DUSA PHARMACEUTICALS INC
Form 10-Q
November 12, 2004

FORM 10-Q
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

(Mark One)

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

For the quarterly period ended September 30, 2004

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 0-19777

DUSA Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

25 Upton Drive

Wilmington, Massachusetts 01887

(Address of principal executive offices)

(Zip Code)

(978) 657-7500

(Registrant s telephone number, including area code)

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

Yes ý No o

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY

PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes o No o

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.

16,870,072 shares as of November 9, 2004

PART I.

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2004 (Unaudited)	December 31, 2003
ASSETS		
Current Assets		
Cash and cash equivalents	$ 10,493,350	$ 4,294,482
Marketable securities available for sale	41,912,004	30,284,841
Accrued interest receivable	468,268	533,796
Accounts receivable	391,733	229,483
Inventory	1,381,444	712,831
Prepaids and other current assets	1,719,113	1,000,413
Total current assets	56,365,912	37,055,846
Restricted cash	140,221	139,213
United States government securities		3,250,940
Property and equipment, net	3,568,262	4,251,489
TOTAL ASSETS	$ 60,074,395	$ 44,697,488
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 115,517	$ 859,282
Accrued payroll	842,125	796,618
Other accrued expenses	1,787,856	1,162,139
Current maturities of long-term debt		270,000
Deferred revenue	294,432	129,900
Total current liabilities	3,039,930	3,217,939
Long-term debt, net of current maturities		1,247,500
TOTAL LIABILITIES	$ 3,039,930	$ 4,465,439
Commitments and Contingencies (Note 10)		
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: 16,866,322 (2003: 13,966,247) shares of common stock, no par.	$ 124,652,171	$ 95,670,554
Additional paid-in capital	2,256,339	2,015,586
Accumulated deficit	(70,482,514)	(58,909,781)
Accumulated other comprehensive income	608,469	1,455,690

TOTAL SHAREHOLDERS EQUITY		57,034,465		40,232,049
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$	60,074,395	$	44,697,488

See the accompanying Notes to the Condensed Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)		(Unaudited)	
REVENUES				
Product sales	$ 2,010,619	$ 163,155	$ 5,442,332	$ 453,800
OPERATING COSTS				
Cost of product sales and royalties	718,168	887,336	2,612,884	2,464,667
Research and development	1,585,099	1,202,130	4,850,159	4,167,121
Marketing and sales	1,835,210	535,114	4,901,813	1,598,604
General and administrative	1,197,707	1,627,364	5,775,500	4,782,385
TOTAL OPERATING COSTS	5,336,184	4,251,944	18,140,356	13,012,777
LOSS FROM OPERATIONS	(3,325,565)	(4,088,789)	(12,698,024)	(12,558,977)
OTHER INCOME				
Interest income, net	350,573	408,931	1,125,291	1,502,030
NET LOSS	$ (2,974,992)	$ (3,679,858)	$ (11,572,733)	$ (11,056,947)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (0.18)	$ (0.26)	$ (0.72)	$ (0.79)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	16,855,504	13,954,450	16,131,017	13,926,690

See the accompanying Notes to the Condensed Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30, 2004 (Unaudited)	2003 (Unaudited)
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES		
Net loss	$ (11,572,733)	$ (11,056,947)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of premiums and accretion of discounts on marketable securities available for sale, net	93,582	72,181
Depreciation and amortization expense	1,190,605	1,077,083
Issuance of common stock to consultants	240,753	110,000
Changes in other assets and liabilities impacting cash flows from operations:		
Restricted cash	(1,008)	(1,014)
Accrued interest receivable	65,528	264,759
Accounts receivable	(162,250)	(58,666)
Inventory	(668,613)	235,498
Prepaids and other current assets	(718,700)	348,748
Accounts payable	(743,765)	(23,125)
Accrued payroll and other accrued expenses	671,224	(865,354)
Deferred revenue	164,532	47,940
Net cash used in operating activities	(11,440,845)	(9,848,897)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES		
Purchases of marketable securities	(30,767,026)	(4,000,000)
Proceeds from maturing marketable securities	21,450,000	11,000,000
Purchases of property and equipment	(507,378)	(399,667)
Net cash provided by (used in) investing activities	(9,824,404)	6,600,333
CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES		
Issuance of common stock	28,462,500	
Stock offering costs	(200,202)	
Payments of long-term debt	(1,517,500)	(202,500)
Proceeds from exercise of options	719,319	29,000
Net cash provided by (used in) financing activities	27,464,117	(173,500)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	6,198,868	(3,422,064)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,294,482	6,925,699
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 10,493,350	$ 3,503,635

Non-Cash Transaction

During 2004, the Company issued 155,250 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 $1,707,750 (See Note 6.)

See the accompanying Notes to the Condensed Consolidated Financial Statements.

4

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of September 30, 2004, Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2004 and 2003, and Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2004 and 2003 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, 2003 audited consolidated financial statements and notes thereto. Certain amounts for 2003 have been reclassified to conform to the current year presentation. Such reclassifications had no impact on the net loss or shareholders equity for any period presented.

