DUSA PHARMACEUTICALS INC
Form 10-Q
May 04, 2004

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 March 31, 2004

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from_____ to

Commission file number 0-19777

DUSA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

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

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

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

Yes X No
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APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of 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.

16,765,122 shares as of April 30, 2004

PART 1.

ITEM 1. FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS
CURRENT ASSETS
    Cash and cash equivalents
    United States government securities
    Accrued interest receivable
    Accounts receivable
    Inventory
    Prepaids and other current assets

          TOTAL CURRENT ASSETS
    Restricted cash
    United States government securities
    Property and equipment, net

TOTAL ASSETS

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES
    Accounts payable
    Accrued payroll
    Other accrued expenses
    Current maturities of long-term debt
    Deferred revenue

         TOTAL CURRENT LIABILITIES
    Long-term debt, net of current

TOTAL LIABILITIES

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: 16,407,372 (2003: 13,966,247)
          shares of common stock, no par.
    Additional paid-in capital
    Accumulated deficit
    Accumulated other comprehensive income

TOTAL SHAREHOLDERS' EQUITY

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY

See the accompanying Notes to the Condensed Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	THREE MONTHS ENDED MARCH 31,	
	2004 (UNAUDITED)	2003 (UNAUDITED)
REVENUES		
Product sales	$ 1,255,685	$ 143,370
TOTAL REVENUES	1,255,685	143,370
OPERATING COSTS		
Cost of product sales and royalties	826,005	753,304
Research and development	1,687,766	1,516,391
Marketing and sales	1,367,458	530,512
General and administrative	2,175,247	1,475,271
TOTAL OPERATING COSTS	6,056,476	4,275,478
LOSS FROM OPERATIONS	(4,800,791)	(4,132,108)
OTHER INCOME		
Interest income, net	399,137	566,135
NET LOSS	$ (4,401,654)	$ (3,565,973)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (0.30)	$ (0.26)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	14,802,474	13,892,514

See the accompanying Notes to the Condensed Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	THREE MONTH
	2004 (UNAUDITED)

CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES	
Net loss	$ (4,401,65
Adjustments to reconcile net loss to net cash used in operating activities	
Amortization of premiums and accretion of discounts on U.S. government securities available for sale, net	27,51
Depreciation and amortization expense	460,71
Issuance of common stock to consultants	240,75
Changes in other assets and liabilities impacting cash flows from operations:	
Accrued interest receivable	161,42
Accounts receivable	35,77
Inventory	(128,65
Prepaids and other current assets	81,95
Accounts payable	(484,44
Accrued payroll and other accrued expenses	443,50
Deferred revenue	91,81
Restricted cash	(31
NET CASH USED IN OPERATING ACTIVITIES	(3,471,61
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES	
Proceeds from maturing United States government securities	4,000,00
Purchases of property and equipment	(222,51
NET CASH PROVIDED BY INVESTING ACTIVITIES	3,777,48
CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES	
Issuance of common stock	24,750,00
Stock offering costs	(214,40
Proceeds from exercise of options	297,29
Payments of long-term debt	(67,50
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	24,765,38
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	25,071,25
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,294,48
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 29,365,73

On March 2, 2004, the Company issued 135,000 shares of its common stock in a private placement at $11.00 per share as commission and non-refundable retainer to the placement agent for a total value of $1,485,000.

See the accompanying Notes to the Condensed Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of March 31, 2004, and the Condensed Consolidated Statements of Operations and Cash Flows for the three months ended March 31, 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) UNITED STATES GOVERNMENT SECURITIES

The Company's United States government securities available for sale consist of securities of the United States government and its agencies, with current yields, as of March 31, 2004, ranging from 3.66% to 7.46% and maturity dates ranging from April 5, 2004 to September 24, 2007.

