DUSA PHARMACEUTICALS INC
Form 10-Q
November 07, 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 September 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.

13,852,890 shares as of November 5, 2001

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PART 1.
Item 1. FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2001 (Unaudited)	December 31, 2000
ASSETS		
Current Assets		
Cash and cash equivalents	$6,064,306	$16,441,114
U.S. government securities available for sale	60,669,875	58,055,463
Accrued interest receivable	812,091	990,083
Accounts receivable	131,141	914,959
Receivable from co-development partner	1,794,562	722,570
Inventory	2,051,226	1,331,966
Other current assets	1,612,673	562,240
Total current assets	73,135,874	79,018,395
Property and equipment, net	2,661,840	1,699,530
Deferred charges	1,883,646	886,792
Deferred royalty	694,392	739,671
Other assets	301,518	98,000
TOTAL ASSETS	$78,677,270	$82,442,388

LIABILITIES AND SHAREHOLDERS EQUITY

Current Liabilities

Accounts payable
$183,038 $100,500
Accrued payroll and other accrued expenses
1,433,675 1,810,047
Deferred revenue
540,365 509,207
Due to licensor
47,477 417,004

Total current liabilities
2,204,555 2,836,758
Deferred revenue
22,808,332 24,295,834
Other deferred liability
833,332

TOTAL LIABILITIES
25,846,219 27,132,592

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. Issued and outstanding: 13,847,890 (2000:		
13,730,890) shares of common stock, no par	95,310,811	94,757,532
Additional paid-in capital	1,860,519	1,860,519
Accumulated deficit	(47,119,773)	(42,487,349)
Accumulated other comprehensive income	2,779,494	1,179,094
TOTAL SHAREHOLDERS EQUITY	52,831,051	55,309,796
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$78,677,270	$82,442,388

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2001	2000	2001	2000
REVENUES				
Product sales	$58,837	$139,583	$469,516	$139,583
Research grant and milestone revenue	495,834		1,487,502	
Research revenue earned under collaborative agreements	881,895		2,186,262	602,504
TOTAL REVENUES	1,436,566	139,583	4,143,280	742,087
OPERATING COSTS				
Cost of product sales	441,979	139,583	1,818,064	139,583
Research and development	2,805,803	2,027,420	7,068,130	5,496,268
General and administrative	984,745	531,142	2,902,931	1,671,322

TOTAL OPERATING COSTS
4,232,527 2,698,145 11,789,125 7,307,173

LOSS FROM OPERATIONS
(2,795,961) (2,558,562) (7,645,845) (6,565,086)

OTHER INCOME

Interest income
978,932 944,475 3,013,421 2,269,846

NET LOSS
$(1,817,029) $(1,614,087) $(4,632,424) $(4,295,240)

BASIC AND DILUTED NET LOSS PER COMMON SHARE
$ (.13) $(.12) $(.34) $(.33)

WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING			
13,796,004	13,619,731	13,770,494	13,136,280

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30, (Unaudited)	
	2001	**2000**
OPERATING ACTIVITIES		
Net loss	$(4,632,424)	$(4,295,240)
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	759,428	(225,934)
Depreciation and amortization expense	721,344	181,887
Amortization of deferred revenue		(1,487,502)
Changes in other assets and liabilities impacting cash flows from operations:		
Accrued interest receivable	177,992	(585,107)
Accounts receivable	783,818	(139,583)
Receivable from co-development partner	(71,992)	(602,504)
Inventory	(719,260)	(882,711)
Other current assets	(1,050,433)	(252,672)
Deferred charges		(1,400,000)
Accounts payable	82,538	144,533
Accrued payroll and other accrued expenses	(376,372)	265,165
Due to licensor	(369,527)	(370,936)
Deferred revenue		31,158
Net cash used in operating activities	(7,551,232)	(6,763,102)