2) MARKETABLE SECURITIES AVAILABLE FOR SALE

The Company s investment securities consist of securities of the United States government and its agencies, and investment grade corporate bonds, all classified as available for sale. Current yields, as of September 30, 2004, range from 1.25% to 7.63% and maturity dates range from October 15, 2004 to February 15, 2007. In August 2004, the Company commenced investing in investment grade corporate securities, in accordance with the Company s investment policy. The estimated fair value and cost of marketable securities at September 30, 2004 and December 31, 2003 are as follows:

	September 30, 2004		December 31, 2003	
	Fair Value	Cost	Fair Value	Cost
	(Unaudited)			
United States government securities	$ 32,206,395	$ 31,590,499	$ 33,535,781	$ 32,080,091
Investment grade corporate securities	9,705,609	9,713,036		
Total marketable securities available for sale	$ 41,912,004	$ 41,303,535	$ 33,535,781	$ 32,080,091

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

3) INVENTORY

Inventory consisted of the following:

	September 30, 2004 (Unaudited)	December 31, 2003
Finished goods	$ 1,003,172	$ 582,382
Work in process	262,138	
Raw materials	116,134	130,449
	$ 1,381,444	$ 712,831

4) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	September 30, 2004 (Unaudited)	December 31, 2003
Research and development costs	$ 234,780	$ 184,912
Marketing and sales costs	95,497	113,020
Product related costs	478,112	144,826
Legal and other professional fees	515,123	359,747
Employee benefits	217,472	189,051
Other expenses	246,872	170,583
	$ 1,787,856	$ 1,162,139

5) LONG-TERM DEBT

In May 2002, DUSA entered into a secured term loan promissory note (Note) with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility and borrowed $1,900,000. DUSA repaid the outstanding loan balance in June 2004 without premium or penalty. The security interest in approximately $3,000,000 of the Company s United States government securities that were pledged as collateral to secure the loan was released.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

6) SHAREHOLDERS EQUITY

On February 27, 2004, the Company completed a private placement of 2,250,000 shares of its common stock at a purchase price of $11.00 per share, resulting in gross proceeds of $24,750,000. The closing date of the private placement was March 2, 2004. The Company also granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at $11.00 per share. These additional investment rights were exercised on April 14, 2004, resulting in additional gross proceeds of $3,712,500. Offering costs incurred in connection with the placement were $1,907,952, of which $1,707,750 consisted of the placement agent s commission and non-refundable retainer paid in the form of 155,250 shares of common stock calculated at the offering price.

On March 18, 2004, the Company granted a total of 30,000 fully vested options to three consultants on its Medical Advisory Board as compensation for services. These options were valued at $240,753 in accordance with the fair value-based method as required by Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure, 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 recorded as part of research and development costs in the Condensed Consolidated Statement of Operations.

7) 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 as permitted by SFAS No. 123, as amended by SFAS No. 148. Under the intrinsic value method, compensation expense, if any, is recognized for the difference between the exercise price of the option and the fair value of the underlying common stock as of a measurement date. The measurement date is the time when both the number of shares and the exercise price is known. Stock or other equity-based compensation for non-employees must be accounted for under the fair value-based method as required by SFAS No. 123, as amended by SFAS No. 148, and EITF No. 96-18, and other related interpretations. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the measurement date, which is generally the grant date. The resulting compensation cost is recognized and charged to operations over the service period, which is generally the vesting period.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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 common share for the three and nine months ending September 30, 2004 and 2003 would have been as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)		(Unaudited)	
Net Loss - As reported	$ (2,974,992)	$ (3,679,858)	$ (11,572,733)	$ (11,056,947)
Deduct: Total stock-based employee compensation expense determined under fair value based method, net of related tax effects	(438,535)	(482,455)	(1,935,133)	(1,613,376)
Net Loss - Proforma	$ (3,413,527)	$ (4,162,313)	$ (13,507,866)	$ (12,670,323)
Basic and Diluted Net Loss Per Common Share - As reported	$ (0.18)	$ (0.26)	$ (0.72)	$ (0.79)
Basic and Diluted Net Loss Per Common Share - Proforma	$ (0.20)	$ (0.30)	$ (0.84)	$ (0.91)

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. Stock options and warrants are not included in the computation of the weighted average number of shares outstanding for dilutive net loss per common share during each of the periods presented in the Condensed Consolidated Statements of Operations, as the effect would be antidilutive. For the periods ended September 30, 2004 and 2003, such potentially dilutive securities totaling approximately 3,043,000 and 2,711,000 shares, respectively, have been excluded from the computation of diluted net loss per common share.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

9) COMPREHENSIVE LOSS

For the three and nine months ended September 30, 2004 and 2003, comprehensive loss consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)		(Unaudited)	
NET LOSS	$ (2,974,992)	$ (3,679,858)	$ (11,572,733)	$ (11,056,947)
Change in net unrealized gains and losses on marketable securities available for sale	(130,812)	(407,119)	(847,221)	(774,450)
COMPREHENSIVE LOSS	$ (3,105,804)	$ (4,086,977)	$ (12,419,954)	$ (11,831,397)

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.

10) 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, was 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., infringe the patent. The final hearing in the Federal Court of Australia was held in April 2004, and a decision is expected in late 2004 or early 2005. Each party has the right to appeal within approximately one month following the Court s decision. The Company is unable to predict the outcome of the case at this time.

