

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

DUSA PHARMACEUTICALS INC
Form 10-Q
May 14, 2002

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, 2002

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 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.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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.

13,865,390 shares as of May 9, 2002

PART 1.

ITEM 1. FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	MARCH 31, 2002 (Unaudited)

ASSETS	
CURRENT ASSETS	
Cash and cash equivalents	\$ 2,945,193
United States government securities	56,429,372
Accrued interest receivable	783,300
Accounts receivable	191,473
Receivable under co-development program	779,137
Inventory	2,224,785
Other current assets	1,423,429

TOTAL CURRENT ASSETS	64,776,689
Property and equipment, net	4,580,362
Deferred charges	1,378,770
Deferred royalty	664,206

TOTAL ASSETS	\$ 71,400,027
	=====
LIABILITIES AND SHAREHOLDERS' EQUITY	
CURRENT LIABILITIES	
Accounts payable	\$ 854,643
Accrued payroll	189,643
Other accrued expenses	1,703,008
Deferred revenue	149,074
Due to licensor	15,774

TOTAL CURRENT LIABILITIES	2,912,142
Deferred revenue	21,816,664
Other deferred reimbursement	499,996

TOTAL LIABILITIES	25,228,802

COMMITMENTS AND CONTINGENCIES (NOTE 11)	
SHAREHOLDERS' EQUITY	

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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: 13,865,390 (2001: 13,865,390) shares of common stock, no par	95,440,561
Additional paid-in capital	2,015,586
Accumulated deficit	(52,712,996)
Accumulated other comprehensive income	1,428,074

TOTAL SHAREHOLDERS' EQUITY	46,171,225

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 71,400,027
	=====

See the accompanying Notes to the Condensed Consolidated Financial Statements.

2

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31, 2002 (Unaudited)	Three Months Ended March 31, 2001 (Unaudited)
	-----	-----
REVENUES		
Product sales and rental income	\$ 50,527	\$ 213,961
Research grant and milestone revenue	495,834	495,834
Research revenue earned under collaborative agreement	779,137	480,165
	-----	-----
TOTAL REVENUES	1,325,498	1,189,960
	-----	-----
OPERATING COSTS		
Cost of product sales and royalties	678,769	655,029
Research and development	3,281,724	1,826,828
General and administrative	1,006,975	1,062,941
	-----	-----
TOTAL OPERATING COSTS	4,967,468	3,544,798
	-----	-----
LOSS FROM OPERATIONS	(3,641,970)	(2,354,838)
	-----	-----
OTHER INCOME		
Interest income	774,419	1,102,778
	-----	-----
NET LOSS	\$ (2,867,551)	\$ (1,252,060)
	=====	=====
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (.21)	\$ (.09)
	=====	=====
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	13,865,390	13,746,982
	=====	=====

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

See the accompanying Notes to the Condensed Consolidated Financial Statements.

3

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Month 2002 (Unaudited)
<hr style="border-top: 1px dashed black;"/>	
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES	
Net loss	\$ (2,867,551)
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	72,524
Depreciation and amortization expense	441,935
Amortization of deferred revenue	(495,834)
Changes in other assets and liabilities impacting cash flows from operations:	
Accrued interest receivable	140,159
Accounts receivable	(70,193)
Receivable under co-development program	85,397
Inventory	108,295
Deferred charges	(100,000)
Other current assets	(168,479)
Accounts payable	539,754
Accrued payroll and other accrued expenses	(506,832)
Due to licensor	(47,018)
Deferred revenue	(124,284)
	(2,992,127)
NET CASH USED IN OPERATING ACTIVITIES	
CASH FLOWS USED IN INVESTING ACTIVITIES	
Purchases of United States government securities	(5,075,100)
Proceeds from maturing United States government securities	4,918,568
Purchases of property and equipment	(1,474,648)
Deposits on equipment	--
	(1,631,180)
NET CASH USED IN INVESTING ACTIVITIES	
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES	
Proceeds from exercise of options and warrants	--
	--
NET CASH PROVIDED BY FINANCING ACTIVITIES	
NET DECREASE IN CASH	(4,623,307)
CASH AT BEGINNING OF PERIOD	7,568,500
CASH AT END OF PERIOD	\$ 2,945,193

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

See the accompanying Notes to the Condensed Consolidated Financial Statements.

