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	SEPTEMBER 30, 2005 (UNAUDITED) -----	DECEMBER 31, 2004 -----
Research and development costs	\$ 343,809	\$ 778,926
Marketing and sales costs	101,729	153,167
Product related costs	266,446	261,444
Legal and other professional fees	691,842	374,142
Employee benefits	338,869	229,304
Restructuring	14,824	--
Other expenses	77,663	104,858
	-----	-----
	\$1,835,182	\$1,901,841
	=====	=====

### 7) ACCOUNTING FOR STOCK-BASED COMPENSATION

The Company accounts for its stock-based compensation for employee stock option awards in accordance with Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," using the intrinsic value method. Under APB Opinion 25, stock compensation expense is recognized for the excess, if any, of intrinsic value of the award over the exercise price.

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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 nine months ended September 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 employee stock compensation, the Company's pro forma net loss, and pro forma net loss per share for the three and nine months ending September 30, 2005 and 2004 would have been as follows:

THREE MONTHS ENDED  
SEPTEMBER 30,

NINE MONTHS END  
SEPTEMBER 30,



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	(UNAUDITED)		(UNAUDITED)	
	2005	2004	2005	2004
NET LOSS				
As reported	\$ (3,608,281)	\$ (2,974,992)	\$ (12,766,014)	\$ (11,444,000)
Add: stock-based compensation expense included in reported net loss	--	--	19,444	--
Less: stock-based compensation expense determined under the fair value method	(339,471)	(438,535)	(1,439,514)	(1,439,514)
Pro forma	\$ (3,947,752)	\$ (3,413,527)	\$ (14,186,084)	\$ (12,883,514)
BASIC AND DILUTED NET LOSS PER COMMON SHARE				
As reported	\$ (0.21)	\$ (0.18)	\$ (0.75)	\$ (0.64)
Effect on net loss per common share if fair value method had been used	(0.02)	(0.02)	(0.09)	(0.09)
Pro forma	\$ (0.23)	\$ (0.20)	\$ (0.84)	\$ (0.73)

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. As this standard is effective for the Company on January 1, 2006, the Company will

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

recognize the expense attributable to stock awards that are granted or vest in periods subsequent to December 31, 2005. As stock award grants are potentially issued in each annual period, the increase or decrease in stock compensation expense as a result of adoption of SFAS No. 123(R) cannot be predicted with certainty.

8) 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 September 30, 2005, and 2004, stock options, warrants and rights totaling approximately 3,396,000 and 3,043,000 shares, respectively, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive.

9) COMPREHENSIVE LOSS

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

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	THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)		NINE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)	
	2005	2004	2005	2004
NET LOSS	\$ (3,608,281)	\$ (2,974,992)	\$ (12,766,014)	\$ (11,572,733)
Change in net unrealized gains and losses on marketable securities available-for-sale	(166,714)	(130,812)	(413,323)	(847,221)
COMPREHENSIVE LOSS	\$ (3,774,995)	\$ (3,105,804)	\$ (13,179,337)	\$ (12,419,954)

Accumulated other comprehensive (loss) 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.

10) COMMITMENTS AND CONTINGENCIES

Legal Matters - The Company continues to negotiate with PhotoCure ASA and Galderma S.A. 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 the Company's patents licensed to us by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario.

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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 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.

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

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Termination of Distribution Agreement - In September 2005, the Company exercised its right to terminate its distribution agreement with its non-exclusive distributor of the Kerastick(R) in the United States. The termination is scheduled to become effective on December 31, 2005. Following termination, the Company plans to perform these activities using its existing employees and infrastructure.

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

#### OVERVIEW

DUSA is a pharmaceutical company engaged primarily in the research, development, and marketing of a drug named 5-aminolevulinic acid, or ALA, 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.