INVESTING ACTIVITIES		
Purchases of U.S. government securities	(21,276,198)	(50,506,441)
Proceeds from maturing U.S. government securities	19,502,758	11,450,000
Payment to restructure supplier contract		(250,000)
Purchases of property and equipment	(1,401,897)	(990,652)
Deposits on equipment	(203,518)	(85,088)
Net cash used in investing activities	(3,378,855)	(40,382,181)
FINANCING ACTIVITIES		
Issuance of common stock and underwriters options, net of offering costs of $2,051,714:		40,698,286
Proceeds from exercise of options and warrants	553,279	1,522,402
Net cash provided by financing activities	553,279	42,220,688

NET DECREASE IN CASH	(10,376,808)	(4,924,595)
CASH AT BEGINNING OF PERIOD	16,441,114	7,028,618
CASH AT END OF PERIOD	$6,064,306	$2,104,023

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of September 30, 2001, Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2001 and 2000, and Condensed Consolidated Statements of Cash Flows for the nine months ended September 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

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 4.39% to 6.91% and maturity dates ranging from October 1, 2001 to August 15, 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 September 30, 2001 and December 31, 2000:

	September 30, 2001 (Unaudited)	December 31, 2000
Finished goods	$1,891,856	$1,151,537
Raw materials	159,370	175,344
Purchased parts and subassemblies		5,085
	$2,051,226	$1,331,966

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4) OTHER CURRENT ASSETS

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

	September 30, 2001 (Unaudited)	December 31, 2000
Prepaid expenses and deposits	$690,843	$293,069
Commercial light sources under lease or rental	593,562	261,923
Other current assets	328,268	7,248
	$1,612,673	$562,240

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 September 30, 2001 and December 31, 2000:

	September 30, 2001 (Unaudited)	December 31, 2000
Milestone and unrestricted grant payments	$22,808,332	$24,295,834
Sale of commercial light sources	540,365	509,207
	$23,348,697	$24,805,041

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 calculated under the treasury stock method were 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 nine-month periods ended September 30, 2001, approximately 647,000 and 764,000 stock options and warrants were excluded from the computation of diluted net loss per share. For the three and nine-month periods ended September 30, 2000, approximately 1,420,000 and 1,368,000 stock options and warrants were excluded from the computation of diluted net loss per share.

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7) COMPREHENSIVE LOSS

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

	Three Months Ended September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2001	**2000**	**2001**	**2000**
NET LOSS	$(1,817,029)	$(1,614,087)	$(4,632,424)	$(4,295,240)
Net unrealized gains on United States securities available for sale	1,445,831	385,400	1,600,400	453,084
COMPREHENSIVE LOSS	$ (371,198)	$(1,228,687)	$(3,032,024)	$(3,842,156)

8) COMMITMENTS AND CONTINGENCIES

The Company has entered into a series of agreements for research projects and clinical studies. As of September 30, 2001, future payments to be made pursuant to these agreements, under certain terms and conditions, total approximately $697,000 for the remainder of 2001 and $2,366,000 thereafter. On October 4, 2001, the Company executed a master service agreement, effective June 15, 2001, with Therapeutics, Inc. for an initial term of two years to engage Therapeutics to manage the clinical development of the Company products in the field of dermatology. Minimum payments under this agreement have been included in the total future payments as noted above. In addition, with the execution of this agreement, Therapeutics received 5,000 shares of the Company s common stock and also has the opportunity for additional grants, bonuses, and other incentives for each indication ranging from $250,000 to $1,250,000 depending on the phase of development for each indication.

In February 2001, the Company agreed to compensate North Safety Products, Inc. (North), the manufacturer of our Kerastick® brand applicator, for certain overhead expenses associated with the manufacture of the Kerastick® to cover underutilization of North s facilities since current orders are below certain previously anticipated levels. Approximately $401,000 of underutilization charges were recorded in cost of product sales based on the production levels through June 2001. In July 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 $400,000 covering the period from the execution of this amendment to the agreement through December 31, 2002 of which $100,000 has already been paid. The Company 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. Of this amount, $1,000,000 of the underutilized fees has been reimbursed through an amendment to the Company s Marketing, Development and Supply agreement with Schering AG as discussed in Note 9, Collaboration Agreement Amendment. In consideration for the underutilization fees, North has agreed to maintain its Kerastick® manufacturing capabilities in

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a state of readiness, with the capability of producing at least 25,000 Kerastick® units per month in accordance with established procedures. In addition, North is obligated to 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®. 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® units produced from July 1, 2001 through June 30, 2003.