4

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of March 31, 2002, Condensed Consolidated Statements of Operations for the three months ended March 31, 2002 and 2001, and Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2002 and 2001 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 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, 2001 audited consolidated financial statements and notes thereto.

2) PRINCIPLES OF CONSOLIDATION

The Company's condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, DUSA Pharmaceuticals New York, Inc., which was formed on March 3, 1994 to be the research and development center for the Company. All 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, as of March 31, 2002, ranging from 4.14% to 7.13% and maturity dates ranging from April 30, 2002 to January 3, 2007.

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.

5

4) INVENTORY

Inventory consisted of the following:

MARCH 31, 2002	DECEMBER 31,
(UNAUDITED)	2001

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

	-----	-----
Finished goods	\$1,822,584	\$2,013,799
Raw materials	402,201	319,281
	-----	-----
	\$2,224,785	\$2,333,080
	=====	=====

5) OTHER CURRENT ASSETS

Other current assets consisted of the following:

	MARCH 31, 2002 (UNAUDITED)	DECEMBER 31, 2001
	-----	-----
Prepaid expenses and deposits	\$533,434	\$447,520
Commercial light sources under lease or rental	847,502	764,025
Other current assets	42,493	43,405
	-----	-----
	\$1,423,429	\$1,254,950
	=====	=====

6) DEFERRED CHARGES AND ROYALTIES

Deferred charges and royalties, which include costs paid in advance to third parties under various agreements, are being amortized on a straight-line basis over their expected terms (1 1/2 - 12 years).

Deferred charges, which are being amortized over 18 months and 4 1/2 years, respectively, are as follows:

	MARCH 31, 2002 (UNAUDITED)	DECEMBER 31, 2001
	-----	-----
Facilities underutilization costs	\$774,998	\$933,333
Facilities reimbursement costs	603,772	660,375
	-----	-----
	\$1,378,770	\$1,593,708
	=====	=====

Prepaid royalties to PARTEQ are being amortized over 12 1/2 years.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

7) DEFERRED REVENUE

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Deferred revenue associated with the Company's milestone payments, unrestricted research grants, and the sale of commercial light sources consisted of the following:

	MARCH 31, 2002 (UNAUDITED)	DECEMBER 31 2001
	-----	-----
Milestone and unrestricted grant payments	\$21,816,664	\$22,312,498
Sale of commercial light sources	149,074	273,358
	-----	-----
	\$21,965,738	\$22,585,856
	=====	=====

8) SHAREHOLDERS' EQUITY

On January 17, 2002, the Company extended the term of 300,000 Class B warrants from January 29, 2002 to January 29, 2007 that were issued to the Chief Executive Officer of the Company. 50,000 of the Class B warrants lapsed.

9) 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 each of the periods presented in the Statements of Operations, as the effect would be antidilutive. For the three months ended March 31, 2002, and 2001, stock options and warrants totaling approximately 2,486,000, and 2,449,000 shares, respectively, have been excluded from the computation of diluted net loss per share.

7

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

10) COMPREHENSIVE LOSS

For the three months ended March 31, 2002 and 2001, comprehensive loss consisted of the following:

	Three Months Ended March 31, (Unaudited)	
	2002	2001
	-----	-----
NET LOSS	\$ (2,867,551)	\$ (1,252,060)
Net unrealized gains (losses) on United States securities available for sale	(795,761)	573,066
	-----	-----
COMPREHENSIVE LOSS	\$ (3,663,312)	\$ (678,994)
	=====	=====

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

11) COMMITMENTS AND CONTINGENCIES

Kerastick(R) Manufacturing Line - Following the amendments to the Company's agreement with North Safety Products, Inc. that will lead to the expiration of the Company's current Kerastick(R) manufacturing arrangement on or before June 30, 2003, and the Company's commitment to Schering AG through its Marketing, Development and Supply Agreement, as amended, the Company commenced the construction of a Kerastick(R) manufacturing facility at its Wilmington office. Construction started in January 2002, and is expected to be completed during 2002. As of March 31, 2002, the Company has expended \$1,682,000 for certain equipment, construction and pre-construction activities, which have been classified as construction work-in-progress in property and equipment in the Consolidated Balance Sheet.