Kerastick(R) unit sales to end-users were 20,286 and 69,162 for the three and nine month periods ended September 30, 2005, respectively, including 17,766 and 59,172, respectively, sold in the United States, and 2,520 and 9,990, respectively, sold in Canada by Coherent-AMT, our Canadian marketing and distribution partner. This represents an increase from 20,196 and 50,160 Kerastick(R) units sold in the three and nine-month periods ended September 30, 2004, respectively, including 18,870 and 46,926, respectively, sold in the United States, and 1,326 and 3,234, respectively sold in Canada by Coherent-AMT.

During the quarter ended September 30, 2005, 818 customers in the United States ordered 17,766 Kerastick(R) units, of which approximately 73% were existing customers and 27% 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, 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 the end of 2004, which we believe has negatively impacted 2005 revenues. Approximately 39% 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.

While overall Kerastick(R) unit sales for the quarter ended September 30, 2005 were relatively flat on a sequential basis, United States sales during the quarter represented a 7.6% increase over the quarter ended June 30, 2005, driven by a combination of new customers and orders by existing customers. We are encouraged with this unit increase in light of the fact that

the summer months are traditionally slow periods in the dermatology market, particularly with laser and light-based therapies.

During the quarter, we received FDA approval to manufacture our BLU-U(R) in our Wilmington, Massachusetts facility. However, at this time, we expect to utilize our own facility only as a back-up to our current third-party manufacturer or for repairs. The net number of BLU-U(R) units placed in doctors' offices during the three months ended September 30, 2005 was 98, including 22 placed in Canada. As of September 30, 2005 there were 1,215 units in doctor's offices, consisting of 1,037 in the United States and 178 in Canada as compared with 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. See section entitled "Results of Operations - Marketing and Sales Costs." We are encouraged by the increase in sales on a year-to-date basis, despite the circumstances outlined above, as well as the positive feedback we continue to receive from physicians across the country that believe Levulan PDT should become a routine part of standard dermatological practice.

Historically, we devoted most of our resources to fund research and development efforts in order to advance the Levulan(R) PDT/PD technology platform. More recently, we have also devoted significant resources to our sales and marketing efforts. As a result, we have experienced significant operating losses. As of September 30, 2005, we had an accumulated deficit of approximately \$87,305,000. 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 to physicians relative to our products 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, the effect of this increase was partially offset by a simultaneous change in drug reimbursement methodologies, which also became effective on January 1, 2005. Drug reimbursement amounts are now based on 106% of a drug's average selling price (ASP) rather than 85% of the drug's average wholesale price (AWP), which was the previous standard. Reimbursement for the Kerastick(R) will vary from quarter to quarter based on the ASP to the end-user during a prior quarter, including all discounts. While we believe that 2005 reimbursement changes related to treatment of AK are positive for physicians 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, which we believe impacts adoption of our products and ultimately, our revenues. We continue to support ongoing efforts that might lead to further increases in

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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.

Several of the major private insurers have approved coverage for our AK therapy. We continue to work to educate other private insurance carriers in an attempt to gain more widespread coverage. We believe that these efforts, along with our education and marketing programs, should result in an increased adoption of our therapy 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 believe that these activities are positively affecting the sales of our products.

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. We believe that these activities are 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 September 30, 2005, our staff included 69 full-time employees and 2 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 nine-month period ended September 30, 2005, we increased the size of our sales force to 28 from 22 at the end of 2004. During the three-month period ended September 30, 2005, we eliminated 14 positions, representing 16% of our workforce, to align headcount more closely with our assessment of our resource requirements at this time. These workforce reductions were made across all functions of the Company. We anticipate that this reduction in staff will reduce our future operating costs by \$1,400,000 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 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; as well as 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 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, if any, that are 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 September 30, 2005, our total property, plant and equipment had a carrying value of \$3,168,000, including \$2,320,000 associated with our

manufacturing facility. As of September 30, 2005, we had intangible assets totaling \$162,000 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.