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

3) INVENTORY

Inventory consisted of the following:

	MARCH 31, 2004 (UNAUDITED)	DECEMBER 31, 2003
Finished goods	$ 326,663	$ 582,382
Work in process	359,914	-
Raw materials	154,904	130,449
	$ 841,481	$ 712,831

4) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	MARCH 31, 2004 (UNAUDITED)	DECEMBER 31, 2003

Accrued research and development costs	$ 197,264	$ 184,912
Accrued marketing and sales costs	172,887	113,020
Accrued product related costs	242,431	144,826
Accrued legal and other professional fees	1,074,403	359,747
Accrued employee benefits	214,969	189,051
Other accrued expenses	156,862	170,583
	$ 2,058,816	$ 1,162,139

5) 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. The offering costs incurred during the period ended March 31, 2004 in connection with the placement were $1,699,402 of which $1,485,000 consisted of the placement agent's commission and non-refundable retainer paid in the form of 135,000 shares of common stock, calculated at the offering price. The Company also issued 20,250 shares to the placement agent as additional commission and non-refundable retainer with respect to the exercise of the additional investment rights.

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 approximately $240,753 in accordance with the fair value-based method as required by 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.

6) ACCOUNTING FOR STOCK BASED COMPENSATION

SFAS No. 123, as amended by SFAS No. 148, addresses the financial accounting and reporting standards for stock or other equity-based compensation arrangements. The Company has elected to continue to use the intrinsic value-based method to account for employee stock option awards under the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and to provide disclosures based on the fair value method in the Notes to the Consolidated Financial Statements as permitted by SFAS No. 123, as amended by SFAS No. 148. Under the intrinsic value method, compensation expense, if any, is recognized for the difference between the strike price of the option and the fair value of the underlying common stock as of a measurement date. The measurement date is the time when both the number of shares and the strike price is known. Stock or other equity-based compensation for non-employees must be accounted for under the fair value-based method as required by SFAS No. 123, as amended by SFAS No. 148, 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.

As described above, the Company uses the intrinsic value method to measure compensation expense associated with grants of stock options to employees. Had the Company used the fair value method to measure compensation, the Company's pro forma net loss, and pro forma net loss per share for the three months ending March 31, 2004 and 2003 would have been as follows:

	2004 (UNAUDITED)	2003 (UNAUDITED)
NET LOSS		
As reported	$ (4,401,654)	$ (3,565,973)
Effect on net loss if fair value method had been used	(717,145)	(587,209)
Proforma	$ (5,118,799)	$ (4,153,182)
BASIC AND DILUTED NET LOSS PER COMMON SHARE		
As reported	$ (0.30)	$ (0.26)
Effect on net loss per common share if fair value method had been used	(0.05)	(0.04)
Proforma	$ (0.35)	$ (0.30)

7) BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per common share is based on the weighted average number of shares outstanding during each period. Stock options, warrants and rights 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 Statements of Operations, as the effect would be antidilutive. For the three months ended March 31, 2004, and 2003, stock options, warrants and rights totaling approximately 3,396,000 and 2,661,000 shares, respectively, have been excluded from the computation of diluted net loss per share.

8) COMPREHENSIVE LOSS

For the three months ended March 31, 2004 and 2003, comprehensive loss consisted of the following:

2004 (UNAUDITED)	2003 (UNAUDITED)

NET LOSS	$ (4,401,654)	$ (3,565,973)
Change in net unrealized gains on United States securities available for sale	(147,659)	(246,998)
COMPREHENSIVE LOSS	$ (4,549,313)	$ (3,812,971)

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 has filed a lawsuit in Australia alleging that Australian Patent No. 624985, which is one of the patents relating to the Company's 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University assigned the Australian patent to the Company so that DUSA could participate directly in this litigation. The Company filed a response setting forth its defenses, and a related countersuit alleging that certain activities of PhotoCure and its marketing partner, Galderma S.A., 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. Each party has the right to appeal within approximately one month following the judge's decision.

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(R) 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 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. 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 DISTRIBUTION AGREEMENT

On March 31, 2004, DUSA signed an exclusive marketing and distribution agreement for Canada with Coherent-AMT Inc. ("Coherent"), a leading Canadian medical device and laser distribution company. Coherent began marketing the BLU-U(R) for moderate inflammatory acne immediately, and the Company expects Coherent to market the Kerastick(R) later in 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, either party may terminate the agreement earlier, on certain terms, or in the event that the

other party shall have materially breached any of its obligations in the agreement.