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 is 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. DUSA is evaluating the situation with Queen's and PARTEQ, as PARTEQ has an obligation to diligently maintain its patents under its license agreement with DUSA.

12) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment of Disposal of Long-lived Assets." This statement supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived

8

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Assets to Be Disposed Of." SFAS 144 establishes a single accounting model, based on the framework established in SFAS 121, for long-lived assets to be disposed of by sale, and resolves implementation issues related to SFAS 121. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. On January 1, 2002, the Company adopted this statement, which had no effect on its financial position or results of operations.

In July 2001, the Financial Accounting Standards Board issued 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 September 30, 2001 and that the use of the pooling-of-interest method is no longer permitted. 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. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. On January 1, 2002, the Company adopted these statements, which had no effect on its financial

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

position or results of operations.

13) SUBSEQUENT EVENTS

Manufacturing Facilities Loan - On May 13, 2002, the Company entered into a commercial loan agreement to borrow up to \$2,700,000 under a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility. Until June 30, 2002, the Note will bear interest at the bank's prime commercial lending rate. At that time, DUSA, at its option, may select a fixed rate or a rate at the LIBOR interest rate plus 1 3/4%, for varying periods. At the end of such LIBOR rate period, DUSA may select the then current LIBOR rate or convert, one time only, to a fixed rate loan at any time during the first year of the term. The Company must borrow on this financing instrument by June 30, 2002 and will make monthly principal plus interest payments on this instrument, with the final principal and interest payment due on June 30, 2009. Certain of its United States Government Securities secure the loan.

Third-party Leasing Agreement - On April 18, 2002, the Company engaged Auric Capital Corp., a leasing company, to complete the rental transactions of its BLU-U(R) brand light source to physicians, including coordinating payment plans with the physicians. DUSA will sell the BLU-U(R) to the leasing company, and will be paid for the units by the leasing company after the renter makes its initial rental payment. The leasing company will rent the BLU-U(R) to physicians for a 36-month period with payments by the physician deferred until the seventh month of the term. Revenues and costs from BLU-U(R) rentals will be recognized over the last 30 months of the rental period. In the event a physician does cancel a rental agreement, DUSA has agreed to repurchase the unit from the leasing company at an agreed upon price.

9

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, 2001 and its Condensed Consolidated Financial Statements and Notes to the Condensed Consolidated Financial Statements for the three month periods ended March 31, 2002 and 2001. DUSA is engaged primarily in the research and development, and commercialization 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, 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 source, producing photodynamic therapy for treatment of non-hyperkeratotic actinic keratoses (AKs) of the face or scalp.

We have devoted substantial resources to funding research and development in order to advance the Levulan(R) PDT/PD technology platform, and as a result, have experienced significant operating losses. As of March 31, 2002, we had an accumulated deficit of approximately \$52,713,000. Achieving our goal of becoming a profitable operating company is dependent upon the market penetration of our products in the United States by Schering AG, our worldwide dermatology

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

marketing partner (except Canada), and Berlex Laboratories, Inc. (Berlex), the United States affiliate of Schering AG, acceptance of our therapy by the medical and consumer constituencies, and our ability to develop and/or acquire new products. As of March 31, 2002, 328 BLU-U(R) brand light units were in place, an increase of 33 units as compared to the end of 2001. We primarily rent or lease the BLU-U(R) to physicians, medical institutions and academic centers throughout the country. Berlex has advised us that during this quarter, end-user Kerastick(R) sales totaled 1800, similar to the average quarterly sales during 2001, but lower than the 2448 units sold to end-users in the fourth quarter of 2001.