In December 2003, the Company was served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland alleging that DUSA s BLU-U® caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint names Berlex Laboratories, Inc., a subsidiary of the Company s former marketing partner, as another defendant. The case has been removed to the U.S. District Court for the Eastern District of Michigan Southern Division. The damages are unspecified. The Company has

9

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

filed its answer denying the claims, and Berlex has requested indemnification from the Company under the terms of the Company s former agreement with Schering AG, Berlex s parent. Currently, the Company has declined to indemnify Berlex. Recently the Court entered an order allowing the Plaintiff s attorney to withdraw. Plaintiff is currently acting on her own behalf. A Motion to Dismiss for No Progress is scheduled for hearing on November 22, 2004. While it is not possible to predict or determine the outcome of this action, the Company believes that the costs associated with all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to the consolidated results of operations in any one period to the extent costs are not covered by DUSA s insurance.

11) THIRD-PARTY CANADIAN MARKETING AND DISTRIBUTION AGREEMENT

On March 31, 2004, DUSA signed an exclusive Canadian marketing and distribution agreement for the Kerastick® and BLU-U® with Coherent-AMT Inc. (Coherent), a leading Canadian medical device and laser distribution company. Coherent began marketing the BLU-U® for moderate inflammatory acne in April 2004 and the Kerastick® for the treatment of non-hyperkeratotic actinic keratoses, or AKs, in June 2004, following receipt of the applicable regulatory approval from Health Canada. The agreement has a three-year term, which can be automatically renewed for additional one-year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. In addition, during the initial three-year term, either party may terminate the agreement earlier by providing formal written notice of its intention to do so at least 90 days in advance of each anniversary of the effective date, or in the event that the other party shall have materially breached any of its obligations in the agreement. DUSA recognizes product sales when Coherent sells the Kerastick® and the BLU-U® to the end-user, as the price is fixed and final at that point.

12) AMENDED AND RESTATED PURCHASE AND SUPPLY AGREEMENT

On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation (NBC), the manufacturer of its BLU-U® light source. This agreement provides for the elimination of certain exclusivity clauses, permits DUSA to order on a purchase order basis without minimums, and other modifications of the original agreement providing both parties greater flexibility related to the development and manufacture of light sources, and the associated technology within the field of PDT. DUSA paid $110,000 to NBC upon execution of the agreement which will be amortized over the remaining term of the agreement, expiring November 5, 2008.

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®. When Levulan® is used and followed with exposure to light to produce a therapeutic effect, the technology is called photodynamic therapy, or PDT. When Levulan® is used and followed with exposure to light to detect medical conditions, the technology is called photodetection, or PD. Our products are Levulan® 20% topical solution using our Kerastick® brand applicator, and our BLU-U® 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® is used without Levulan® for the treatment of moderate inflammatory acne vulgaris. Both products have received approval or market clearance as required from the United States Food and Drug Administration (FDA).

Marketing and sales activities since the October 2003 launch of our sales force have resulted in significant additional revenues and expenses. Kerastick® unit sales to end-users were 20,196 for the three months ended September 30, 2004, consisting of 18,870 sold in the United States (U.S.), and 1,326 sold by Coherent-AMT, our Canadian marketing and distribution partner. To date, approximately ten percent of licensed dermatologists in the U.S. have used our Kerastick®. A summary of Kerastick® unit sales to end users during the periods ended September 30, 2004 and 2003 consisted of the following:

2004					2003			
Q1	**Q2**	**Q3**	**Total**		**Q1**	**Q2**	**Q3**	**Total**
12,054	16,002	18,870	46,926	**U.S.**	1,842	1,914	1,938	5,694
	1,908	1,326	3,234	**Canada**				
12,054	17,910	20,196	50,160	**Total**	1,842	1,914	1,938	5,694

The net number of BLU-U® units placed in doctors offices during the three months ended September 30, 2004 was 95, including 25 placed in Canada. As of September 30, 2004 there were 870 units in doctor s offices, consisting of 784 in the U.S. and 86 in Canada. There were 406 BLU-U units in doctors offices at December 31, 2003.

Although the costs related to the addition of our sales force and related marketing activities are significant as compared to the revenue generated from the increase in sales, we are encouraged with the ongoing increases in sales. We have continued our efforts to penetrate the market by expanding our sales coverage in key geographic locations. As of September 30, 2004, our direct sales force consisted of 22 representatives plus our Associate Vice President of Sales. We expect to continue to incur operating losses until sales of our products increase substantially above the current levels. We do not intend to hire a significant number of additional sales personnel for the balance of 2004, and we have replaced some of our independent representatives

with full-time DUSA representatives.

At this time, our core objectives include focusing on increasing sales in the United States, conducting clinical trials to treat acne vulgaris and photodamaged skin, which, if successful, could lead to additional regulatory approvals. In addition, we continue to advance development of Levulan® PDT for the treatment of dysplasia in patients with Barrett s esophagus and support independent investigator trials to advance research in the use and applicability of Levulan® PDT for dermatology and internal indications. We have begun to examine the costs and procedures associated with seeking foreign regulatory approvals for our products, which could cause our operating cost budget to increase. We expect that an important focus during 2005 will include seeking partnerships or other relationships for the marketing and sales of Levulan® PDT outside of the U.S. and Canada subject to appropriate regulatory approvals.

