DUSA PHARMACEUTICALS INC
Form 10-Q
August 13, 2001
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FORM 10-Q
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 June 30, 2001

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

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.

13,799,890 shares as of August 9, 2001

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PART 1.

ITEM 1. FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

| | June 30, 2001 (Unaudited) | Dece |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $4,386,928 | $16,4 |
| U.S. government securities available for sale | 64,116,981 | 58,0 |
| Accrued interest receivable | 1,055,871 | 9 |
| Accounts receivable | 222,486 | 9 |
| Receivable under co-development program | 824,202 | 7 |
| Inventory | 1,796,002 | 1,3 |
| Other current assets | 1,383,249 | 5 |
| TOTAL CURRENT ASSETS | 73,785,719 | 79,0 |
| Property and equipment, net | 2,483,566 | 1,6 |
| Deferred charges | 773,584 | 8 |
| Deferred royalty | 709,485 | 7 |
| Other assets | 281,393 | |
| | $78,033,747 | $82,4 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable | $158,307 | $1 |
| Accrued payroll | 411,640 | 6 |
| Other accrued expenses | 551,051 | 1,1 |
| Deferred revenue | 751,744 | 5 |
| Due to licensor | 189 | 4 |
| Income taxes payable | -- | |
| TOTAL CURRENT LIABILITIES | 1,872,931 | 2,8 |
| Deferred revenue | 23,304,166 | 24,2 |
| | 25,177,097 | 27,1 |
| COMMITMENTS AND CONTINGENCIES (NOTE 8) | | |
| 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. | 94,965,212 | 94,7 |
| Issued and outstanding: 13,768,640 (2000: 13,730,890) shares of common stock, no par. | | |
| Additional paid-in capital | 1,860,519 | 1,8 |
| Accumulated deficit | (45,302,744) | (42,4 |
| Accumulated other comprehensive income | 1,333,663 | 1,1 |
| | 52,856,650 | 55,3 |
| | $78,033,747 | $82,4 |

See the accompanying Notes to the Condensed Consolidated Financial Statements.





DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Three Months Ended June 30, (Unaudited) | | |
|---|---|---|---|
| | 2001 | 2000 | |
| REVENUES | | | |
| Product sales | $196,718 | $ -- | $4 |
| Research grant and milestone revenue | 495,834 | -- | 9 |
| Research revenue earned under collaborative agreements | 824,202 | 167,347 | 1,3 |
| TOTAL REVENUES | 1,516,754 | 167,347 | 2,7 |
| OPERATING COSTS | | | |
| Cost of product sales | 721,056 | -- | 1,3 |
| Research and development | 2,329,178 | 2,109,074 | 4,2 |
| General and administrative | 961,566 | 440,828 | 1,9 |
| TOTAL OPERATING COSTS | 4,011,800 | 2,549,902 | 7,5 |
| LOSS FROM OPERATIONS | (2,495,046) | (2,382,555) | (4,8 |
| OTHER INCOME | | | |
| Interest income | 931,711 | 942,627 | 2,0 |
| NET LOSS | $(1,563,335) | $(1,439,928) | $(2,8 |
| BASIC AND DILUTED NET LOSS PER COMMON SHARE | $ (.11) | $ (.11) | $ |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | 13,767,959 | 13,556,659 | 13,7 |

See the accompanying Notes to the Condensed Consolidated Financial Statements.



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DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Six Months E (Unaud |
|---|---|
| | 2001 |
| OPERATING ACTIVITIES: | |
| Net loss | $(2,815,395) |
| 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 | (192,576) |
| Depreciation and amortization expense | 416,558 |
| Amortization of deferred revenue | (991,668) |
| Changes in other assets and liabilities impacting cash flows from operations: | |
| Accounts receivable | 692,473 |
| Receivable under co-development program | (101,632) |
| Inventory | (464,036) |
| Accrued interest receivable | (65,788) |
| Other current assets | (821,009) |
| Accounts payable | 57,807 |
| Accrued payroll and other accrued expenses | (791,356) |
| Due to licensor | (416,815) |
| Income taxes payable | (56,000) |
| Deferred revenue | 242,537 |
| NET CASH USED IN OPERATING ACTIVITIES | (5,306,900) |
| INVESTING ACTIVITIES: | |
| Purchases of U.S. government securities | (18,232,131) |
| Proceeds from maturing U.S. government securities | 12,517,758 |
| Payment to restructure supplier contract | -- |
| Purchases of property and equipment | (1,057,200) |
| Deposits on equipment | (183,393) |
| NET CASH USED IN INVESTING ACTIVITIES | (6,954,966) |
| FINANCING ACTIVITIES: | |
| Issuance of common stock and underwriters' options, net of offering costs of $94,274 | -- |
| Proceeds from exercise of options and warrants | 207,680 |