Up to this point, market acceptance has unfortunately been far below our original expectations. Although we have been encouraged by positive responses from many physicians and patients who have used our therapy, we recognize that the therapy has not yet been widely accepted as a routine therapy for AKs. At this time, Berlex is continuing to market the therapy, but we cannot determine when, or if, significant sales increases will occur. Under our Marketing, Development and Supply Agreement with Schering AG, dated November 1999, Schering AG has the right to terminate the agreement on twelve (12) months prior written notice, which it could exercise at any time. Should Schering AG decide to terminate the agreement, DUSA would have to market the products itself or enter into arrangements with other third parties at significant expense. In addition, if Schering AG should decide to terminate the agreement, DUSA would

10

have to evaluate certain items on its Consolidated Balance Sheets for impairment including inventories, commercial light sources under lease or rental, and deferred charges and royalties, as well as any unamortized deferred revenue related to previously received milestone payments received under the agreement (See Note 7 to the Company's Notes to the Consolidated Condensed Financial Statements.) Furthermore, if Schering AG fails to adequately fund marketing efforts or develop, train and manage a sufficiently large sales force, the demand for our product would be limited and our royalties from Schering AG on sales of the Kerastick(R), our income from our light device, and our revenue on supply fees on the Kerastick(R) would be adversely affected until we substituted other marketing initiatives. Under our agreement with Schering AG, Schering AG has an obligation to launch the Kerastick(R) in Brazil where regulatory approval was granted in March 2002 within certain time parameters. Regulatory approval of the BLU-U(R) in Brazil is pending. Schering AG has informed DUSA that its launch date will be dependent upon sales progress in the United States, and will not be made before its 2003 marketing budget is determined in the fall of 2002. Should Schering AG not launch the product within the time frame provided for in our agreement, the rights to market the product in Brazil would revert to DUSA.

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. DUSA's research and development efforts are continuing, both in dermatology (in partnership with Schering AG), and in our internal indication development program for Barrett's esophagus dysplasia. As of March 31, 2002, our staff included 56 full-time employees as compared to 55 at the end of 2001, in support of all activities including production, maintenance, customer support, and financial operations for our products, as well as the research and development programs for dermatology and internal indications. While our financial position is strong, DUSA cannot predict when royalties and supply fees that we are entitled to under our Schering AG agreement, along with interest and/or other income, may offset the cost of these efforts.

On January 11, 2002, we paid \$100,000 to National Biological Corporation ("NBC"), the manufacturer of our BLU-U(R) light source, to compensate NBC to

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

cover certain overhead costs. We had previously agreed to reimburse NBC for such costs if we did not order a certain number of BLU-U(R) brand units by January 2, 2002 for delivery in 2002. In consideration for this payment, NBC agreed to maintain its BLU-U(R) manufacturing capabilities in a state of readiness during 2002 with the capability of producing BLU-U(R) units in accordance with established procedures. DUSA has reported the payment in deferred charges, which is being recognized in cost of product sales on a straight-line basis during 2002.

In July 2001, we revised our agreement with our Kerastick(R) manufacturer, North Safety Products ("North"), covering the period from the execution of this amendment through December 31, 2002. In accordance with this amendment, we paid North \$1,200,000 in up-front underutilization fees during 2001, and have agreed to make additional payments totaling \$200,000 in 2002. DUSA has reported the total commitment of \$1,400,000 in deferred charges, which is being recognized in cost of product sales on a straight-line basis over the term of the amendment. In consideration for the underutilization fees, North has agreed to maintain its Kerastick(R) manufacturing capabilities in a state of readiness through December 31, 2002, with the capability of producing at least 25,000 Kerastick(R) units per month in accordance with established procedures. The term of the agreement

11

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. The Company has not determined if we will need to extend the term of this agreement.

In September 2001, in accordance with an amendment to our agreement with Schering AG, Schering AG reimbursed DUSA \$1,000,000 of the costs incurred to modify our manufacturing agreement with North. This amount has been reported in deferred liabilities and is being recognized as an offset to cost of product sales on a straight-line basis over the term of the agreement with North.