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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 when it becomes effective on January 1, 2006. 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. We will recognize the expense attributable to stock options that are granted or vest in periods subsequent to December 31, 2005. As stock award grants are potentially issued in each annual period, 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 nine-month periods ended September 30, 2005 were \$2,392,000 and \$7,989,000, respectively, as compared to \$2,011,000 and \$5,442,000 in the comparable periods in 2004, and were comprised of the following:

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	THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)			NINE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)		
	2005	2004	INCREASE/ (DECREASE)	2005	2004	INCRE (DECRE
<b>KERASTICK (R) REVENUES</b>						
United States	\$1,630,000	\$1,414,000	\$216,000	\$5,389,000	\$3,513,000	\$1,876
Canada	176,000	85,000	91,000	693,000	185,000	508
Total	\$1,806,000	\$1,499,000	\$307,000	\$6,082,000	\$3,698,000	\$2,384
<b>BLU-U (R) REVENUES</b>						
United States	\$ 462,000	\$ 432,000	\$ 30,000	\$1,488,000	\$1,481,000	\$ 7
Canada	124,000	80,000	44,000	419,000	263,000	156

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Total	\$ 586,000	\$ 512,000	\$ 74,000	\$1,907,000	\$1,744,000	\$ 163
Total Revenues	\$2,392,000	\$2,011,000	\$381,000	\$7,989,000	\$5,442,000	\$2,547

Kerastick(R) unit sales to end-users were 20,286 and 69,162 for the three and nine month periods ended September 30, 2005, respectively, including 17,766 and 59,172, respectively, sold in the United States, and 2,520 and 9,990, respectively, sold in Canada by Coherent-AMT, our Canadian marketing and distribution partner. This represents an increase from 20,196 and 50,160 Kerastick(R) units sold in the three and nine-month periods ended September 30, 2004, respectively, including 18,870 and 46,926, respectively, sold in the United States, and 1,326 and 3,234, respectively sold in Canada by Coherent-AMT. The increase in Kerastick(R) revenues for the three months ended September 30, 2005 compared with the same 2004 period was driven mainly by an increase in our average net selling price, which increased to \$89.02 during the current quarter from \$74.20 for the third quarter of 2004. For the first nine months of 2005, the increase in revenues is attributable to increased sales volumes, an increase in our average unit selling price, increased levels of our direct distribution to customers and a reduction in our overall sales volume discount programs. Our average net selling price for the Kerastick(R) increased to \$87.94 for the first nine months of 2005 from \$73.72 for the first nine months of 2004. Our average net selling price for the Kerastick(R) includes sales made directly to our end-user customers, as well as sales made to our distributors, both in the United States and Canada.

While overall Kerastick(R) unit sales for the quarter ended September 30, 2005 were relatively flat on a sequential basis, United States sales during the quarter represented a 7.6% increase over the quarter ended June 30, 2005, driven by a combination of new customers and orders by existing customers. We are encouraged with this unit increase in light of the fact that the summer months are traditionally slow periods in the dermatology market. However, we also believe that due to various factors mentioned above, that physicians ordered more Kerastick(R) units in 2004 than their usage necessitated at that time. As a result, approximately 39% of our top 114 volume customers from 2004 have not ordered Kerastick(R) units during the first nine

months of 2005 and, in some cases, may still be working down their supplies through the remainder of the year.

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 \$6,390 for the nine-month period ended September 30, 2005 from \$4,038 for the nine-month period ended September 30, 2004. In the three and nine-month periods ended September 30, 2005, there were 82 and 294 units sold, respectively, versus 103 units and 432 units in the comparable 2004 periods. The 2005 total consists of 219 units sold in the United States and 75 sold in Canada by Coherent-AMT. The 2004 total consists of 355 sold in the United States and 77 sold in Canada. The decrease in BLU-U(R) units sold in the three and nine-month periods ended September 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 increased efforts of our sales force and related marketing and



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sales activities. With respect to United States sales, we increased our average selling prices, increased our direct selling and distribution efforts, while still maintaining the services of one external distributor, and reduced our overall sales volume discount programs, all of which have had a positive impact on our average selling prices during 2005. 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, the on-going consumption of the Kerastick(R) by our customers, the addition of new customers and the publication of positive results of independent investigators' studies in peer reviewed journal articles, that sales will continue to increase as we approach year end.