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, which were launched in September 2000 in the United States, are Levulan(R) 20% topical solution using our Kerastick(R) brand applicator, and our BLU-U(R) brand light unit. 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, we received market clearance from the United States Food and Drug Administration ("FDA") in September 2003 to market the BLU-U(R) without Levulan(R) for the treatment of moderate inflammatory acne vulgaris.

In February 2004, we commenced commercial production of the Levulan(R) Kerastick(R) at our Wilmington manufacturing facility. The initial commercial product from the Wilmington facility became available for distribution early in the second quarter of 2004. As of March 31, 2004, we had 16,908 Kerastick(R) units in inventory. This inventory was produced in 2002 by our former third-party manufacturer to meet product demand during the execution of our project to complete construction and gain FDA approval of our new manufacturing facility. Although we have adequate inventory to meet short-term demand, the start of production at this time is intended to insure that we will have an adequate supply of inventory to meet the increasing market demand throughout 2004 and beyond. Initial production planning is based on the anticipated near term demand for the Kerastick(R). The plant has the capacity to make over one million Kerastick(R) units annually.

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 our 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. The offering costs incurred during the period in connection with the placement were $1,699,402 of which $1,485,000 consisted of the placement agent's commission and non-refundable retainer, which was paid in the form of 135,000 shares of common stock calculated at the offering price. An additional 20,250 shares were issued to the placement agent with respect to the

exercise by the investors of the Additional Investment Rights. 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.

On February 24, 2004, DUSA reacquired the rights to the aminolevulinic acid (Levulan(R)) 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(R) 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 a royalty on sales of the Levulan(R) Kerastick(R) 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(R) for moderate inflammatory acne immediately, and we expect Coherent-AMT to market the Kerastick(R) later in 2004 following receipt of the applicable regulatory approval from Health Canada.

We have primarily devoted our resources to fund research and development in order to advance the Levulan(R) PDT/PD technology platform and, as a result, we have experienced significant operating losses. As of March 31, 2004, we had an accumulated deficit of approximately $63,311,000. 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.

During 2003, DUSA implemented new sales, marketing, physician education, and development strategies, including the October 2003 launch of our initial sales force. These marketing and sales activities have resulted in significant additional expenses; however, the impact on sales has been positive. Kerastick(R) unit sales to end-users were 12,054 for the three months ended March 31, 2004, compared to 1,842 in the comparable 2003 period. Although the costs related to the addition of our sales force and related marketing activities are currently greater than the gross profit generated from the increased sales, we are encouraged with the initial increase in sales. We have continued our efforts to penetrate the market through expanding our sales coverage in key geographic locations, have increased the size of our direct sales force from 8 total representatives as of March 31, 2004, to 14 as of May 3, 2004 and have plans to increase the number to 16 by the end of June 2004. We expect to continue to incur operating losses until sales of our products increase substantially. 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, and seeking a partner to help develop and market Levulan(R) PDT for the treatment of dysplasia in patients with Barrett's esophagus. In addition, we continue to support independent investigator trials to advance research in the use and applicability of Levulan(R) PDT for other indications in dermatology.

We have continued to support efforts to improve reimbursement levels to physicians. Some physicians have suggested that current reimbursement levels do not fully reflect the required efforts to routinely employ our therapy in their practices. We believe that this issue has affected the economic competitiveness of our products with other AK therapies and has hindered the adoption of our therapy. In addition, we continue to work to educate the major private insurance carriers such that they will approve our therapy for coverage. As of March 31, 2004, several major private insurers have approved coverage for our AK therapy. We believe that due to these efforts, along with our education and marketing programs, more widespread adoption by the medical community should occur over time. In addition, we are aware that some 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, these activities are positively affecting the sales of our products.

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.

As of March 31, 2004, our staff included 51 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 increase our staff in 2004 as we focus on sales, marketing activities and customer support associated with our AK products, and research and development programs for dermatology and internal indications.

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.

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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. Research revenue generally compensates us for a portion of agreed-upon research and development expenses and is recognized as revenue at the time the research and development activities are performed under the terms of the related agreements and when no future performance obligations existed. Milestone or other up-front payments are typically recorded as deferred revenue upon receipt and recognized as income on a straight-line basis over the term of an agreement. 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. We recognized no research or milestone revenues in the three months ended March 31, 2004 and 2003.