| | |
|---|---|
| NET CASH PROVIDED BY FINANCING ACTIVITIES | 207,680 |
| NET INCREASE (DECREASE) IN CASH | (12,054,186) |
| CASH AT BEGINNING OF PERIOD | 16,441,114 |
| CASH AT END OF PERIOD | $4,386,928 |
| SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION | |
| Income tax payments | $160,700 |

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 June 30, 2001, Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2001 and 2000, and Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 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) 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 4.61% to 7.22% and maturity dates ranging from July 2, 2001 to May 30, 2006.

Accumulated other comprehensive income consists of net unrealized gains or losses 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 at June 30, 2001 and December 31, 2000:

| | JUNE 30, 2001 (UNAUDITED) | DECEMBER 31, 2000 |
|---|---|---|
| Finished goods | $1,607,071 | $1,151,537 |
| Work in progress | 72,612 | - |
| Raw materials | 116,319 | 175,344 |
| Purchased parts and subassemblies | -- | 5,085 |
| | $1,796,002 | $1,331,966 |



4) OTHER CURRENT ASSETS

Other current assets consisted of the following at June 30, 2001 and December 31, 2000:

| | JUNE 30, 2001 (UNAUDITED) | DECEMBER 2 |
|---|---|---|
| Prepaid expenses and deposits | $808,926 | $293, |
| Commercial light sources under lease | 504,340 | 261, |
| Other current assets | 69,983 | 7, |
| | $1,383,249 | $562, |

5) DEFERRED REVENUE

Deferred revenue associated with the Company's milestone payments, unrestricted research grants, and the sale of commercial light sources, sold primarily through a third-party leasing company, consisted of the following at June 30, 2001 and December 31, 2000:

| | JUNE 30, 2001 (UNAUDITED) | DECEMBER |
|---|---|---|
| Milestone and unrestricted grant payments | $23,304,166 | $24,295 |
| Sale of commercial light sources | 751,744 | 509 |
| | $24,055,910 | $24,805 |

6) 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 and six-month periods ended June 30, 2001, approximately 822,000 and 879,000 stock options and warrants were excluded from the computation of net loss per share. For the three and six-month periods ended June 30, 2000, approximately 1,352,000 and 1,438,000 stock options and warrants were excluded from the computation of net loss per share.



7) COMPREHENSIVE LOSS

For the three and six months ended June 30, 2001 and 2000, comprehensive loss consisted of the following:

| | Three Months Ended June 30, (Unaudited) | | Six Mon |
|---|---|---|---|
| | 2001 | 2000 | 2001 |
| NET LOSS | $(1,563,335) | $(1,439,928) | $(2,815,3 |
| Net unrealized gains (losses) on United States securities available for sale | (418,497) | 116,773 | 154, |
| COMPREHENSIVE LOSS | $(1,981,832) | $(1,323,155) | $(2,660,8 |

8) COMMITMENTS AND CONTINGENCIES

The Company has entered into a series of agreements for research projects and clinical studies. As of June 30, 2001, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately $527,000 for the remainder of 2001 and $562,000 thereafter.

In February 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 underutilization of North's facilities since current orders are below certain previously anticipated levels. For the six months ended June 30, 2001, approximately $401,000 of underutilization charges were recorded in cost of product sales based on the current production levels. In July 2001, the Company modified this agreement as defined in Footnote 9, Subsequent Event.