To further our objectives concerning treatment of Barrett s esophagus and other internal indications using Levulan® photodynamic therapy (PDT), on September 27, 2004 we signed a clinical trial agreement with the National Cancer Institute (NCI) Division Of Cancer Prevention (DCP) for the clinical development of Levulan® PDT for the treatment of high-grade dysplasia within Barrett s Esophagus. In addition, 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 will be working together to prepare overall clinical development plans for Levulan® PDT in these indications, starting with Phase II BE trials, and Phase I/II oral cavity 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®, device(s) and the necessary training for the investigators involved in the studies. DUSA will maintain full ownership of its existing intellectual property, has options on new intellectual property and, subject to successful clinical trial results, intends to seek FDA approvals in due course.

On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation (NBC), the manufacturer of its BLU-U® light source. This agreement eliminated certain exclusivity clauses, permits DUSA to order on a purchase order basis without minimums, and made other modifications to the original agreement providing both parties greater flexibility related to the development and manufacture of light sources, and the associated technology within the field of PDT. DUSA paid $110,000 to NBC upon execution of the agreement which will be amortized over the remaining term of the agreement, expiring November 5, 2008. The Company has ordered additional BLU-U® units under the amended agreement and expects to be re-supplied during the first quarter of 2005. We may experience an inventory backlog until the new supply of light sources is available. If a backlog occurs, BLU-U® revenues would be negatively impacted and customers could purchase devices from other manufacturers rather than simply delay a purchase of a BLU-U®. In addition, growth of Kerastick® sales could be adversely affected by limited BLU-U® sales, though we believe this effect should not be significant.

On February 24, 2004, DUSA reacquired the rights to the aminolevulinic acid (Levulan®) technology for Canada held by Draxis Health Inc. (Draxis), DUSA s former parent. These rights were initially assigned to Draxis in 1991 at the time of the original licensing of the patents underlying our Levulan® PDT platform from PARTEQ Research and Development Innovations, the licensing arm of Queen s University, Kingston, Ontario. DUSA and Draxis terminated the assignment and DUSA agreed to pay to Draxis an upfront fee and an ongoing royalty on sales of the Levulan® Kerastick® in Canada over a five year term. In addition, on March 31, 2004 DUSA signed an exclusive marketing and distribution agreement for Canada with Coherent-AMT, a leading Canadian medical device and laser distribution company. Coherent-AMT began marketing the BLU-U® for moderate inflammatory acne upon entering our agreement and the Kerastick® in June 2004 for the treatment of non-hyperkeratotic actinic keratoses, or AKs, following receipt of regulatory approval from Health Canada.

In February 2004, DUSA commenced commercial production of the Levulan® Kerastick® at its Wilmington, Massachusetts manufacturing facility. During the second quarter, we commenced the distribution of the initial commercial product produced at our manufacturing facility. Production has continued during the current quarter based upon the anticipated demand for the Kerastick®.

On February 27, 2004, DUSA entered into definitive agreements with certain institutional and other accredited investors for the private placement of 2,250,000 shares of its common stock at a purchase price of $11.00 per share, resulting in gross proceeds to DUSA of $24,750,000. The closing date of the private placement was March 2, 2004. DUSA also issued additional investment rights providing the investors with the right to purchase up to an aggregate of an additional 337,500 shares of common stock at $11.00 per share. All of the additional investment rights were exercised on April 14, 2004. Offering costs incurred in connection with the placement were $1,908,000, of which $1,708,000 consisted of the placement agent s commission and non-refundable retainer paid in the form of 155,250 shares of common stock calculated at the offering price. DUSA will use the proceeds from the sale of the securities to expand its sales force and for general working capital purposes, including research and development activities.

DUSA has devoted its resources primarily to fund research and development in order to advance the Levulan® PDT/PD technology platform and, as a result, we have experienced significant operating losses. As of September 30, 2004, we had an accumulated deficit of approximately $70,483,000. Achieving our goal of becoming a profitable operating company is dependent upon acceptance of our therapy by the medical and consumer constituencies and our ability to develop new products.

DUSA has continued to support efforts to improve reimbursement levels to physicians. Some physicians have suggested that current reimbursement levels still do not fully reflect the required efforts to routinely employ our therapy in their practices. We believe that this issue has adversely affected the economic competitiveness of our products with other AK therapies and has hindered the adoption of our therapy. However, we continue to work to improve reimbursement levels. We have also educated the major private insurance carriers about our AK

therapy, and several major private insurers have approved coverage. We believe that due to these efforts, along with our education and marketing programs, and increased interest in other uses for our products, more widespread adoption by the medical community will occur over time.

We have been encouraged by the positive response from many physicians and patients who have used our therapy, but we recognize that we have to continue to demonstrate the clinical value of our unique therapy, and the related product benefits as compared to other well-established conventional therapies, in order for the medical community to accept our products on a large scale. While our financial position is strong, we cannot predict when product sales may offset the costs associated with these efforts. We are aware that some physicians have been using Levulan® with the BLU-U®, 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, these activities are positively affecting the sales of our products.