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 that should remain on the Consolidated Balance Sheet. Management believes that the level of remaining

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 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 March 31, 2004, our total property, plant and equipment had a carrying value of $4,013,000, including $2,082,000 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 March 31, 2004.

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. 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 - THREE MONTHS ENDING MARCH 31, 2004 VERSUS MARCH 31, 2003

REVENUES - Total revenues for the three months ended March 31, 2004 were $1,256,000 as compared to $143,000 in 2003, and were comprised of the following:

	THREE MONTHS ENDED MARCH 31, (UNAUDITED)		
PRODUCT SALES REVENUES	2004	2003	INCREASE/ (DECREASE)
Direct Kerastick(R) sales to physicians	$ 896,000	$ 143,000	$ 753,000
BLU-U(R) sales to physicians	360,000	-	360,000
Total product sales	$1,256,000	$ 143,000	$1,113,000

The increase in 2004 product sales reflects Kerastick(R) sales to end-users of 12,054 for the three months ended March 31, 2004 as compared to 1,842 in the comparable 2003 period, and an increase in the BLU-U(R) units placed in physician's offices to 534 units as of March 31, 2004, up from 406 units at December 31, 2003. The increase of both Kerastick(R) and BLU-U(R) sales is a result of the efforts of our sales force which we launched in October 2003, and includes sales generated at dermatology conferences including the American Academy of Dermatology ("AAD") annual meeting in February 2004, which is the largest and most important dermatology conference each year. In addition, the increase in BLU-U(R)

placements is caused, in part by our ability to sell the BLU-U(R) to physicians as a stand alone device for the treatment of moderate inflammatory acne vulgaris. Although the level of Kerastick(R) sales to end-users for 2004 is higher than those in the prior year, Kerastick(R) sales must continue to increase significantly in order for DUSA to become profitable. Sales through April also showed a continuing positive trend, due in part to our participation at the American Society of Laser Medicine and Surgery ("ASLMS") annual meeting. We are in the process of increasing our sales force's geographic and numeric reach, and we will continue to participate in medical conferences throughout the year, but we do not expect to generate the same level of sales activities from smaller conferences as we did at the AAD annual meeting. Therefore, sales increases during the rest of the year are not expected to remain at the same level of percentage increases that we have experienced during the last two quarters. See "Results of Operations-Marketing and Sales Costs".

COST OF PRODUCT SALES AND ROYALTIES - Cost of product sales and royalties for the three months ended March 31, 2004 were $826,000 as compared to $753,000 in 2003. A summary of the components of cost of product sales and royalties is provided below:

	THREE MONTHS ENDED MARCH 31, (UNAUDITED)		
COST OF PRODUCT SALES AND ROYALTIES	2004	2003	INCREASE/ (DECREASE
Product costs including internal costs (e.g. customer service, quality assurance, purchasing, depreciation, amortization and other product support operations) assigned to support products (1)	$ 395,000	$ 654,000	$ (259,00
Direct Kerastick(R) product costs	233,000	36,000	197,00
Costs incurred to ship, install and service the BLU-U(R) in physicians offices (2)	162,000	46,000	116,00
Royalty and supply fees (3)	36,000	17,000	19,00
Total cost of product sales and royalties	$ 826,000	$ 753,000	$ 73,00

1) The decrease in product costs for 2004 primarily reflects the capitalization of labor and overhead associated with the start of Kerastick(R) production, these costs were expensed in the prior year as underutilization due to the absence of production.

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

3) Royalty and supply fees are paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs for the three months ended March 31, 2004 were $1,688,000 as compared to $1,516,000 for 2003. This increase in 2004 was primarily due to compensation of $241,000 recorded for 30,000 fully vested stock options issued to three consultants for services. The increase was partly offset by lower third-party expenditures for our FDA mandated Phase IV clinical study of the long-term efficacy of our marketed product. This

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(R). Based on market research that was completed in 2003, we have moved forward with our Phase II clinical studies for use of Levulan(R) PDT in photodamaged skin and moderate to severe acne vulgaris. The Phase II study for moderate to severe acne is planned to be proposed to the FDA by mid 2004 and expect to begin the acne study later in 2004. We plan to initiate the photodamaged skin study during the second quarter of 2004 based on the Investigational New Drug, or IND, application which has been cleared by the FDA. We expect to incur research and development costs of approximately $6,500,000 to $7,500,000 during 2004 due primarily to initiating these studies.

