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DUSA PHARMACEUTICALS INC

Form 10-Q

May 11, 2001

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

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended March 31, 2001  
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OR

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

Commission file number 0-19777

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

New Jersey  
(State or other  
jurisdiction of  
incorporation or  
organization)

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

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

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

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

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

Yes                                  No  
-----                                  -----

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

13,768,640 shares as of May 8, 2001

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PART 1.  
ITEM 1.     FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.  
  
CONDENSED CONSOLIDATED BALANCE SHEETS

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ASSETS

CURRENT ASSETS

- Cash and cash equivalents
- U.S. government securities available for sale
- Accrued interest receivable
- Accounts receivable
- Receivable under co-development program
- Inventory
- Other current assets

TOTAL CURRENT ASSETS

- Property and equipment, net
- Deferred charges
- Deferred royalty
- Other assets

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES

- Accounts payable
- Accrued payroll
- Other accrued expenses
- Deferred revenue
- Due to licensor
- Income taxes payable

TOTAL CURRENT LIABILITIES

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Deferred revenue

COMMITMENTS AND CONTINGENCIES (NOTE 9)

SHAREHOLDERS' EQUITY

Capital Stock

Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in series or classes. Issued and outstanding: 13,766,640 (2000: 13,730,890) shares of common stock, no par.

Additional paid-in capital

Accumulated deficit

Accumulated other comprehensive income

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31, 2000 (Unaudited)
	-----
REVENUES	
Product sales	\$21,180
Research grant and milestone revenue	49
Research revenue earned under collaborative agreements	48
	-----
TOTAL REVENUES	1,180
OPERATING COSTS	
Cost of product sales	65
Research and development	1,820
General and administrative	1,060
	-----
TOTAL OPERATING COSTS	3,540
	-----
LOSS FROM OPERATIONS	(2,354)
	-----
OTHER INCOME	
Interest income	1,100
	-----
NET LOSS	\$ (1,252)
	-----

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BASIC AND DILUTED NET LOSS PER COMMON SHARE

\$

WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING

13,74

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

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CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES

Net loss

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

Depreciation and amortization expense

Amortization of deferred revenue

Changes in other assets and liabilities impacting cash flows from operations:

Accounts receivable

Receivable under co-development program

Inventory

Accrued interest receivable

Other current assets

Accounts payable

Accrued payroll and other accrued expenses

Due to licensor

Income taxes payable

Deferred revenue

NET CASH USED IN OPERATING ACTIVITIES

CASH FLOWS USED IN INVESTING ACTIVITIES

Purchases of United States government securities

Proceeds from maturing United States government securities

Purchases of property and equipment

Deposits on equipment

NET CASH USED IN INVESTING ACTIVITIES

CASH FLOWS PROVIDED BY FINANCING ACTIVITIES

Issuance of common stock and underwriters' options, net of offering costs of  
\$94,274

Proceeds from exercise of options and warrants

NET CASH PROVIDED BY FINANCING ACTIVITIES

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NET INCREASE (DECREASE) IN CASH

CASH AT BEGINNING OF PERIOD

CASH AT END OF PERIOD

SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION

Income tax payments

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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### 1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of March 31, 2001 and the Condensed Consolidated Statements of Operations and Cash Flows for the three months ended March 31, 2001 and 2000 have been prepared in accordance with accounting principles generally accepted in the United States of America. These condensed financial statements are unaudited but include all normal recurring adjustments which the management of DUSA Pharmaceuticals, Inc. ("DUSA" or the "Company") believes to be necessary for fair presentation of the periods presented.

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 financial statements should be read in conjunction with the Company's December 31, 2000 audited consolidated financial statements and notes thereto.

### 2) PRINCIPLES OF CONSOLIDATION

The Company's consolidated financial statements include the accounts of its subsidiary, DUSA Pharmaceuticals New York, Inc. All significant intercompany balances and transactions have been eliminated.

### 3) UNITED STATES GOVERNMENT SECURITIES AVAILABLE FOR SALE

The Company's United States government securities available for sale consist of securities of the United States government, and its agencies, with current yields ranging from 4.62% to 7.17% and maturity dates ranging from April 2, 2001 to January 19, 2006.