As of September 30, 2004, DUSA s staff included 66 full-time employees and 2 part-time employees as compared to 50 full-time employees and 1 part-time employee at the end of 2003. 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 expect to continue to increase our staff during the remainder of 2004 and into 2005 as we focus on sales, marketing activities and customer support associated with our AK products, research and development programs for dermatology and internal indications, and other support functions.

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, 2003. 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 there is reasonableness of collection. 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 or excess items. Inventory items identified as slow-moving are evaluated to determine

if an adjustment is required. Additionally, our industry is characterized by regular technological developments that could result in obsolete inventory. Although we make every effort to assure the reasonableness of our estimates, any significant unanticipated changes in demand, technological development, or significant changes to our business model could have a significant impact on the value of our inventory and our results of operations. We use sales projections to estimate the appropriate level of inventory that should remain on the Condensed Consolidated Balance Sheet. Management believes that the level of remaining Kerastick® inventory 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 considered important which could trigger an impairment review include significant changes relative to: (i) projected future operating results; (ii) the use of the assets or the strategy for the overall business; (iii) business collaborations; and (iv) industry, business, or economic trends and developments. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. If it is determined that the carrying value of long-lived or intangible assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, the asset is written down to its estimated fair value on a discounted cash flow basis. At September 30, 2004, our total property, plant and equipment had a carrying value of $3,568,000, including $2,007,000 associated with our manufacturing facility, which received FDA approval in July 2003 and began inventory production in February 2004. We had no intangible assets recorded as of September 30, 2004 and December 31, 2003.

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 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. As we utilize stock and stock options as one means of compensating employees, consultants, and others, a change in accounting for stock-based compensation could, under certain circumstances, result in an adverse material effect on our results of operations, but would not affect cash flows.

Results of Operations

Revenues Total revenues for the three and nine months ended September 30, 2004 were $2,011,000 and $5,442,000, respectively, as compared to $163,000 and $454,000 in the same periods in 2003, and were comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)		(Unaudited)	
Kerastick® sales to physicians				
U.S.	$ 1,414,000	$ 163,000	$ 3,513,000	$ 454,000
Canada	85,000		185,000	
Total	$ 1,499,000	$ 163,000	$ 3,698,000	$ 454,000
BLU-U® sales to physicians				
U.S.	$ 432,000	$	$ 1,481,000	$
Canada	80,000		263,000	
Total	$ 512,000	$	$ 1,744,000	$
Total product sales	$ 2,011,000	$ 163,000	$ 5,442,000	$ 454,000

The increase in 2004 product sales reflects sales to physicians for the three and nine months ended September 30, 2004 of 20,196 and 50,160 Kerastick® units, respectively, as compared to 1,938 and 5,694 Kerastick® units for the 2003 periods. The increase in product revenues also reflects an increase in the BLU-U® units in place in physician s offices of 870 units as of September 30, 2004, up from 406 units at December 31, 2003. With respect to Kerastick sales, we have increased our direct selling effort, while still maintaining the services of one distributor. We expect that in the near future we will bring a significant level of the distribution function in-house which will increase our gross revenue per unit recognizing that we will have increased costs to support this function.

On March 31, 2004, DUSA signed an exclusive marketing and distribution agreement for the Kerastick® and BLU-U® in Canada with Coherent-AMT Inc. (Coherent), a leading Canadian medical device and laser distribution company. Following receipt of regulatory approval from Health Canada, Coherent began marketing the BLU-U® for moderate inflammatory acne in April 2004, and the Kerastick® for the PDT treatment of non-hyperkeratotic actinic keratoses, or AKs, in June 2004. DUSA recognizes product sales when Coherent sells the Kerastick® and/or the BLU-U® to the end-user, as the price is fixed and final at that point. Product sales through our Canadian distributor for the three and nine months ended September 30, 2004 included Kerastick® units of 1,326 and 3,234, respectively, and BLU-U® units placed of 25 and 86, respectively. Kerastick® sales by Coherent during the quarter ended September 30, 2004 decreased as compared to the prior quarter as the initial launch sales of 1,908 during the second quarter of 2004 included built up demand as a result of DUSA receiving marketing approval in Canada. It is anticipated that fourth quarter sales will increase over those seen in the third quarter.

The increase of Kerastick® and BLU-U® sales in the United States is a result of the efforts of our sales force, which we launched in October 2003, and related marketing and sales

activities. In addition, the increase in BLU-U® placements is caused, in part, by our ability to sell the BLU-U® to physicians as a stand alone device for the treatment of moderate inflammatory acne vulgaris following FDA clearance in September 2003. BLU-U® sales during the quarter ended September 30, 2004 decreased, as expected, as compared with the prior quarter due to a planned price increase that became effective at the beginning of the current quarter, and a decreased emphasis on BLU-U® placements by our sales-force, in light of our shrinking BLU-U inventory levels. We have now ordered additional BLU-U® units, and expect to be re-supplied during the quarter ended March 31, 2005. As we expect to experience a backlog until the new supply of light sources is available, BLU-U® revenues are expected to be limited. In addition, growth of Kerastick® units could be adversely affected by limited BLU-U® sales, though we believe this effect should not be significant.