9) SUBSEQUENT EVENT

On July 27, 2001, DUSA revised its agreement with North pertaining to the payment of underutilization fees as current orders have been below certain previously anticipated levels. With the execution of this amendment, the Company paid North $1,000,000 in up-front underutilization fees and agreed to pay payments totaling $400,000 covering the period from the execution of this amendment to the agreement through December 31, 2002. In consideration for the underutilization fees, North has agreed to maintain its Kerastick(R) manufacturing capabilities in a state of readiness, with the capability of producing at least 25,000 Kerastick(R) units per month in accordance with established procedures. In addition, North will provide the Company with manufacturing records, personnel support, and a list of consultants and

suppliers that have supported the development and manufacturing of the Kerastick(R). The term of the agreement ends on December 31, 2002 unless DUSA exercises an option to extend the term through June 30, 2003. If DUSA should decide to extend the term, North will be entitled to payment of





additional underutilization fees of up to $500,000, prorated based on the level of Kerastick(R) units produced from July 1, 2001 through June 30, 2003.

10) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENT

On July 20, 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations" and SFAS No. 142 "Goodwill and Other Intangible Assets". SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001 and that the use of the pooling-of-interest method is no longer allowed. SFAS No. 142 requires that upon adoption, amortization of goodwill will cease and instead, the carrying value of goodwill will be evaluated for impairment on an annual basis. Identifiable intangible assets will continue to be amortized over their useful lives and reviewed for impairment in accordance with SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of". SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. The Company is evaluating the impact of the adoption of these standards and does not believe the effect of adoption of these statements will have any material effect on the Company's financial position or results of operation.

On January 1, 2001, the Company adopted SFAS 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 position or results of operation.





ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS 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 and six-month periods ended June 30, 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 Levulan(R) is used and is 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 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 the United States, in cooperation with Berlex Laboratories, Inc. (Berlex), the United States affiliate of Schering AG. At the end of June 2001, 190 BLU-U(TM) brand light units were in place in physician's offices. 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. Our current products have now also been approved by the Health Protection Branch - Canada. Our former Canadian affiliate, Draxis Health, Inc., retained the marketing rights for Canada, and we will be entitled to royalties on its sales in that country. We will be working to establish a supply arrangement for the Canadian market in the near future. In addition, Schering AG has made regulatory filings for approval of our therapy outside of the United States including the first filings in Austria, Australia, and Brazil. We are bringing our products into compliance with CE marking and ISO 9000 requirements in order to be ready to supply these markets upon regulatory approval which Schering AG expects to occur next year.

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 June 30, 2001, we had an accumulated deficit of approximately $45,303,000.

Achieving our goal of becoming a profitable operating company is dependent upon the market penetration by Berlex and Schering AG of our products, acceptance of our therapy by the medical and consumer constituencies, and our ability to meet the supply needs of our customer base. We have manufactured sufficient inventory of Kerastick(R) units and BLU-U(TM) brand light devices to meet Berlex's supply requirements in the United States for the balance of 2001; 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), in the future,



could have a significant adverse impact on our financial results. In February 2001 we leased additional space in our Wilmington, Massachusetts facilities to provide warehouse, office space, and production areas as we are evaluating the option of developing our own Kerastick(R) manufacturing capabilities. We are also investigating other suppliers for components or the complete manufacture of our products so that we could react more quickly if our supply was interrupted for any reason. Also see discussion of relationship with North Safety Products, Inc., below.

We are encouraged by the early positive response from physicians and patients who have used our therapy, but we recognize that market acceptance will take longer than we 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 codes are established at varying rates at both a national and/or state level, we believe that reimbursement for our therapy will have to be competitive with other reimbursement rates for treatment of actinic keratoses of the face and scalp, in order for the medical community to accept our products on a large scale.

We expect to continue to incur operating losses as we continue to invest in our research and development programs, and until product sales increase significantly. We have incurred scale-up and certain fixed costs resulting in under-absorbed overhead, which are included in cost of product sales. Management plans to maintain a program to continuously monitor the cost of product sales with the goal of reducing our cost of product sales over time. It is with this focus that we are gathering cost estimates associated with development of our own manufacturing operation in our leased Wilmington, Massachusetts facilities.