We incur certain fixed costs resulting in under-absorbed overhead, which are included in cost of product sales. We expect that the development of our own facility will enable us to better manage and control the costs of production; however, our unit cost per Kerastick(R) will initially increase as compared to our unit cost under our agreement with North, until product sales increase significantly. DUSA commenced the construction of its Kerastick(R) manufacturing facility during January 2002. The cost to build and complete testing of such manufacturing capabilities, including equipment, is estimated to be approximately \$2,700,000. This cost also includes all costs of calibration, validation testing and equipment, and any related FDA fees. As of March 31, 2002, the Company has expended \$1,682,000 for certain equipment, construction and pre-construction activities. The initial build-out is expected to be completed by mid-2002, followed by facility and drug stability testing, which is expected to take approximately six months. FDA inspection is expected to occur within six months following the construction and testing stages, or approximately eighteen (18) months from the start of the construction process. This new facility will serve to replace our current Kerastick(R) manufacturer.

RESULTS OF OPERATIONS

Revenues - Revenues recognized for the three-month period ended March 31, 2002 were \$1,325,000 as compared to \$1,190,000 for the comparable period in 2001. Of these amounts, we earned significantly more research and development revenue of \$779,000 from Schering AG during the current three-month period as compared to \$480,000 in the comparable period in 2001 as our dermatology

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

co-development expenses were higher. Total revenues for both the current and prior three-month periods include amortization of up-front milestone and unrestricted grant payments of \$496,000 from Schering AG.

Also included in revenues during the current three-month period were product sales of \$51,000, as compared to \$214,000 in the prior year period. Product sales for the current period included royalty revenues of \$28,000 earned by DUSA for Kerastick(R) sales by Berlex to its distributor, and rental income on BLU-U(R) units of \$19,000. There were no direct sales of the Kerastick(R) to Berlex during the current three-month period. Product sales for the three months ended March 31, 2001 included \$201,000 of direct sales of the Kerastick(R) to Berlex, and rental income on BLU-U(R) units of \$10,000. There were minimal Kerastick(R) sales by Berlex to its

12

distributor for the quarter ended March 31, 2001. Based on Berlex's current forecast, we have met Berlex's Kerastick(R) supply needs through 2002 and do not expect any direct Kerastick(R) sales until demand for our product increases or the current inventory expires.

Under a BLU-U(R) marketing program launched in September 2001, revenues and costs from BLU-U(R) rentals will be recognized over the last 30 months of the 36-month term of the rental agreement. Under our previous marketing program, we sold the BLU-U(R) to a medical device leasing company. We then engaged the leasing company to complete the leasing and/or rental transactions, including coordinating payment plans with the physicians. The leasing company had been paying us for the units within 30 days after installation in the physicians' offices. DUSA, Berlex and the leasing company will continue to support customers that remain on this initial program; however, the majority of such customers have converted to the new program. Under the original program, physicians have the right to cancel their leases after periods of up to one year. Therefore, payments received by DUSA upon sale of the BLU-U(R) to the original leasing company are reported as deferred revenues until the physician's right to cancel the lease has expired. Revenues and costs totaling \$149,000 and \$106,000, respectively, related to the initial program have remained deferred as we anticipate a complete transition away from the initial program. As of March 31, 2002, there were 328 BLU-U(R) units installed in physicians' offices of which the majority, 263, are under the new marketing program with 114 customers having converted from the initial program to the new program. 51 units leased or rented by physicians remain under the initial program, and 14 units are in the field based on direct sales and demonstration units. The converted units have been repurchased from the leasing company and the corresponding deferred revenue and cost has been reversed from the financial statements. Under the current program, DUSA will sell the BLU-U(R) to the leasing company, and will be paid for the units by the leasing company after the renter makes its initial rental payment. The leasing company will rent the BLU-U(R) to physicians for a 36-month period with payments by the physician deferred until the seventh month of the term. In the event a physician does cancel a rental agreement, DUSA has agreed to repurchase the unit from the leasing company at an agreed upon price. As of March 31, 2002, a total of 63 units have been returned to DUSA since the product launch in September 2000.