COST OF PRODUCT REVENUES AND ROYALTIES - Cost of product revenues and royalties for the three and nine-month periods ended September 30, 2005 were \$1,307,000 and \$4,782,000, respectively, as compared to \$718,000 and \$2,613,000 in the comparable periods in 2004. A summary of the components of cost of product revenues and royalties is provided below:

	THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)		
	2005	2004	INCREASE/ (DECREASE)
KERASTICK(R) COST OF PRODUCT REVENUES AND ROYALTIES			
Direct Kerastick(R) Product costs	\$369,000	\$ 390,000	\$ (21,000)
Other Kerastick(R) Product costs including internal costs assigned to support products	354,000	(162,000)	516,000
Royalty and supply fees (1)	93,000	75,000	18,000
Total Kerastick(R) cost of product revenues and royalties	\$816,000	\$ 303,000	\$513,000

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	2005	2004	INCREASE/ (DECREASE)
BLU-U(R) COST OF PRODUCT REVENUES			
Direct BLU-U(R) Product costs (2)	\$ 284,000	\$ --	\$ 284,000
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	207,000	415,000	(208,000)
Total BLU-U(R) cost of product revenues	\$ 491,000	\$415,000	\$ 76,000
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$1,307,000	\$718,000	\$ 589,000

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	NINE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)		
	2005	2004	INCREASE/ (DECREASE)
KERASTICK(R) COST OF PRODUCT REVENUES AND ROYALTIES			
Direct Kerastick(R) Product costs	\$1,339,000	\$ 969,000	\$ 370,000
Other Kerastick(R) Product costs including internal costs assigned to support products	985,000	79,000	906,000
Royalty and supply fees (1)	318,000	175,000	143,000
Total Kerastick(R) cost of product revenues and royalties	\$2,642,000	\$1,223,000	\$1,419,000

	2005	2004	INCREASE/ (DECREASE)
BLU-U(R) COST OF PRODUCT REVENUES			
Direct BLU-U(R) Product costs (2)	\$ 998,000	\$ --	\$ 998,000
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	1,142,000	1,390,000	(248,000)
Total BLU-U(R) cost of product revenues	\$2,140,000	\$1,390,000	\$ 750,000
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$4,782,000	\$2,613,000	\$2,169,000

- 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 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.

MARGINS - Total product margins for the three and nine-month periods ended September 30, 2005 were \$1,085,000 and \$3,207,000, respectively, as compared to \$1,292,000 and \$2,829,000 in the comparable periods in 2004, as shown below:

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### THREE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)

	2005		2004		INCREASE/ (DECREASE)
Kerastick (R)	\$ 990,000	55%	\$1,195,000	80%	\$ (205,000)
BLU-U (R)	95,000	16%	97,000	19%	(2,000)
Total Margin	\$1,085,000	45%	\$1,292,000	64%	\$ (207,000)

### NINE MONTHS ENDED SEPTEMBER 30, (UNAUDITED)

	2005		2004		INCREASE/ (DECREASE)
Kerastick (R)	\$3,440,000	57%	\$2,474,000	67%	\$ 966,000
BLU-U (R)	(233,000)	(12)%	355,000	20%	588,000
Total Margin	\$3,207,000	40%	\$2,829,000	52%	\$1,554,000