The development of our own facility should enable us to better manage and control the costs of production; however, cost of product sales may increase if we incur capital expenditures associated with developing our own facility and if product sales do not increase significantly. 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 clinical research and development center in order to properly support all activities relating to production, maintenance, customer support for our products, as well as the research and development programs for dermatology and internal indications.

In February 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 underutilization of North's facilities since current orders are below certain previously anticipated levels. For the six months ended June 30, 2001, approximately $401,000 of underutilization charges were recorded in cost of product sales based on the current production levels. On July 27, 2001, we revised this agreement and paid North $1,000,000 in up-front underutilization fees and agreed to pay additional payments totaling $400,000 covering the period from the execution of this amendment to the agreement through December 31, 2002. In consideration for the underutilization fees, North has agreed to maintain its Kerastick(R) manufacturing capabilities in a state of readiness, with the capability of producing at least 25,000 Kerastick(R) units per month in accordance with established procedures. In addition, North will provide us with manufacturing records, personnel support, and a list of consultants and suppliers that



have supported the development and manufacturing of the Kerastick(R). The term of the agreement ends on December 31, 2002 unless DUSA exercises an option to extend the term through June 30, 2003. If DUSA should decide to extend the term, North will be entitled to payment of additional underutilization fees of up to $500,000, prorated based on the level of Kerastick(R) units produced from July 1, 2001 through June 30, 2003.

RESULTS OF OPERATIONS

REVENUES - Total revenues recognized for the three and six-month periods ended June 30, 2001 were approximately $1,517,000 and $2,707,000, and include product sales of $197,000 and $411,000, respectively, primarily reflecting direct sales of the Kerastick(R) to Berlex. Based on the agreed upon development plan and the timing of the start of the clinical trials, revenues also include research and development revenue of approximately $824,000 and $1,304,000 for the current three and six-month periods, 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. 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 revenues for the current three and six-month periods are $496,000 and $992,000 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 three and six-month periods in 2000, total revenues recognized were

approximately $167,000 and $603,000, respectively, reflecting reimbursement for earned revenue payments from Schering to support our dermatology co-development program.

Based on Berlex's current forecast, we have met Berlex's entire 2001 Kerastick(R) supply needs as of June 30, 2001. We will earn royalties when Berlex sells the Kerastick(R) into the marketplace; however, such royalties were minimal during the first half of 2001 as Berlex met its distributor's initial supply needs in the fourth quarter of 2000, and the royalties on those sales were received in the first quarter of 2001. 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 three and six-month periods, the number of BLU-U(TM) brand light units in place in physician's offices increased by 43 and 93, respectively to 190. We primarily lease or rent the BLU-U(TM) to our customers and have engaged a medical device leasing company to complete the leasing and/or rental transactions, including coordinating payment plans with the physicians. We sell the leased BLU-U(TM)s to the leasing company, which usually 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 units in the second half of 2001.

COST OF PRODUCT SALES - Cost of product sales for the three and six-month periods ended June 30, 2001 were approximately $721,000 and $1,376,000, respectively, including $157,000 and $358,000 in direct Kerastick(R) related product costs, and $198,000 and $401,000 incurred to our Kerastick(R) manufacturer for underutilization costs due to orders falling below certain previously anticipated levels. During the current three and six-month periods, cost of product sales also includes $56,000 and $113,000 in amortization of deferred charges reflecting consideration paid by us in 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 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. Such personnel-related costs allocated to cost of product sales were approximately $210,000 and $386,000 for the three and six-month periods ended June 30, 2001. There were no product sales and therefore no cost of product sales during the comparative period in 2000. 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 June 30, 2001, deferred inventory costs were approximately $504,000.

The higher cost of product sales as compared to product sales is primarily a result of the lower than anticipated level of Kerastick(R) sales, and under-absorbed overhead attributed to the payment of underutilization 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.

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 is being 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 June 2001, approximately $248,000 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 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. Research and development costs for the three and six-month periods ended June 30, 2001 increased approximately $220,000 and $884,000, respectively, to $2,329,000 and $4,262,000, as compared to same periods in 2000. These increases were attributed to higher expenditures for dermatology and internal indications coupled with increased personnel costs related to certain on-going development activities. During the first half of 2001, this increase was partially offset by the reassignment 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 development activities were completed for our current products in 2000.