Cost of Product Sales and royalties - Cost of product sales and royalties for the current three-month period ended March 31, 2002 were \$679,000 as compared to \$655,000 for the same period in 2001. The current three-month period included internal operations costs of \$304,000 for resources assigned to support product, \$54,000 incurred to ship and install the BLU-U(R) in physicians offices, \$16,000 in royalty and supply fees due to DUSA's licensor, \$56,000 in amortization of deferred charges, and \$4,000 in depreciation on BLU-U(R) rental units. The current period also included a reserve of \$100,000 on BLU-U(R)

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

inventory as we assess the carrying value of such inventories based on current and projected levels of placement. Also included in the current three-month period is \$92,000 in net underutilization costs due to current orders falling below certain previously anticipated levels. As anticipated and previously reported, there were no product sales to Berlex in the current three-month period. The comparable prior-year period included \$201,000 in direct Kerastick(R) related product costs, \$204,000 in underutilization costs, \$56,000 in amortization of deferred charges, \$48,000 in costs incurred for shipping and installing the BLU-U(R) in physicians offices, and personnel costs of \$176,000 assigned to support product.

13

The higher cost of product sales and royalties as compared to revenues from product sales is a result of the lower than anticipated level of Kerastick(R) sales, coupled with 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 per unit will initially increase in our own facility but would be covered by product revenue if the level of Kerastick(R) sales significantly increases, which is dependent upon the market penetration of our products.

Inventory costs related to the BLU-U(R) commercial light sources under rental or lease are deferred and recorded in other current assets until the BLU-U(R) is no longer returnable to DUSA by the physician, which is one year under the initial marketing program. Under the new marketing program, the BLU-U(R) is rented to physicians and returnable at any point during the rental period. The costs of BLU-U(R) inventory under the new program will be recognized over the last 30 months of the term of the rental. As of March 31, 2002 and December 31, 2001, deferred inventory costs were approximately \$848,000 and \$764,000, respectively.

Research and Development Costs - Total research and development costs for the three-month period ended March 31, 2002 were \$3,282,000, as compared to \$1,827,000 for the three-month period ended March 31, 2001. This increase was mainly attributed to higher third-party expenditures in support of FDA mandated Phase IV clinical studies of our existing product, demonstrating feasibility in other dermatological indications; as well as, to fund our research and development efforts on various internal indications.

In the dermatology pipeline, a recent review of interim data from DUSA's Phase I/II clinical study using Levulan(R) PDT in the treatment of persistent plantar warts showed encouraging results. In warts treated with Levulan(R) PDT, 52% of lesions showed a greater than 50% reduction in surface area at 16 weeks follow-up, vs. 33% of the vehicle and light treated lesions. Although the final data will not be available until later this year, and this study was not designed to be statistically significant, DUSA believes that this data, combined with published independent results, is sufficient to justify continued development of this indication. Further development plans will not be finalized until this fall when the full results are available. Initial results from the Phase I/II onychomycosis (nail fungus) study are also expected this fall.

DUSA also intends to start a study in the near future to explore the application of Levulan(R) PDT using the Kerastick(R) and the BLU-U(R) for the treatment of actinic keratosis over the entire face, whereas the currently approved indication only allows application to scattered individual lesions. We believe that full development and approval of this indication, which we term Broad Area AKs (BAAKs), could enhance the usefulness of the therapy.

DUSA has also been conducting Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett's esophagus, and

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

preliminary analyses are currently underway. These results, when available, will be used to consider future development.

14

General and Administrative Costs - General and administration expenses for the current three-month period were \$1,007,000, as compared to \$1,063,000 for the same period in 2001. General and administrative costs are expected to remain stable for the remaining 2002 periods as compared to 2001 as staffing levels for these functions have been established.