Accumulated other comprehensive income consists of net unrealized gains or losses on securities available for sale, which is reported as part of shareholders' equity in the Condensed Consolidated Balance Sheets. For the three months ended March 31, 2001 and 2000, comprehensive loss was \$678,994 and \$1,290,314, respectively

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4) INVENTORY

Inventory consisted of the following at March 31, 2001 and December 31, 2000:

	MARCH 31, 2001 (UNAUDITED)	DECEMBER 31, 2000
	-----	-----
Finished goods	\$1,543,191	\$1,151,537
Work in progress	139,761	-
Raw materials	145,319	175,344
Purchased parts and subassemblies	-	5,085
	-----	-----
	\$1,828,271	\$1,331,966
	=====	=====

5) OTHER CURRENT ASSETS

Other current assets consisted of the following at March 31, 2001 and December 31, 2000:

	MARCH 31, 2001 (UNAUDITED)	DECEMBER 31, 2000
	-----	-----
Prepaid expenses and deposits	\$602,506	\$293,069
Commercial light sources under lease	398,289	261,923
Other current assets	117,709	7,248
	-----	-----
	\$1,118,504	\$562,240
	=====	=====

6) DEFERRED REVENUE

Deferred revenue associated with the Company's milestone payments, unrestricted research grants, and the sale of commercial light sources consisted of the following at March 31, 2001 and December 31, 2000:

	MARCH 31, 2001 (UNAUDITED)	DECEMBER 31, 2000
	-----	-----
Milestone and unrestricted grant payments	\$23,800,000	\$24,295,834
Sale of commercial light sources	695,382	509,207
	-----	-----
	\$24,495,382	\$24,805,041
	=====	=====

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### 7) SHAREHOLDERS' EQUITY

On March 22, 2000, the Company issued 1,500,000 shares of its common stock in a private placement pursuant to Regulation D of the Securities Act of 1933. The Company received proceeds of \$42,750,000. The offering costs incurred in connection with the placement were \$2,018,024 of which \$1,923,750 was paid subsequent to March 31, 2000.

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### 8) 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 and warrants are not included in the computation of the weighted average number of shares outstanding for dilutive net loss per common share during the period, as the effect would be antidilutive. For the three months ended March 31, 2001 and 2000, stock options and warrants totaling approximately 2,449,000 and 2,657,000, respectively, have been excluded from the computation of net loss per share.

### 9) COMMITMENTS AND CONTINGENCIES

The Company has entered into a series of agreements for research projects and clinical studies. As of March 31, 2001, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$483,000 for the remainder of 2001.

During the first quarter of 2001, the Company agreed to compensate North Safety Products, Inc. (North), the manufacturer of our Kerastick(R) brand applicator, for certain overhead expenses associated with the manufacture of the Kerastick(R) to cover under-utilization of North's facilities since current orders are below certain previously anticipated levels. As of March 31, 2001, approximately \$204,000 was recorded as a liability due to North based on the current production levels. As consideration for the payment of under-utilization fees, the Company expects that North will provide at least fifteen (15) months prior written notice to the Company (rather than only six (6) months as provided in our current supply agreement), if North wishes to exercise its right to terminate our supply agreement. Under our existing agreement North's right to terminate may be exercised on or after August 13, 2001. The Company is considering other contract manufacturing options, as well as whether the Company should manufacture the Kerastick(R) in its new facilities in Wilmington.

### 10) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENT

On January 1, 2001, the Company adopted Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities", which was issued by the Financial Accounting Standards Board. The adoption of this statement did not have any effect on the Company's financial statements.

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

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## OF OPERATIONS

### OVERVIEW

The following discussion should be read in conjunction with the Company's Consolidated Financial Statements and Notes to the Consolidated Financial Statements for the year ended December 31, 2000 and its Condensed Consolidated Financial Statements and Notes to the Condensed Consolidated Financial Statements for the three-month period ended March 31, 2001. DUSA is engaged primarily in the research and development of a drug named 5-aminolevulinic acid, or ALA, 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 we use Levulan(R) and follow it with exposure to light to produce a therapeutic effect, the technology is called photodynamic therapy, or PDT. When we use Levulan(R) and follow it with exposure to light to detect medical conditions, the technology is called photodetection, or PD. Our first products are the Levulan(R) Kerastick(R) 20% Topical Solution with photodynamic therapy, for treatment of non-hyperkeratotic actinic keratoses (AKs) of the face or scalp, in combination with our BLU-U(TM) brand light source. From our inception in 1991 until September 2000 we were classified as a development stage enterprise. However, in late September 2000, we launched our first commercial products, Levulan(R) Kerastick(R) 20% Topical Solution and the BLU-U (TM) brand light device, in cooperation with Berlex Laboratories, Inc. (Berlex), the United States affiliate of Schering AG. From the product launch through the end of March 2001, DUSA entered into 157 contracts for BLU-U (TM) brand light units. We lease or rent the BLU-U (TM) to physicians, medical institutions and academic centers throughout the country. Our other dermatology and internal potential indications are at exploratory, Phase I or Phase II stages.