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.

In July 2001, the United States Food and Drug Administration completed its review of three Investigational New Drug applications allowing initiation of clinical trials using Levulan(R) Photodynamic Therapy for the treatment of onychomycosis (nail fungus), warts, and Barrett's esophagus. Subject to success in these Phase I/II feasibility studies, DUSA plans to move forward with more expensive pre-pivotal Phase II studies for such indications, starting in 2002.

With respect to Levulan(R) PDT for brain cancer, although we also originally intended to initiate a clinical study during 2001, we have decided to first examine the market opportunities for various brain cancers. DUSA is also supporting and collaborating in new investigator studies on Barrett's esophagus and restenosis inhibition. In addition, independent investigators have reported to DUSA that positive long-term results were achieved in a pilot study using Levulan(R) PDT following balloon angioplasty to inhibit arterial restenosis. Additional indications are being considered for future development including detection and treatment of cervical dysplasia and dysfunctional uterine bleeding. There have been no further developments regarding bladder cancer detection, but DUSA continues to evaluate possible approaches for this indication.

General and Administrative Costs. General and administration costs for the three and six-month periods ended June 30, 2001 increased approximately $521,000 and $688,000, respectively, to $962,000 and $1,918,000, as compared to the same periods in 2000. These increases were 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 half of 2001. In addition, this increase also reflects the aforementioned

reassignment 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 June 30, 2001 decreased slightly to $932,000 as compared to $943,000 for the comparable period in 2000 and was attributed to lower interest rates and higher broker fees, offset by higher investable cash balances. During the six-month period ended June 30, 2001, interest income increased significantly to $2,034,000 as compared to $1,325,000 for the same period in 2000 mainly due to earnings on the $15,000,000 received from Schering AG during the fourth quarter of 2000 and 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 in the United States and Schering AG in the rest of the world, excluding Canada, and our ability to meet the supply needs of our customer base, do not offset our expenditures, interest



income will decline as our investable cash balances are reduced to support operating activities of the company.

Net Losses. The Company incurred a net loss of approximately $1,563,000, or $0.11 per share, and $2,815,000, or $0.20 per share, for the three and six-month periods ended June 30, 2001, as compared to a net loss of $1,440,000, or $0.11 per share, and $2,681,000, or $0.21 per share, for the three and six-month periods ended June 30, 2000. These losses were within management's expectations 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 approximately $78,034,000 at June 30, 2001, compared to $82,442,000 as of December 31, 2000. This decrease is mainly the result of net operating activities costs incurred during the first half of 2001.

As of June 30, 2001, we had inventory of $1,796,000, representing finished goods, work-in-progress and raw materials, as compared to $1,332,000 as of December 31, 2000. Also, at the end of the current quarter we had net fixed assets of $2,484,000, compared to $1,700,000 as of December 31, 2000, due primarily to the acquisition of equipment and software. We expect to make additional capital expenditures during the second half of 2001 and 2002 in order to acquire equipment for the manufacture of the Kerastick(R) for either a back up second source of supply or the development of our own manufacturing capabilities. As of June 30, 2001, the Company has acquired or incurred deposits of approximately $248,000 in manufacturing equipment, which has been recorded in other assets.

As of June 30, 2001, we had accounts receivable of $222,000, representing net sales associated with product sales, compared to $915,000 at the end of 2000. In addition, based on our co-development program with Schering AG, a receivable of $824,000 has been recorded during the current quarter for reimbursable research and development costs. As of December 31, 2000, we recorded a co-development receivable of $723,000.

As of June 30, 2001, we had current liabilities of $1,873,000, compared to $2,837,000 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 June 30, 2001, we held securities with an aggregate cost of approximately $62,783,000 and a current aggregate market value of $64,117,000, resulting in a net unrealized gain on securities available for sale of $1,334,000, which has been included in shareholders' equity. As of December 31, 2000, these securities had an aggregate cost of $56,876,000 and a current aggregate market value of $58,055,000 resulting in a net unrealized gain on securities available for sale of





$1,179,000. 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 4.61% to 7.22% and maturity dates ranging from July 2, 2001 to May 30, 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 suitable organizations to help develop and/or market some of our potential non-dermatology products and technologies.