Interest Income - Interest income for the three-month period ended March 31, 2002 decreased approximately \$329,000, to \$774,000, as compared to \$1,103,000 for the same period in 2001. This decrease is mainly attributed to lower investable cash balances as we used cash in support of DUSA's operating activities and the development of our new Kerastick(R) manufacturing facility, and due to lower yields. Interest income will continue to decline as our investable cash balances are reduced to support DUSA's operating activities.

Net Losses - The Company incurred a net loss of \$2,868,000, or \$0.21 per share, for the three-month period ended March 31, 2002, as compared to a net loss of \$1,252,000, or \$0.09 per share for the three-month period ended March 31, 2001. These losses were within management's expectations, and are expected to continue unless market penetration of our first products increases significantly.

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 \$71,400,000 as of March 31, 2002, compared to \$75,864,000 as of December 31, 2001. This decrease is mainly the result of net operating activities during the quarter.

As of March 31, 2002, we had inventory of \$2,225,000, representing finished goods, and raw materials, as compared to \$2,333,000 as of December 31, 2001. Also, at the end of the current quarter we had net fixed assets of \$4,580,000, compared to \$3,384,000 as of December 31, 2001, due mainly to the development of our Kerastick(R) manufacturing facility. We expect to make additional capital expenditures of approximately \$1,000,000 during 2002 to complete the development of this facility.

As of March 31, 2002, we had accounts receivable of \$191,000, representing net sales associated with product sales, compared to \$121,000 at the end of 2001. In addition, based on our co-development program with Schering AG, a receivable of approximately \$779,000 has been recorded during the current quarter for reimbursable research and development costs as compared to \$864,000 as of December 31, 2001.

As of March 31, 2002, we had current liabilities of \$2,912,000, compared to \$3,051,000 as of December 31, 2001. On May 13, 2002, we secured a seven-year term loan to finance the construction of our Kerastick(R) manufacturing facility in DUSA's Wilmington headquarters (see "Contractual Obligations and Other Commercial Commitments -- Manufacturing Facility Loan" below and Note 13 to the Notes to the Consolidated Condensed Financial Statements.)

15

We invest our cash in United States government securities, which are

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

classified as available for sale. As of March 31, 2002, we held securities with an aggregate cost of \$55,001,000 and a current aggregate market value of \$56,429,000, resulting in a net unrealized gain on securities available for sale of \$1,428,000, which has been included in shareholders' equity. As of December 31, 2001, DUSA held securities with an aggregate cost of \$54,917,000 and a current aggregate market value of \$57,141,000 resulting in a net unrealized gain on securities available for sale of \$2,224,000. 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 4.14% to 7.13% and maturity dates ranging from April 30, 2002 to January 3, 2007.

We believe that we have sufficient capital resources to proceed with our current development program for Levulan(R) PDT/PD, 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. DUSA is actively seeking to expand or enhance its business by using its resources to acquire by license, purchase or other arrangements, businesses, technologies, or products. We also plan to 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 March 31, 2002, we had deferred revenues of \$21,965,000, compared to \$22,586,000 at December 31, 2001. 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 \$21,817,000, and the deferral of \$149,000 in BLU-U(R) product sales. Commencing with our product launch in September 2000, we began to amortize the Schering AG milestone and unrestricted grant payments over approximately 12 1/2 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.

We have not made any material capital expenditures for environmental control facilities. However, as we are in the process of developing a production line for Kerastick(R) manufacturing, we expect that environmental laws will govern our facility. We have estimated that the capital costs to develop this facility, including equipment will be \$2,700,000 (see "Contractual Obligations and Other Commercial Commitments" below). There can be no assurance, however, that we will not be required to incur significant additional costs to comply with environmental laws and regulations in the future, or that our operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

Kerastick(R) Manufacturing Line - DUSA has commenced the development of a Kerastick(R) manufacturing facility at our Wilmington, Massachusetts location. Construction started in January 2002. The initial build-out is expected to be completed by mid-2002, followed by facility and drug stability testing, which is

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

expected to take approximately six months. FDA inspection is expected to occur within approximately six months following the construction and testing stages. The Company has estimated that the cost to construct this facility, including equipment, is approximately \$2,700,000. This cost includes estimates to build the facility and all costs of calibration, validation testing and equipment, and any related FDA approval costs. As of March 31, 2002, the Company has expended \$1,682,000 for certain pre-construction activities.