Kerastick(R) margins for the three and nine months ended September 30, 2005 were 55% and 57%, respectively, versus 80% and 67% for the comparable 2004 periods. The decrease in the Kerastick(R) margins, in terms of both dollars and percentages, for the three and nine months ended September 30, 2005 in comparison to the comparable 2004 periods is due to favorable manufacturing variances experienced during the quarter ended September 30, 2004 attributable to elevated Kerastick(R) production during that quarter. This favorable manufacturing variance resulted in Other Kerastick Product costs being negative for the three-month period ended September 30, 2004. Despite the favorable manufacturing variances experienced during the third quarter of 2004, in general, 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 nine months ended September 30, 2005 were 16% and (12%), respectively, versus 19% and 20% for the comparable 2004 periods. The erosion on margin is directly attributable to the fact that in 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

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and a decrease in Other BLU-U(R) Product costs. 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 nine-month periods ended September 30, 2005 were \$1,414,000 and \$4,809,000, respectively, as compared to \$1,585,000 and \$4,850,000 in the comparable periods in 2004. We have completed patient accrual to both the efficacy phase of our Phase II photodamaged skin study and to our Phase II multi-center moderate to severe inflammatory acne study. We now anticipate that we will have preliminary efficacy and safety data for both of the Phase II studies early in the first quarter of 2006. During September 2005, the FDA issued draft guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. DUSA has studied these guidelines, and in combination with positive new information learned from independent investigator studies on acne, the Company now believes that additional Phase II work is likely to be required before we commence Phase III acne trials. 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.

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. DUSA and the NCI DCP have prepared outlines of clinical studies in both indications. The NCI DCP has solicited letters of intent regarding these studies from its extramural expert clinical investigator consortium, and is in the process of reviewing the letters it has received. After the investigators are selected, 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. Our costs related to these studies will be limited to providing Levulan(R), device(s) and the necessary training for the investigators involved. All other costs of these studies will be the responsibility of the NCI DCP. 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, our small single-center pilot Phase II clinical trial using our new proprietary endoscopic light delivery device is continuing.

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MARKETING AND SALES COSTS - Marketing and sales costs for the three and nine-month periods ended September 30, 2005 were \$1,804,000 and \$6,886,000, respectively, as compared to \$1,835,000 and \$4,902,000 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 \$1,566,000 and \$5,256,000 for the three and nine-month periods ended September 30, 2005, compared to \$1,438,000 and

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\$3,731,000 in the comparable periods in 2004. These increases were mainly attributable to the expansion of our sales force from 22 employees as of September 30, 2004 to 28 employees as of September 30, 2005, including sales management. The remaining expenses consist of tradeshows, miscellaneous marketing and outside consultants totaling \$238,000 and \$1,630,000 for the three and nine-month periods ended September 30, 2005, compared to \$397,000 and \$1,171,000 for the comparable periods in 2004. We expect that our marketing and sales costs for the remainder of 2005 will remain relatively flat for the remainder of 2005.

GENERAL AND ADMINISTRATIVE COSTS - General and administrative costs for the three and nine-month periods ended September 30, 2005 were \$1,664,000 and \$5,187,000, respectively, as compared to \$1,198,000 and \$5,776,000 in the comparable periods in 2004. The increase for the three month period is due to increased legal and other professional fees, as well as increased general corporate expenses in relation to the comparable 2004 period for the reason described in this paragraph below. The decrease for the nine-month period is mainly attributable to lower legal expenses of \$1,551,000 as compared to \$2,822,000 in the comparable period 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 regarding settlement of patent issues, as well as litigation costs against two compounding pharmacies, as described below. Additionally, general corporate expenses, including increased personnel related costs, have increased as our business has expanded.

We continue to negotiate with PhotoCure ASA and Galderma S.A. 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 patents licensed to us by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario.

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.

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RESTRUCTURING CHARGE - During the quarter ended September 30, 2005, the Company eliminated 14 staff positions, representing 16% of the workforce, to align headcount more closely with management's assessment of its resource requirements at this time. These workforce reductions were made across all functions of the Company. As a result of these actions the Company recorded a restructuring charge of \$150,000. The Company expects that future operating costs will be reduced by \$1.4 million on an annualized basis as a result of these actions. As of September 30, 2005, the Company had paid an aggregate of \$136,000 and expects to pay the remainder of the charges by December 31, 2005.