We have primarily devoted our resources to funding 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, 2001, we had an accumulated deficit of \$43,739,409.

Achieving our goal of becoming a profitable operating company is dependent upon the market penetration by Berlex of our products, acceptance of our therapy by the medical and consumer constituencies, and our ability to meet the supply needs of the growing customer base. Currently, we are meeting Berlex's supply requirements; however, any significant delays in delivery of sufficient product supplies from our sole source third-party suppliers of Levulan(R), the Kerastick(R) and/or the BLU-U(TM) could have a significant adverse impact on our financial results. We have built up our inventory to help us meet marketplace demand as it develops, and in February 2001 we leased additional space in our Wilmington, Massachusetts facilities to provide immediate warehouse, office space, and production areas should we need to develop our own manufacturing capabilities. We are also investigating other suppliers for components of our products so that we could react more quickly if our supply was interrupted for any reason. (See discussion of relationship with North Safety Products, Inc., below.)

We are excited about the early positive response from physicians and patients who have used our therapy, but we recognize that full market penetration will take longer than we

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originally anticipated, while third-party reimbursement costs for our products are established during the coming months by insurance companies and state and federal healthcare agencies.

As reimbursement policies are determined and the marketplace develops



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during 2001, we expect to continue to incur operating losses. During the initial stages of the Kerastick(R) product launch, we have incurred scale-up and certain fixed costs resulting in under-absorbed overhead, which management expects to fully absorb these costs as the level of Kerastick(R) sales increases. Management also plans to maintain an internal product cost program to continuously monitor the cost of product sales with the goal of reducing our cost of product sales over time. We expect to reduce losses and achieve profitability dependent upon sales levels achieved by Berlex, the amount of royalties and supply fees which we will receive based on those sales, and the degree of expansion of our research and development activities. Our research and development efforts are expanding, both in dermatology (in partnership with Schering AG), and in our internal indication development programs. We have increased our staff in our Wilmington, Massachusetts headquarters and in our Valhalla, New York research and development coordination center in order to properly support all activities relating to production, maintenance, customer support for our first and future products, as well as the research and development programs for dermatology and internal indications.

During the first quarter of 2001, we agreed to compensate North Safety Products, Inc. (North), the manufacturer of our Kerastick(R) brand applicator, for certain overhead expenses associated with the manufacture of the Kerastick(R) to cover under-utilization of North's facilities since current orders are below certain previously anticipated levels. As of March 31, 2001, approximately \$204,000 was recorded as a liability due to North based on the current production levels. As consideration for the payment of under-utilization fees, DUSA expects that North will provide at least fifteen (15) months prior written notice to DUSA (rather than only six (6) months as provided in our current supply agreement), if North wishes to exercise its right to terminate our supply agreement. Under our existing agreement North's right to terminate may be exercised on or after August 13, 2001. We are considering other manufacturing options, including whether we should manufacture the Kerastick(R) in our new facilities in Wilmington.

### RESULTS OF OPERATIONS

REVENUES - Revenues recognized for the three-month period ended March 31, 2001 were \$1,189,960. Revenues include product sales of approximately \$214,000 reflecting the direct sales of the Kerastick(R) to Berlex. We expect to meet Berlex's entire 2001 Kerastick(R) supply needs by the end of the second quarter of 2001. Revenues also include research and development revenue of approximately \$480,000 reflecting revenue earned payments from Schering AG to support our dermatology co-development program. Under our agreement with Schering AG, two-thirds of the agreed upon dermatology research and development expenses, up to \$3,000,000 per year, are reimbursable to DUSA by Schering AG for 2001. Based on the agreed upon development plan and the timing of the start of the clinical trials, we are entitled to reimbursement of approximately \$480,000 for the three-month period ended March 31, 2001. In early 2001, both parties agreed upon the development program that will be subject to reimbursement for 2001. The total budget for approved co-development, research and development projects totals \$3,954,000 so far for 2001, which will entitle us to a reimbursement from Schering of \$2,636,000, assuming the full budget is spent. Also included in revenue for the current period is \$496,000 of milestone and unrestricted grant payments, also from Schering AG, reflecting the amortization of up front payments that have been recorded as deferred revenue upon receipt and are recognized as income on a straight-line basis over the term of the Company's alliance agreement with Schering AG. During the comparative period

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for earned revenue payments from Schering to support our dermatology co-development program.