As expected, due to the potential for elective dermatological procedures to decline during the summer months, sales for the third quarter of 2004 did not increase at the same rate as compared to the rates during the last three quarters. However, product sales to new customers and the results of adding additional sales representatives did offset some of the effects of this seasonal fluctuation. Due to the increased number of sales representatives and the increasing acceptance of our therapy, we do expect that sales levels will increase during the fourth quarter of 2004 and into 2005. See Results of Operations-Marketing and Sales Costs .

Although the level of Kerastick® sales to end-users for 2004 is substantially higher than the level in the prior year, Kerastick® sales must continue to increase significantly in order for DUSA to become profitable. To reach that goal, we have increased our sales force s numbers and geographic reach, and we will continue to participate in medical conferences.

Cost of Product Sales and Royalties Cost of product sales and royalties for the three and nine months ended September 30, 2004 were $718,000 and $2,613,000, respectively, as compared to $887,000 and $2,465,000 in the comparable 2003 periods. A summary of the components of cost of product sales and royalties is provided below:

Three Months Ended September 30,				Nine Months Ended September 30,			
2004	2003 (Unaudited)	Increase (Decrease)		2004	2003 (Unaudited)	Increase (Decrease)	
$ 54,000	$ 781,000	$ (727,000)	Product costs including internal costs (e.g. customer service, quality assurance, purchasing, depreciation, amortization and other product support operations) assigned to support products (1)	$ 754,000	$ 2,133,000	$ (1,379,000)	
390,000	37,000	353,000	Kerastick® product costs	969,000	109,000	860,000	
199,000	51,000	148,000	Costs incurred to ship, install and service the BLU-U® in physicians offices (2)	715,000	169,000	546,000	
75,000	18,000	57,000	Royalty and supply fees (3)	175,000	54,000	121,000	
$ 718,000	$ 887,000	$ (169,000)	Total cost of product sales and royalties	$ 2,613,000	$ 2,465,000	$ 148,000	

(1) The decrease in product costs for 2004 primarily reflects the capitalization of labor and overhead associated with the start of Kerastick® production in our facility. These costs were expensed in the prior year due to the absence of production.

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

(3) Royalty and supply fees include fees paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen s University, Kingston, Ontario, and in 2004 amortization of an upfront fee and a royalty paid to Draxis, DUSA s former parent, on sales of the Levulan® Kerastick® in Canada.

Research and Development Costs Research and development costs for the three and nine month periods ended September 30, 2004 were $1,585,000 and $4,850,000, respectively, as compared to $1,202,000 and $4,167,000 in the same periods in 2003. These increases reflect the preparation work associated with initiating the Phase II photodamaged skin trial, protocol finalization for our acne trial, and the start of our Phase II pilot study for Barrett s esophagus offset, in part, by lower third-party expenditures for our FDA mandated Phase IV clinical study of the long-term efficacy of the Kerastick®. This FDA mandated Phase IV study was completed in late 2003 and we incurred only limited costs to file the final report with the FDA in 2004. We have concentrated our dermatology development program on indications that use our approved Kerastick®. Based on market research that was completed in 2003, we have moved forward with our Phase II clinical studies for use of Levulan® PDT in photodamaged skin and moderate to severe acne vulgaris. We initiated the photodamaged skin study during the second quarter of 2004, and a Phase II study on Levulan® PDT for the treatment of acne vulgaris at the end of October 2004. In addition, the current nine month period includes compensation of $241,000 for 30,000 fully vested stock options issued to three consultants for services. We expect to incur total research and development costs of approximately $6,500,000 to $7,500,000 during 2004 due primarily to initiating these studies.

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® 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® 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 will be working together to prepare overall clinical development plans for Levulan® 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®, 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.

Marketing and Sales Costs Marketing and sales costs for the three and nine month periods ended September 30, 2004 were $1,835,000 and $4,902,000, respectively, as compared to $535,000 and $1,599,000 in the comparable periods in 2003. These costs consist of overhead expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling $1,438,000 and $3,731,000 for the three and nine month periods ended September 30, 2004, respectively, as compared to $233,000 and $600,000 in 2003. The remaining expenses consist of tradeshows, miscellaneous marketing and outside consultants totaling $397,000 and $1,171,000 for the three and nine month periods ended September 30, 2004, respectively, as compared to $302,000 and $999,000 in 2003. These increases were mainly attributable to the launch of our direct sales force in October 2003 and related marketing and sales activities.

As of September 30, 2004, our sales force was comprised of 22 direct representatives and various independent representatives in key target markets. We anticipate that the level of marketing and sales expenses will remain relatively stable for the balance of 2004 as we do not plan to significantly expand our sales force any further at this point in time.

General and Administrative Costs General and administrative costs for the three and nine month periods ended September 30, 2004 were $1,198,000 and $5,776,000, respectively, as compared to $1,627,000 and $4,782,000 in the comparable periods in 2003. The decrease in the current three month period is due mainly to lower legal expenses of $291,000 in 2004, as compared to $814,000 in 2003 due to the absence of patent litigation costs in Australia as the final hearing in the PhotoCure litigation was held in April 2004. The increase in the current nine month period is mainly attributable to legal expenses amounting to $2,822,000 during 2004, as compared to $2,400,000 in the comparable 2003 period, due to higher patent litigation costs primarily associated with the final hearing in Australia earlier in 2004.