We have also been following patients who completed Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett's esophagus. In preparation for new Phase II clinical trials, we are planning to carry out a small single-center pilot Phase II clinical trial using DUSA's new proprietary endoscopic light delivery device for the treatment of high-grade dysplasia associated with Barrett's Esophagus. However, currently, we do not plan to fund other Phase II or III clinical trials for this indication on our own. Therefore, we are seeking a strategic partner to join in the development, marketing, and distribution of our treatment for Barrett's esophagus dysplasia. There can be no assurance that we will be able to consummate any collaboration on terms acceptable to us.

MARKETING AND SALES COSTS - Marketing and sales costs for the three months ended March 31, 2004 were $1,367,000 as compared to $531,000 for 2003. This increase is mainly attributable to the hiring of an Associate Vice President of Sales in August 2003, the launch of our direct sales force in October 2003, and related marketing and sales activities. As of March 31, 2004, our sales force was comprised of 8 direct representatives and various independent representatives in key target markets. We anticipate that the level of marketing and sales expenses and related support functions will continue to increase in 2004 as we seek to expand our sales capacity as a result of the initial success of our sales initiatives. Subsequent to the end of the current quarter, we hired 6 additional representatives bringing our total number of representatives to 14 as of May 3, 2004 and are planning to increase the total number of direct representatives to approximately 16 by the end of June 2004.

GENERAL AND ADMINISTRATIVE COSTS - General and administrative costs for the three months ended March 31, 2004 increased to $2,175,000 as compared to $1,475,000 for 2003. This increase is mainly attributable to higher legal

expenses of $1,199,000 incurred in 2004 as compared to $684,000 in 2003, due primarily to patent litigation costs. It is expected that legal expenses will remain at elevated levels until the patent dispute is resolved.

In April 2002, we received a copy of a notice issued by PhotoCure ASA to Queen's University at Kingston, Ontario, alleging that Australian Patent No. 624985, which is one of the

patents licensed by PARTEQ to us, relating to ALA technology, is invalid. As a consequence of this action, Queen's University assigned the Australian patent to us so that we could participate directly in this litigation. We filed 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 judge's decision will be rendered in late 2004. We are unable to predict the outcome at this time. However, should PhotoCure prevail in either part of the case, i.e. the judge finds that the patent is invalid, or if valid, if 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 judge's decision.

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(R) 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. The Company has filed its answer denying the claims. Berlex has requested indemnification from the Company under the terms of the Company's former agreement with Schering AG, Berlex's parent. 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.

OTHER INCOME, NET - Other income for the three months ended March 31, 2004 decreased to $399,000, as compared to $566,000 in 2003. This decrease was 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 initially increase and then may decline, dependent on interest rates and as our investable cash balances are used to support our operating activities. During the three months ended March 31, 2004, we incurred interest expense of $11,000 on borrowings associated with the construction of our new Kerastick(R) manufacturing facility as compared to $17,000 in 2003, which was capitalized in property and equipment in the Condensed Consolidated Balance Sheet as of March 31, 2003.

NET LOSSES - The Company incurred a net loss of $4,402,000, or $0.30 per share, for the three months ended March 31, 2004, as compared to a net loss of $3,566,000 or $0.26 per share for the comparable period in 2003. This increase is due in part to a higher level of legal and marketing and sales expenses offset, in part, by an increase in product sales. 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

We are in a strong cash position to continue to fund increased Levulan(R) PDT sales and marketing expenses and our current research and development activities for our Levulan(R) PDT/PD platform. At March 31, 2004, we had approximately $58,866,000 of total cash resources comprised of $29,366,000 of cash and cash equivalents, United States government securities totaling $29,361,000, and restricted cash of $140,000. All of our United States government securities are classified as available for sale. As of March 31, 2004, these securities had yields ranging from 3.66% to 7.46% and maturity dates ranging from April 5, 2004 to September 24, 2007.