9) COLLABORATION AGREEMENT AMENDMENT

On September 26, 2001, DUSA and Schering AG, a German corporation, agreed to amend their Marketing, Development and Supply agreement, dated November 22, 1999. With the execution of this amendment, Schering and its United States affiliate, Berlex Laboratories, Inc., agreed to reimburse DUSA $1,000,000 for costs DUSA incurred to modify its manufacturing agreement with North as discussed in Footnote 8, Commitments and Contingencies. 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 amendment. In consideration for this amendment, DUSA agreed to be responsible for certain additional liabilities in the event of DUSA s failure to supply Schering AG s requirements of finished product as defined in the original agreement. In addition, DUSA agreed to use its best efforts to qualify itself as the primary manufacturer and supplier of the Kerastick® within six months following the date that North ceases production. DUSA and Schering also agreed to terminate the guaranty by Schering AG to DUSA of BLU-U® lease payments by physicians, and the secured line of credit promissory note from Schering to DUSA for up to $1,000,000 to finance inventory of BLU-U® units.

10) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In July 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 September 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

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Board. The adoption of this statement did not have any effect on the Company s financial position or results of operation.

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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 nine-month periods ended September 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®. When Levulan® is used and is followed with exposure to light to produce a therapeutic effect, the technology is called photodynamic therapy, or PDT. When Levulan® is used and followed with exposure to light to detect medical conditions, the technology is called photodetection, or PD. Our first products are Levulan® 20% topical solution using our Kerastick® brand applicator, with photodynamic therapy, for treatment of non-hyperkeratotic actinic keratoses (AKs) of the face or scalp, and our BLU-U® brand light source. From our inception in 1991 until September 2000 we were classified as a development stage enterprise. In late September 2000, we launched our first commercial products, Levulan® Kerastick® and the BLU-U® 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 September 2001, 231 BLU-U® brand light units were in place in physician s offices. We lease or rent the BLU-U® 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 9001 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® PDT/PD technology platform and, as a result, we have experienced significant operating losses. As of September 30, 2001, we had an accumulated deficit of approximately $47,120,000.

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® units and BLU-U® brand light devices to meet Berlex s supply requirements in the United States for the balance of 2001 and into 2002. However, any significant delays in delivery of sufficient product supplies from our sole source third-party suppliers of Levulan®, the Kerastick® and/or the BLU-U®, in the future,

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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, so we can be in a position to develop our own Kerastick® 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 is taking longer than we originally anticipated. We believe that the uncertainty of third-party reimbursement has caused potential users of our therapy to delay the use of our therapy. We also 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. In addition, we also recognize that Berlex has to demonstrate to physicians the clinical value of our therapy, and the benefits compared to other therapies, in order for the medical community to accept our products on a large scale. On November 2, 2001, the American Medical Association issued a new Current Procedural Terminology code for Levulan® PDT and the Centers for Medicare & Medicaid Services (CMS) proposed national fees for the procedure and the expected drug reimbursement levels. Subject to any final revisions, the fee proposals will come into effect on January 1, 2002. This will also allow doctors offices to use the new codes electronically, rather than having to use the current manual miscellaneous codes for the procedure. The CMS has a 60-day comment period during which they will accept input regarding the proposed values they have placed on this application process. Berlex plans to work closely with medical professionals and policy makers to examine the proposed reimbursement levels, and make additional submissions if appropriate. At this time, management believes that the proposed reimbursement fees will allow the therapy to gain increasing acceptance in the marketplace.