Manufacturing Facility Loan - On May 13, 2002, the Company entered into a commercial loan agreement to borrow up to \$2,700,000 under a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility. Until June 30, 2002, the Note will bear interest at the bank's prime commercial lending rate. At that time, DUSA, at its option, may select a fixed rate or a rate at the LIBOR interest rate plus 1 3/4%, for varying periods. At the end of such LIBOR rate period, DUSA may select the then current LIBOR rate or convert, one time only, to a fixed rate loan at any time during the first year of the term. The Company must borrow on this financing instrument by June 30, 2002 and will make monthly principal plus interest payments on this instrument, with the final principal and interest payment due on June 30, 2009. Certain of its United States Government Securities secure the loan.

Legal Matters- On April 12, 2002, the Company received notice that one of the patents licensed to DUSA by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario is 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 DUSA's 5-aminolevulinic acid technology, is invalid. DUSA intends to evaluate the situation with Queen's and PARTEQ, as PARTEQ has an obligation to diligently maintain its patents under its license agreement with DUSA.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment of Disposal of Long-lived Assets." This statement supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." SFAS 144 establishes a single accounting model, based on the framework established in SFAS 121, for long-lived assets to be disposed of by sale, and resolves implementation issues related to SFAS 121. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. On January 1, 2002, DUSA adopted this statement, which had no effect on our financial position or results of operations.

In July 2001, the Financial Accounting Standards Board issued 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 September 30, 2001 and that the use of the pooling-of-interest method is no longer permitted. 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. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. On January

1, 2002, DUSA adopted these statements, which had no effect on our financial

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

position or results of operations.

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

18

statements regarding management's goal of becoming profitable, impact on DUSA should Schering AG terminate our agreement, rights to our product in Brazil, expectations for continuing operating losses, North's entitlement to under-utilization fees, expectations for completion of our manufacturing facility and costs relating thereto, replacement of our current manufacturer, support of our initial BLU-U(R) leasing arrangements, and terms under our newer rental plan, absorption of overhead expenses and reduction of cost of product sales, 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(R), intentions to evaluate and pursue licensing and acquisition opportunities, beliefs regarding environmental compliance, expectations regarding the clinical trials results for warts, onychomycosis, and Barrett's esophagus and intention to start a BAAK trial, requirements of cash resources for our future liquidity, and potential impact on conversion of government securities, expectations for future strategic opportunities and research and development programs, need for additional funds, increasing research and development expenses, stability of administrative expenses, levels of interest income and net losses, and sufficiency of our capital resources and expectations for capital expenditures, evaluation of the legal proceeding between PhotoCure ASA and Queens University, expectations regarding inflation and market risks. 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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

PART II- OTHER INFORMATION

Items 1 through 5.

None.

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

a) Exhibits -

i) Exhibit 10.1 - Program Agreement between the Company and Auric Capital Corp. dated April 18, 2002 portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b) of the Securities Exchange Act of 1934, as amended.

19

(ii) Exhibit 99.1 - Commercial Loan Agreement, Secured Term Loan Promissory Note and Pledge and Security Agreement between the Company and Citizens Bank of Massachusetts dated May 13, 2002.

(iii) Exhibit 99.2 - Press Release dated May 14, 2002 issued by the Company regarding quarterly results for the period ended March 31, 2002.

b) i) Form 8-K dated January 22, 2002 announcing expectations for December 31, 2001 financial results, financial guidance for 2002, and updates on end-user sales and its research and development efforts.

ii) Form 8-K dated April 15, 2002 noting that the Company had received notice on Friday, April 12, 2002 that PhotoCure ASA filed litigation against Queen's University alleging invalidity of one of the patents licensed to DUSA by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario.

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: MAY 14, 2002

BY: /S/JOHN E. MATTERN

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