On February 27, 2004, DUSA completed a private placement of 2,250,000 shares of our common stock at a purchase price of $11.00 per share resulting in gross proceeds of $24,750,000. DUSA 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 proceeds of $3,712,500. The offering costs incurred during the period in connection with the placement were $1,699,402 of which $1,485,000 consists of the placement agent's commission and non-refundable retainer paid in the form of 135,000 shares of common stock calculated at the offering price.

As of March 31, 2004, working capital (total current assets minus total current liabilities) was $54,509,000 as compared to $33,838,000 as of December 31, 2003. Total current assets increased $20,722,000 in 2004 due primarily to the gross proceeds received from the private placement of $24,750,000, offset, in part, by the use of $3,472,000 of cash and cash equivalents to support our operating activities.

As of March 31, 2004 we had inventory of $841,000, representing finished goods of $326,000, work in process of $360,000 and raw materials of $155,000, as compared to $713,000 as of December 31, 2003 representing finished goods of $582,000, and raw materials of $130,000. Also, as of March 31, 2004, we had net property, plant and equipment of $4,013,000, as compared to $4,251,000 as of December 31, 2003, representing construction costs associated with our manufacturing facility, commercial light units in the field, and other property, plant and equipment.

As of March 31, 2004, we had accounts receivable of $194,000 as compared to $229,000 as of December 31, 2003, representing net sales associated with Kerastick(R) and BLU-U(R) product sales.

As of March 31, 2004, we had current liabilities of $3,269,000, as compared to $3,218,000 as of December 31, 2003. 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. The Note currently bears interest at a 360-day LIBOR-based rate of 2.755% through June 30, 2004. Based on the terms of the Note, at June 30th of each year DUSA can either continue to choose a LIBOR-based rate at that time, execute a one-time conversion to a fixed rate loan, or repay the loan balance. Approximately $3,000,000 of our United States government securities are pledged as collateral to secure the loan. As of March 31, 2004, the total outstanding loan balance is $1,450,000, of which $270,000 is current.

We believe that we have sufficient capital resources to proceed with our current programs for Levulan(R) PDT, and to fund operations and capital expenditures for the foreseeable future. We have invested our funds in liquid investments, so that we will have ready access to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis.

We anticipate that the level of marketing and sales expenses and related support functions will continue to increase in 2004 as we seek to expand our sales coverage as a result of the initial success of our sales initiatives. We may also seek to expand or enhance our business by using resources to acquire by license, purchase or other arrangements, businesses, new technologies, or products, especially in PDT-related areas. For 2004, we are focusing primarily on increasing the sales of the Levulan(R) Kerastick(R) and the BLU-U(R), initiating Phase II studies for use of Levulan(R) PDT in photodamaged skin and acne using our Kerastick(R), and on seeking a partner to join in the development, marketing, and distribution of our treatment for Barrett's esophagus dysplasia. Full development and testing of all potential indications would require additional funding.

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

CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

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

We hold fixed income United States government 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.

We currently have exposure to interest rate risk under a secured term loan promissory note which we issued to fund the construction of our manufacturing facility. Interest on this loan is at a LIBOR-based rate, and calls for an annual renewal on June 30th of each year through June 30, 2009 to either the applicable LIBOR-based rate or a one-time conversion to a fixed rate loan. The current loan rate of 2.755% is based on a LIBOR-based rate plus 175 basis points at the time of renewal. Our exposure to interest rate risk due to changes in LIBOR is not expected to be material.

ITEM 4. CONTROLS AND PROCEDURES

We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act

Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2004.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2004 that have materially affected, or are reasonably likely to materially affect, DUSA's internal control over financial reporting.