We expect to continue to incur operating losses as we continue to invest in our research and development programs 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 will increase as 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® brand applicator, for certain overhead expenses associated with the manufacture of the Kerastick® to cover underutilization of North s facilities, since current orders

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are below certain previously anticipated levels. In July 2001, we revised this agreement and paid North $1,000,000 in up-front underutilization fees and agreed to make additional payments totaling $400,000 covering the period from the execution of this amendment to the agreement through December 31, 2002. Through September 30, 2001, we have paid $1,100,000 of the underutilization fees. DUSA has reported the total commitment of $1,400,000 in deferred charges, which is recognized in cost of product sales on a straight-line basis over the term of the amendment. Of this amount, $1,000,000 of the underutilized fees will be reimbursed through an amendment to DUSA s Marketing, Development and Supply agreement with Schering AG. In consideration for the underutilization fees, North has agreed to maintain its Kerastick® manufacturing capabilities in a state of readiness, with the capability of producing at least 25,000 Kerastick® units per month in accordance with established procedures. In addition, North is obligated to provide us with manufacturing records, personnel support, and a list of consultants and suppliers that have supported the development and manufacturing of the Kerastick®. 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® units produced from July 1, 2001 through June 30, 2003.

On September 26, 2001, DUSA and Schering AG agreed to amend our Marketing, Development and Supply agreement, dated November 1999. With the execution of this amendment, Schering and Berlex agreed to reimburse DUSA $1,000,000 for costs incurred by DUSA 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 amendment. In consideration for this amendment, DUSA agreed to be liable to Schering AG for all consequential damages, including, but not limited to, lost profits, attributed to DUSA s failure to supply Schering AG s requirements of finished product as defined in the original agreement. In addition, DUSA agreed to qualify itself as the primary manufacturer and supplier of the Kerastick® within six months following the date that North ceases production. DUSA and Schering also agreed to terminate the guaranty by Schering AG to DUSA of BLU-U® lease payments by physicians, and the secured line of credit promissory note from Schering to DUSA for up to $1,000,000 to finance inventory of BLU-U® units.

Results of Operations

Revenues. Total revenues recognized for the three and nine-month periods ended September 30, 2001 were approximately $1,437,000 and $4,143,000, and include product sales of $59,000 and $470,000, respectively, primarily reflecting direct sales of the Kerastick® to Berlex. Based on the agreed upon development plan and the timing of the start of the clinical trials, revenues for the current three and nine-month periods also include research and development revenue of approximately $882,000 and $2,186,000, reflecting revenue earned payments from Schering AG to support our dermatology co-development program. Under our agreement with Schering AG, two-thirds of the agreed upon dermatology research and development expenses, up to $3,000,000 per year, are reimbursable to DUSA by Schering AG for 2001. 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

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spent. Also included in revenues for the current three and nine-month periods are $496,000 and $1,488,000 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 nine-month periods in 2000, total revenues recognized were approximately $140,000 and $742,000, respectively, reflecting direct sales of the Kerastick® to Berlex of $140,000 and $603,000 of earned revenue payments from Schering to support our dermatology co-development program.

Based on Berlex s current forecast, we have met Berlex s Kerastick® supply needs into 2002. We earn royalties when Berlex sells the Kerastick® into the marketplace; however, such royalties were minimal during the first nine months of 2001 as Berlex had 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. Management is unable to predict the timing of royalties on future Kerastick® sales by Berlex as DUSA does not control the distribution channel of the Kerastick® and Berlex s forecast for the manufacturing of Levulan®.

During the current three and nine-month periods, the number of BLU-U® brand light units in place in physician s offices increased by 41 and 134, respectively to 231. In July 2001, DUSA and Berlex test-marketed a new program, which was then launched nationally in mid-September 2001. Under this program, DUSA rents the BLU-U® to physicians for 36 months with costs deferred for the first six months, while Berlex provides physicians with Kerastick® samples at its cost. Physicians have the right to terminate the rental at any time. We are negotiating with a medical device leasing company to manage the rental program including coordinating payment plans with the physicians. Berlex is actively working to convert physicians to the new marketing program. Under the new marketing arrangement, revenues will be recognized ratably over the last 30 months of the rental period. In the initial marketing program, we leased or rented the BLU-U® to our customers and engaged a medical device leasing company to complete the leasing and/or rental transactions, including coordinating payment plans with the physicians. We have been selling the leased BLU-U® to the leasing company, which usually pays us for the units within thirty (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, we expect that the majority of such customers will convert to the new program. Under the initial program, physicians have the right to cancel their leases after periods of up to one year. Therefore, 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. As of September 30, 2001, 66 customers from the initial program have converted to the new program and the units have been repurchased from the leasing company and the corresponding deferred revenue has been reversed from the financial statements.