In addition to the revenues we earn on direct product sales, we also earn royalties when Berlex sells the Kerastick(R) into the marketplace; however, such royalties were minimal during the current quarter as Berlex met its distributor's initial supply needs in the fourth quarter of 2000. Since we do not control the distribution channel of the Kerastick(R) and Berlex's forecast for the manufacturing of Levulan(R), management is unable to predict the timing of royalties on future Kerastick(R) sales by Berlex.

During the current period, we entered into 57 contracts for our BLU-U(TM) brand light units. We primarily lease the BLU-U(TM) to our customers and have engaged a medical device leasing company to complete the leasing transactions, including coordinating payment plans with the physicians. We sell the BLU-U(TM)s to the leasing company, which pays us for the units within thirty (30) days after installation in the physicians' offices. However, because physicians have the right to cancel their leases after periods of up to one year, these revenues are reported as deferred revenues until the right to cancel the lease has expired. In the event a customer does cancel a lease, we have agreed to repurchase the units from the leasing company at an agreed upon price. Under this arrangement, we will begin to recognize revenue from the distribution of BLU-U(TM)s later in 2001.

COST OF PRODUCT SALES - Cost of product sales for the three-month period ended March 31, 2001 were \$655,029 mainly reflecting direct Kerastick(R) related product costs of approximately \$201,000 and an estimated \$204,000 liability incurred to our Kerastick(R) manufacturer for under-utilization costs due to current orders falling below certain previously anticipated levels. Cost of product sales also includes \$56,000 in amortization of deferred charges that reflects consideration paid by us during 2000 to amend our Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan(R), as well as costs incurred for shipping and installing the BLU-U(TM) in physicians offices. In 2001, we also commenced allocating personnel to product sale operations and/or general and administrative functions as a significant percentage of manufacturing development activities have been completed for our current products. For the three-month period ended March 31, 2001, such personnel-related costs allocated to cost of product sales were approximately \$176,000. The higher cost of product sales as compared to product sales is a result of the lower than anticipated level of Kerastick(R) sales several months following the Kerastick(R) product launch, under-absorbed overhead attributed to the payment of under-utilization costs to our Kerastick(R) supplier as noted above, and the allocation of personnel to product sales operations. Management expects that such costs will be covered by product revenue as the level of Kerastick(R) sales increases.

Inventory costs related to the BLU-U(TM) units that are leased are deferred and recorded as other current assets until the customer's right to cancel its lease after periods of up to one year expires. As of March 31, 2001, deferred inventory costs were \$398,289. There were no product sales and therefore no cost of product sales during the comparative period in 2000.

In early 2001, in order to meet the production scheduling needs of our third-party manufacturer of the BLU-U(TM), we prepaid raw material costs in the amount of \$400,000 associated with our current orders. This amount will be credited against the final purchase price, which will be due on delivery of finished units at the rate of \$1,000 per completed unit. At the end of March 2001, approximately \$323,000 of this prepayment remained outstanding and was recorded in other current assets. In addition, if we do not order a certain number of BLU-U(TM) brand units for delivery

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in 2002, we have agreed to pay \$100,000 to our manufacturer for certain overhead costs. We do not know at this time whether we will be required to make this payment as we depend upon Berlex to market our products. Accordingly, we have not recorded an accrual of this liability at this point in time.

**Research and Development Costs.** Total research and development costs for the three-month period ended March 31, 2001 were \$1,826,828, as compared to \$1,269,651 for the three-month period ended March 31, 2000. This increase was due to increased expenditures for dermatology and internal indications coupled with higher personnel costs related to certain on-going manufacturing development activities. During the first quarter of 2001, this increase was partly offset by the allocation of personnel costs to product sale operations and/or general and administrative functions, rather than to research and development costs, as a significant percentage of the manufacturing development activities have been completed for our current products.