FORWARD-LOOKING STATEMENTS

This report, including the Management's Discussion and Analysis, contains various "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 which represent our expectations or beliefs concerning future events, including, but not limited to statements regarding management's goal of becoming profitable, beliefs regarding adoption of our therapy, expectations for continuing operating losses, intention to focus on increasing sales and to insure adequate supply of inventory, use of proceeds from the private placement, expectation for the timing of Kerastick(R) sales in Canada, plans for conducting development programs with respect to photodamaged skin and acne, and seeking a partner, expectations of increasing staff and marketing and sales expenses, effects of unanticipated changes in estimates and forecasts, belief regarding inventory level, factors which could trigger impairment review, effect of an accounting change for stock-based compensation and intentions regarding disclosures

thereof, beliefs concerning the effect of improved reimbursement (or failure to achieve it) and our education and marketing programs, continued participation at medical conferences and potential sales activities, intentions to evaluate and pursue licensing and acquisition opportunities, expectations regarding funding of Barrett's esophagus, development of a sales team, and levels of legal expenses, requirements of cash resources, and potential impact on conversion of government securities, need for additional funds for development, levels of interest income and net losses, and sufficiency of our capital resources, expectations regarding other accounting pronouncements, inflation, market risks and controls and procedures. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the timely development, FDA approval, and market acceptance of our products, reliance on third parties for the production and manufacture of our products, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by third-party payors, and other risks noted in our SEC filings from time to time, including our Form 10-K for the period ending December 31, 2003, none of which can be assured.

PART II- OTHER INFORMATION

Items 1, and 3 through 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. The offering costs incurred during the period in connection with the placement were $1,699,402 of which $1,485,000 consists of the placement agent's commission and non-refundable retainer paid in the form of 135,000 shares of common stock calculated at the offering price. The Company also issued 20,250 shares to the placement agent as additional commission in connection with the Additional Investment Rights.

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 10(a) - License, Promotion, Distribution and Supply Agreement dated March 31, 2004 between the Company and Coherent-AMT Inc., portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

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

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

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

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

f) Exhibit 99(a) - Press Release dated May 4, 2004

ii) Forms 8-K

a) Form 8-K, dated and filed January 15, 2004, reporting preliminary Q4 2003 end-user Levulan(R) Kerastick(R) net sales to physicians from the Company's distributors and the promotion of Peter Chakoutis, DUSA's Controller, to Vice President and Chief Financial Officer and the promotion of Richard Christopher to the new position of Vice President, Financial Planning and Business Analysis, both effective January 1, 2004.

b) Form 8-K, dated February 2, 2004 and filed February 3, 2004, submitting a slide presentation which formed the basis of a presentation given on February 2, 2004 by DUSA's President and Chief Executive Officer, Dr. D. Geoffrey Shulman, to various potential

investors and reporting that DUSA was served with a complaint filed on December 4, 2003, in the State of Michigan Circuit Court for the County of Oakland.

c) Form 8-K, dated February 12, 2004 and filed February 13, 2004, reporting DUSA's activities at the American Academy of Dermatology meeting in Washington, D.C. on February 6 -11, 2004.

d) Form 8-K, dated February 16, 2004 and filed February 17, 2004, announcing the presentation at the Roth Capital Partners 16th Annual Growth Stock Conference, by DUSA's President and Chief Executive Officer, Dr. D. Geoffrey Shulman.

e) Form 8-K, dated February 20, 2004 and filed February 20, 2004, noting that during a presentation by the Company's President and Chief Executive Officer on February 19, 2004, at the Roth Capital Conference, several inadvertent disclosures were orally made as follows: (i) DUSA had a net loss of $15,000,000 and a cash and government securities balance of $36,000,000 as of December 31, 2003; and (ii) DUSA planned to hire additional direct sales representatives to its sales force.

f) Form 8-K, dated February 26, 2004 and filed February 27, 2004, reporting the commencement of commercial production of the Levulan(R) Kerastick(R) at the Company's Wilmington manufacturing facility; DUSA's reacquisition of Canadian product rights; and its decision to expand its direct sales force.

g) Form 8-K, dated February 27, 2004 and filed on March 1, 2004, reporting definitive agreements with certain new and existing institutional and other accredited investors for the private placement of 2,250,000 shares of common stock, and the right to purchase up to an aggregate of an additional 337,500 shares.

h) Form 8-K, dated February 27, 2004 and filed on March 2, 2004, noting receipt of all proceeds due as a result of the private placement announced on February 27, 2004.

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: May 4, 2004

By: /s/ Peter M. Chakoutis

Peter M. Chakoutis
Vice President and Chief Financial Officer
(principal financial officer) and Controller
(principal accounting officer)

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Exhibit Index

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