As of June 30, 2001, we had deferred revenues of approximately $24,056,000, compared to $24,805,000 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 $23,304,000, and the deferral of nearly $752,000 of 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 current amount of our liquid assets 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, and/or acquire products and/or new businesses, 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 June 30, 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. However, if we establish our own production line for the manufacture of the Kerastick(R), we expect that environmental laws will govern

our facility. We are currently obtaining estimates for the capital costs associated with this effort. 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

On July 20, 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations" and SFAS No. 142



"Goodwill and Other Intangible Assets". SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001 and that the use of the pooling-of-interest method is no longer allowed. SFAS No. 142 requires that upon adoption, amortization of goodwill will cease and instead, the carrying value of goodwill will be evaluated for impairment on an annual basis. Identifiable intangible assets will continue to be amortized over their useful lives and reviewed for impairment in accordance with SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of". SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. DUSA is evaluating the impact of the adoption of these standards and does not believe the effect of adoption of these statements will have any material effect on our financial position or results of operation.

In June 1998, the Financial Accounting Standards Board issued SFAS 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 position or results of operation.

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.

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 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 the

timing of the establishment of a Canadian supply arrangement, expectations for regulatory approval of our products in non-U.S. countries, the achievement of market acceptance of our products, belief that reimbursement levels must be competitive with other AK products reimbursement levels, the goal of reducing cost of product sales, timing of royalties on Kerastick(R) sales and recognition of revenue on BLU-U(TM) distribution, expectations of the ability to cover under-absorbed overhead, beliefs regarding environmental compliance, expectations regarding the future funding of dermatology Phase II studies, anticipation of hiring additional personnel, dependence on reimbursement policies for significant revenues, expectations for continuing operating losses, increasing research and development costs, levels of interest income, additional capital expenditures, and beliefs regarding the 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 and foreign regulatory 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 mentioned from time to time in our SEC filings.

## PART II- OTHER INFORMATION

Items 1, 3, 5.

None.

Item 4. Submission of Matters to a Vote of Security Holders

Matters submitted to a vote of security holders of the Corporation at the Annual Meeting of Shareholders held June 14, 2001 included the election of five (5) directors and ratification of the selection of Deloitte and Touche LLP as the independent auditors for the Corporation for 2001, and ratification of amendments to the Company's 1996 Omnibus Plan, as amended;

a) The following persons were elected to serve as directors of the Corporation:

| | Votes Cast For | Votes Cast Against | Abstained | N |
|---|---|---|---|---|
| D. Geoffrey Shulman | 10,082,671 | 552,823 | 0 | |
| John H. Abeles | 10,531,536 | 103,958 | 0 | |
| James P. Doherty | 10,531,536 | 103,958 | 0 | |
| Richard C. Lufkin | 10,531,536 | 103,958 | 0 | |
| Jay Haft | 10,531,536 | 103,958 | 0 | |

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b) Shareholders ratified the selection of Deloitte & Touche LLP as the independent auditors for the Corporation for 2001 as follows:

| | Votes Cast For | Votes Cast Against | Abstained |
|---|---|---|---|
| Deloitte & Touche LLP | 10,529,336 | 98,448 | 7,710 |

c) Shareholders also voted to ratified the amendments to the 1996 Omnibus Plan, as amended, by casting the following votes:

| | Votes Cast For | Votes Cast Against | Abstained |
|---|---|---|---|
| 1996 Omnibus Plan Amendment | 4,517,349 | 1,872,257 | 466,938 |

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

a) Form 8-K dated July 17, 2001 regarding an update of the Registrant's research and development advancements, particularly that the United States Food and Drug Administration completed its review of three Investigational New Drug applications.

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.

DATE: AUGUST 13, 2001

BY: /S/JOHN E. MATTERN

JOHN E. MATTERN
VICE PRESIDENT, FINANCE,
AND CHIEF FINANCIAL OFFICER(Chief Financial and Chief Accounting Officer)