As we implement our dermatology program with Schering AG, and expand our internal indication programs, we expect clinical research and development expenses to continue to increase significantly. In late 2000, we initiated a Phase I/II clinical trial of Levulan(R) PDT for moderate to severe acne vulgaris of the face, and we expect to begin clinical studies on onychomycosis, initially testing drug uptake and conversion to protoporphyrin IX in infected nails, during 2001. In addition, DUSA plans to initiate clinical trials using Levulan(R) PDT for treatment of warts during 2001.

With respect to internal indications for Levulan(R) PDT, we intend to initiate new DUSA-sponsored clinical protocols for the treatment of Barrett's esophagus and brain cancer during 2001. DUSA is also supporting and collaborating in new investigator studies on Barrett's esophagus and restenosis inhibition. Additional indications being considered for future development include detection and treatment of cervical dysplasia and dysfunctional uterine bleeding.

**General and Administrative Costs.** General and administration expenses increased approximately \$273,000 for the three-month period to \$1,062,941 as compared to \$789,475 for the same period in 2000. This increase is mainly attributed to the hiring of additional staff, including key management personnel in administrative, technical and operations functions, during the second half of 2000 and first quarter of 2001. This increase also reflects the aforementioned allocation of personnel to general and administrative functions and/or product sale operations, as a significant percentage of the manufacturing development activities have been completed for our current products. General and administrative costs are expected to continue to increase for the remainder of 2001 as we continue to add personnel at all levels of the organization.

**Interest Income.** Interest income for the three-month period ended March 31, 2001 increased approximately \$720,000, to \$1,102,778, as compared to \$382,744 for the same period in 2000. This increase was mainly attributed to earnings on \$15,000,000 received from Schering AG during the fourth quarter of 2000 and the net proceeds of approximately \$40,700,000 received from a private placement in March 2000. If our product sales, which are dependent upon the market penetration by Berlex and our ability to meet the supply needs of the growing customer base, do not offset our expenditures, interest income will decline as funds are spent for our research and development programs.

**Net Losses.** The Company incurred a net loss of \$1,252,060, or \$0.09 per share, for the three-month period ended March 31, 2001, as compared to a net loss of \$1,241,225, or \$0.10 per share for the three-month period ended March 31, 2000. These losses were within management's expectations

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and losses are expected to be incurred until the successful market penetration of our first products occurs.

#### LIQUIDITY AND CAPITAL RESOURCES

We are in a strong cash position to continue to expand our research and development activities for our Levulan(R) PDT/PD platform. Our total assets were \$80,688,650 as of March 31, 2001, compared to \$82,442,388 as of December 31, 2000. This decrease is mainly the result of net operating activities costs incurred during the quarter.

As of March 31, 2001, we had inventory of \$1,828,271, representing finished goods, work-in-progress and raw materials, as compared to \$1,331,966 as of December 31, 2000. Also, at the end of the current quarter we had net fixed assets of \$2,221,564, compared to \$1,699,530 as of December 31, 2000, due primarily to the acquisition of equipment and software. We expect to make additional capital expenditures during 2001 in order to acquire equipment for a back-up second source of supply for the manufacture of the Kerastick(R), as required under our contract with Schering AG. As of March 31, 2001, the Company has acquired or incurred deposits of approximately \$243,000 in manufacturing equipment, which has been recorded in other assets.

As of March 31, 2001, we had accounts receivable of \$411,462, representing net sales associated with product sales, compared to \$914,959 at the end of 2000. In addition, based on our co-development program with Schering AG, a receivable of approximately \$480,000 has been recorded during the current quarter for reimbursable research and development costs. In 2000, the Company recorded a co-development receivable of approximately \$723,000.

As of March 31, 2001, we had current liabilities of \$2,059,027, compared to \$2,836,758 as of December 31, 2000. Since our inception, we have had no long-term debt. DUSA has a secured line of credit from Schering AG for up to \$1,000,000 to help us finance inventory purchases of our BLU-U(TM) from our supplier. This line of credit is interest-free but must be re-paid within one year of our first draw down of funds. As of the end of the current quarter, we had not drawn down any part of this credit facility.

We invest our cash in United States government securities, which are classified as available for sale. As of March 31, 2001, we held securities with an aggregate cost of \$59,243,371 and a current aggregate market value of \$60,995,531, resulting in a net unrealized gain on securities available for sale of \$1,752,160, which has been included in shareholders' equity. As of December 31, 2000, these securities had an aggregate cost of \$56,876,369 and a current aggregate market value of \$58,055,463 resulting in a net unrealized gain on securities available for sale of \$1,179,094. Due to fluctuations in interest rates and depending upon the timing of our need to convert government securities into cash to meet our working capital requirements, some gains or losses could be realized. These securities currently have yields ranging from 4.62% to 7.17% and maturity dates ranging from April 2, 2001 to January 19, 2006.