In April 2002, PhotoCure ASA filed suit against Queen s University at Kingston, Ontario, alleging that Australian Patent No. 624985, which is one of the patents licensed by PARTEQ to us, relating to ALA technology, was invalid. As a consequence of that action,

Queen s University assigned the Australian patent to us so that we could participate directly in this litigation. We filed an answer setting forth our defenses and a related countersuit alleging that certain activities of PhotoCure and its marketing partner, Galderma S.A., infringe the patent. The final hearing in the Federal Court of Australia was held in April 2004, and we expect that the Court s decision will be rendered in late 2004 or early 2005. We are unable to predict the outcome at this time. However, should PhotoCure prevail in either part of the case, i.e. the Court finds that (i) our patent is invalid, or (ii) the patent is valid, but PhotoCure s product does not infringe the patent, PhotoCure will be able to market its product in Australia. Each party has the right to appeal within approximately one month of the Court s decision. In August 2004, DUSA, PhotoCure and Galderma entered into a Mediation Agreement designed to facilitate resolution of the parties potential patent disputes concerning PhotoCure and Galderma s methyl aminolevulinate product. The parties discussions are on-going.

In December 2003, DUSA was served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland alleging that DUSA s BLU-U® caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint names Berlex Laboratories, Inc., a subsidiary of our former marketing partner, as another defendant. The damages are unspecified. The case has been removed to the U.S. District Court, Eastern District of Michigan, Southern Division. We have filed our answer denying the claims. Berlex has requested indemnification from DUSA under the terms of the Company s former agreement with Schering AG, Berlex s parent. Currently, DUSA has declined to indemnify Berlex. Recently the Court entered an order allowing the Plaintiff s attorney to withdraw. Plaintiff is currently acting on her own behalf. A Motion to Dismiss for No Progress is scheduled for hearing on November 22, 2004. While it is not possible to predict or determine the outcome of this action, we believe that the costs associated with all such matters will not have a material adverse effect on its consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one period to the extent costs are not covered by DUSA s insurance.

Other Income, net Other income for the three and nine month periods ended September 30, 2004 was $351,000 and $1,125,000, respectively, as compared to $409,000 and $1,502,000 in the comparable 2003 periods. These decreases were attributable to a reduction in our average investable cash balances during 2003 and early 2004, as we used cash to support our operating activities. With the addition of the proceeds from the private placement in March 2004, interest income will be impacted by the direction of interest rates and as our investable cash balances are used to support our operating activities. During the nine month period ended September 30, 2004, we incurred interest expense of $20,000 on borrowings associated with the construction of our Kerastick® manufacturing facility as compared to $45,000 in the comparable 2003 period, of which $36,000 was capitalized in property and equipment in the Condensed Consolidated Balance Sheet as of September 30, 2003. DUSA repaid the outstanding secured term loan promissory note with Citizens Bank of Massachusetts in June 2004.

Net Losses For the three and nine months ended September 30, 2004, the Company incurred net losses of $2,975,000, or $0.18 per share, and $11,573,000, or $0.72 per share,

respectively, as compared to net losses of $3,680,000, or $0.26 per share, and $11,057,000, or $0.79 per share for the comparable periods in 2003. Net losses are expected to continue until product sales to physicians offset the cost of 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® PDT sales and marketing expenses and current research and development activities for its Levulan® PDT/PD platform. At September 30, 2004, we had approximately $52,545,000 of total cash resources comprised of $10,493,000 of cash and cash equivalents, marketable securities available for sale totaling $41,912,000, and restricted cash of $140,000. As of September 30, 2004, these securities had yields ranging from 1.25% to 7.63% and maturity dates ranging from October 15, 2004 to February 15, 2007. In August 2004, DUSA changed its investment policy to allow investment of a portion of its securities in high grade corporate bonds in order to improve yields earned on its marketable securities.

On February 27, 2004, DUSA completed a private placement of 2,250,000 shares of its common stock at a purchase price of $11.00 per share resulting in gross proceeds of $24,750,000. We also granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at $11.00 per share, which were exercised on April 14, 2004, resulting in additional proceeds of $3,712,500. Offering costs incurred in connection with the placement were $1,908,000, of which $1,708,000 consisted of the placement agent s commission and non-refundable retainer paid in the form of 155,250 shares of common stock calculated at the offering price.

As of September 30, 2004, working capital (total current assets minus total current liabilities) was $53,326,000 as compared to $33,838,000 as of December 31, 2003. Total current assets increased $19,310,000 in 2004 due primarily to the gross proceeds received from the private placement of $28,463,000, offset by the use of $11,441,000 of cash and cash equivalents to support our operating activities.

As of September 30, 2004, DUSA had current liabilities of $3,040,000, as compared to $3,218,000 as of December 31, 2003. This decrease is due in part to the repayment of debt in June 2004 with proceeds from the private placement. In May 2002, we entered into a secured term loan promissory note (Note) with Citizens Bank of Massachusetts to fund the construction of our manufacturing facility and borrowed $1,900,000. DUSA repaid the outstanding loan balance in June 2004.

We believe that we have sufficient capital resources to proceed with our current programs for Levulan® 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 for funding our needs on a short-term and long-term basis.