OTHER INCOME, NET - Other income for the three and nine-month periods ended September 30, 2005 was \$340,000 and \$1,060,000, respectively, as compared to \$351,000 and \$1,125,000 in the comparable 2004 periods. This decrease was attributable to a reduction in our average investment balances as we used cash to support our operating activities, offset in part by an increase in investment yield due to higher interest rates during the period.

NET LOSSES - For the three and nine months ended September 30, 2005, we incurred net losses of \$(3,608,000), or \$(0.21) per share, and \$(12,766,000), or \$(0.75) per share, respectively, as compared to net losses of \$(2,975,000), or \$(0.18) per share, and \$(11,573,000), or \$(0.72) 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

At September 30, 2005, we had approximately \$35,264,000 of total liquid resources comprised of \$2,001,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$33,263,000. As of September 30, 2005, these available-for-sale securities had current yields ranging from 2.54% to 7.25% and maturity dates ranging from October 6, 2005 to June 15, 2008.

As of September 30, 2005, working capital (total current assets minus total current liabilities) was \$36,230,000 as compared to \$48,799,000 as of December 31, 2004. Total current assets and total current liabilities decreased by \$12,852,000 and \$283,000, respectively, during

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the nine months ended September 30, 2005 due primarily to cash used in operating activities of \$12,968,000, offset in part by cash provided by investing activities of \$11,809,000.

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.

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. During 2005, we have focused 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.

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### 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.

On September 15, 2005, the Company exercised its right to terminate its distribution agreement with its non-exclusive distributor of the Kerastick(R) in the United States. The termination is scheduled to become effective on December 31, 2005. Following termination, we will perform these activities using our existing employees and infrastructure.

### 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

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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 September 30, 2005, the weighted average rate of return on our investments was 4.41%. If market interest rates were to change immediately and uniformly by 100 basis points from levels as of September 30, 2005, the fair market value of the portfolio would change by \$326,000. 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 September 30, 2005.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 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

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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 by physicians, expectations for continuing operating losses, expectations regarding our position to take advantage of market opportunities and to exploit our therapy, beliefs regarding increases in sales and revenue, estimates regarding inventory levels and hiring goals, expectations regarding internal distribution capabilities and the utilization of our facility for manufacturing and repairs, estimates regarding the effects of so-called 'off-label' use of our products, expectations for research and development expenses and the need for additional clinical trials, beliefs regarding 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, demand, technological developments and our business model, factors which could trigger impairment review, beliefs concerning reimbursement and the effect on our revenue and the economic competitiveness of our therapy, beliefs regarding our education and marketing programs, 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, beliefs regarding the impact of the activities of compounding pharmacies on our business, beliefs regarding our requirements of

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cash resources to fund our current programs, operations and capital expenditures, beliefs regarding the need for additional funds for development, levels of interest income and net losses and the 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 potential need to hire additional personnel, the impact of competitive products and pricing, the timely development, FDA approval, and market acceptance of our products, the maintenance of our patent portfolio, changes in our long and short term goals, the litigation process, the 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.

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



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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.

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### 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 10.1 - Third Amendment to Supply Agreement, dated July 29, 2005, between DUSA Pharmaceuticals, Inc. and Sochinaz S.A., filed as Exhibit 10.1 to the Registrant's Form 10-Q filed on August 3, 2005, and is incorporated herein by reference, portions of which have been

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omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

- 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.
- 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 November 4, 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  
Chairman and Chief Executive Officer  
(principal executive officer)

Date: November 8, 2005

By: /s/ Richard C. Christopher

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Richard C. Christopher  
Vice President, Finance and Chief  
Financial Officer (principal  
financial officer and principal  
accounting officer)

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