We believe that we have sufficient capital resources to proceed with our current development program for Levulan(R) PDT/PD 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. DUSA may also use its resources to acquire by license, purchase or other arrangements, businesses, technologies, or products that enhance or expand DUSA's business. We continue to actively seek relationships with pharmaceutical or other

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suitable organizations to help develop and/or market some of our potential non-dermatology products and technologies.

As of March 31, 2001, we had deferred revenues of \$24,495,382, compared to \$24,805,041 at December 31, 2000. At the end of the current quarter, deferred revenues reflected unamortized milestone and unrestricted grant payments received from Schering AG in 1999 and 2000 of \$23,800,000, and the deferral of \$695,382 in BLU-U(TM) product sales until the expiration of our customer's right of return on our commercial light sources. Commencing with our product launch, we began to amortize the Schering AG milestone and unrestricted grant payments over approximately 12 years, the term of the Schering AG agreement, based upon current revenue recognition principles.

While the net proceeds of the January 1999 and March 2000 offerings coupled with payments received from Schering AG will enable us to maintain our current research program as planned and support the commercialization of Levulan(R) PDT for AKs for the foreseeable future, in order to maintain and expand continuing research and development programs, DUSA may need to raise additional funds in the future through corporate alliances, financings, or other sources, depending upon the amount of revenues we receive from our first product.

As of the end of March 31, 2001, we had 51 full-time employees. We expect that we will continue to hire more employees as commercialization of Levulan(R) PDT continues, particularly in the operations, research and development, financial and regulatory areas.

We have not made any material capital expenditures for environmental control facilities. If we decide, in the future, to establish a limited production line for the manufacture of the Kerastick(R), we expect that environmental laws will govern our facility, but we do not expect these laws to require material capital expenditures. There can be no assurance, however, that we will not be required to incur significant costs to comply with environmental laws and regulations in the future, or any assurance that our operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

#### RECENTLY ISSUED ACCOUNTING PRONOUNCEMENT

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities." On January 1, 2001, the Company adopted SFAS No. 133 which did not have any effect on our financial statements.

#### INFLATION

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

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

We hold fixed income U.S. government securities that are subject to interest rate market risks. We do not believe that the risk is material at this time as we have apportioned our investments in short-term and longer-term

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instruments, up to five years, 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. As noted above, if significant, sudden fluctuations in interest rates occur, losses could be realized. We do not hold derivative securities. Accordingly, we do not believe that there is a material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this item.

### 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, the impact of any substantial delay in delivery of supplies, expectations regarding the market penetration and timing of the establishment of reimbursement policies, expectations for continuing operating losses, absorption of overhead expenses and reduction of cost of product sales, expectations of our Kerastick(R) supplier's agreement to provide additional lead time on a termination of our agreement, beliefs as to entitlement to reimbursement from Schering AG of dermatology research and development expenses, expectations of Berlex's supply needs, recognition of revenue from the distribution of our BLU-U(TM), intentions to evaluate and pursue licensing and acquisition opportunities, beliefs regarding environmental compliance, expectations regarding the start of clinical trials in 2001 for warts, onychomycosis Barrett's esophagus and brain cancer, requirements of cash resources for our future liquidity, and potential impact on conversion of government securities, anticipation of hiring additional personnel, expectations for future strategic opportunities and research and development programs, need for additional funds, increasing research and development expenses, levels of interest income and sufficiency of our capital resources. 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, manufacture, sales and marketing of our products, the securities regulatory process, the maintenance of our patent portfolio and levels of reimbursement by third-party payors, none of which can be assured. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors.

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### PART II- OTHER INFORMATION

Items 1 through 5.

None.

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

- a) Form 8-K dated January 10, 2001 and filed on January 11, 2001 announcing updated research and development activities at Chase H & Q Healthcare conference.

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the

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registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DUSA PHARMACEUTICALS, INC.

DATE: MAY 11, 2001  
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BY: /S/JOHN E. MATTERN  
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JOHN E. MATTERN  
VICE PRESIDENT, FINANCE,  
AND CHIEF FINANCIAL OFFICER (Chief  
Financial and Chief Accounting Officer)

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