DUSA may also seek to expand or enhance its business by using resources to acquire businesses, new technologies, or products, especially in dermatology-related areas. For the remainder of 2004, we are focusing primarily on increasing sales of the Levulan® Kerastick®.

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

Contractual Obligations and Other Commercial Commitments

In May 2002, DUSA entered into a secured term loan promissory note (Note) with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility and borrowed $1,900,000. DUSA repaid the outstanding loan balance in June 2004. The security interest in approximately $3,000,000 of our United States government securities that were being pledged as collateral to secure the loan was released.

DUSA included a summary of our Contractual Obligations and Other Commercial Commitments in our annual report on Form 10-K for the year ended December 31, 2003. There have been no material changes to the summary provided in that report other than that noted above.

Recently Issued Accounting Pronouncements

The Company has reviewed the latest accounting pronouncement and does not believe any new standard will have a material impact on the Company s financial position or operating results other than those presented in our Annual Report on Form 10-K for the year ended December 31, 2003.

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

DUSA holds fixed income marketable securities that are subject to interest rate market risks. However, we do not believe that the risk is material as we make our investments in relatively short-term instruments and we strive to match the maturity dates of these instruments to our cash flow needs. A ten percent decline in the average yield of these instruments would not have a material effect on our results of operations or cash flows.

ITEM 4. **CONTROLS AND PROCEDURES**

DUSA carried out an evaluation, under the direction of its Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of its 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, 2004.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Forward-Looking Statements

This report, including the Management s Discussion and Analysis, contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 which represent our expectations or beliefs concerning future events, including, but not limited to statements regarding management s goal of becoming profitable, beliefs regarding adoption of our therapy, improving reimbursement levels, marketing costs, expectations for research and development costs, continuing operating losses, increasing sales levels and participation in medical conferences, expectations of increasing staff and hiring levels for our sales force, plans with respect to the NCI DCP clinical trials and anticipated commitment of resources, maintenance of intellectual property, and intentions for seeking regulatory approvals, timing of Phase II acne studies, effects of unanticipated changes in estimates, technology and forecasts, belief concerning reasonableness of inventory levels, factors which could trigger impairment review, effect of an accounting change for stock-based compensation, expectations for the use of our facility to manufacture Kerasticks® and other clinical supplies, plans to conduct additional clinical trials for high-grade dysplasia, expectations for timing of receipt of BLU-U inventory and impact on revenues from a potential backlog, management s use of proceeds from the sale of securities, and consummation of any marketing and sales partnerships, expectations for increased marketing and sales costs and levels of legal fees, beliefs regarding the Australian patent litigation and Michigan product litigation, expectations regarding levels of interest income and net losses, requirements of cash resources, and potential impact on conversion of government securities, need for additional funds for development, intentions to expand or enhance business through acquisition, new technology or new products, evaluation of transactions under new accounting pronouncements, inflation, market risks and controls and procedures. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the FDA approval and market acceptance of our products, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by additional third-party payors, and

other risks noted in our SEC filings from time to time, including our Form 10-K for the period ending December 31, 2003, none of which can be assured.

PART II- OTHER INFORMATION

Items 1, 3, and 5.

None.

Item 2. Changes in Securities and Use of Proceeds.

i) February 2004 Private Placement On February 27, 2004, DUSA entered into definitive agreements with certain new and existing institutional and other accredited investors for the private placement of 2,250,000 shares of our common stock at a purchase price of $11.00 per share resulting in gross proceeds to DUSA of $24,750,000. DUSA granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at $11.00 per share which were exercised on April 14, 2004. Offering costs incurred in connection with the placement were $1,907,952, of which $1,707,750 consisted of the placement agent s commission and non-refundable retainer paid in the form of 155,250 shares of common stock calculated at the offering price. DUSA relied on Rule 506 promulgated under the Securities Act of 1933 in selling these shares. DUSA engaged in due diligence to confirm that all purchasers of the common stock were accredited investors.

DUSA will use the proceeds from the sale of the securities to expand its sales force and for general working capital purposes, including research and development activities.

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

i) 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.

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 November 11, 2004

ii) Form 8-K

a) Form 8-K, dated and filed July 12, 2004, reporting sales results for the quarter ended June 30, 2004.

b) Form 8-K, dated August 17, 2004 and filed August 18, 2004, reporting that DUSA, Queens University at Kingston, Galderma S.A., and PhotoCure ASA have entered into a Mediation Agreement designed to facilitate resolution of the parties potential patent disputes concerning PhotoCure and Galderma s methyl aminolevulinate product.

c) Form 8-K, dated August 20, 2004 and filed August 26, 2004, reporting that Peter Chakoutis, DUSA s Chief Financial Officer and principal financial officer, has resigned for personal reasons. The parties expect the resignation to be effective on December 31, 2004 and Mr. Chakoutis has offered to remain in his position on a part-time basis from January 1, 2005 through March 31, 2005 should the Registrant require his services.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DUSA Pharmaceuticals, Inc.

By: /s/ D. Geoffrey Shulman
D. Geoffrey Shulman
President and Chief Executive Officer
(principal executive officer)

Date: November 11, 2004

By: /s/ Peter M. Chakoutis
Peter M. Chakoutis
Vice President and Chief Financial
Officer (principal financial officer) and
Controller (principal accounting 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 November 11, 2004