Cost of Product Sales. Cost of product sales for the three and nine-month periods ended September 30, 2001 were approximately $442,000 and $1,818,000, respectively, including $358,000 in direct Kerastick® related product costs in the current nine-month period, and $66,000 and $467,000 of underutilization costs due to orders to our Kerastick® manufacturer falling below certain previously anticipated levels. During the current three and nine-month periods, cost of

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product sales also includes $56,000 and $169,000 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®, as well as costs incurred for shipping and installing the BLU-U® 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 $178,000 and $564,000 for the three and nine-month periods ended September 30, 2001. Inventory costs related to the BLU-U® units that are leased under the initial marketing program are deferred and recorded in other current assets until the customer s right to cancel its lease after periods of up to one year expires. As of September 30, 2001, deferred inventory costs were approximately $242,000.

The higher cost of product sales as compared to product sales is primarily a result of the lower than anticipated level of Kerastick® sales, and under-absorbed overhead attributed to the payment of underutilization costs to our Kerastick® supplier, as noted above, and the allocation of personnel to product sales operations. Management expects that such costs may initially increase in our own facility but will be covered by product revenue as the level of Kerastick® sales increases.

In early 2001, in order to meet the production scheduling needs of our third-party manufacturer of the BLU-U®, 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 September 2001, approximately $151,000 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® 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 nine-month periods ended September 30, 2001 increased approximately $778,000 and $1,572,000, respectively, to $2,806,000 and $7,068,000, as compared to the 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 2001 periods, 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 order to better manage the significantly increased number of indications under development, and to provide dedicated staff to our dermatology development program with Schering, on October 4, 2001, the Company executed a master service agreement, effective June 15, 2001, with Therapeutics, Inc. for an initial term of two years to engage Therapeutics to manage the clinical

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development of the Company s products in the field of dermatology including the Phase I/II clinical trial of Levulan® PDT for moderate to severe acne vulgaris of the face. Minimum payments under this agreement are $65,500 per month. In addition, with the execution of this agreement, Therapeutics received 5,000 shares of the Company s common stock and also has the opportunity for additional grants, bonuses, and other incentives for each indication ranging from $250,000 to $1,250,000 depending on the phase of development for each indication.

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® Photodynamic Therapy for the treatment of onychomycosis (nail fungus), warts, and Barrett s esophagus. On October 10, 2001, we initiated a second Phase I/II clinical trial for the treatment of 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 some or all of these indications, starting in 2002.

With respect to Levulan® 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® PDT following balloon angioplasty to inhibit arterial restenosis. There have been no further developments regarding bladder cancer detection, but DUSA continues to evaluate possible approaches for this indication. Additional indications are being considered for future development including detection and treatment of cervical dysplasia and dysfunctional uterine bleeding.

General and Administrative Costs. General and administration costs for the three and nine-month periods ended September 30, 2001 increased approximately $454,000 and $1,232,000, respectively, to $985,000 and $2,903,000, 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, financial, technical and operations functions, during the second half of 2000 and first nine months 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 during the remainder of 2001, and into 2002, as we continue to add personnel as needed at various levels throughout the organization.

Interest Income. Interest income for the three-month period ended September 30, 2001 increased slightly to $979,000 as compared to $944,000 in the comparable period in 2000, attributable to higher investable cash balances, offset partly by lower interest rates. During the nine-month period ended September 30, 2001, interest income increased significantly to $3,013,000 as compared to $2,270,000 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

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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 DUSA s operating activities.

Net Losses. The Company incurred a net loss of approximately $1,817,000, or $0.13 per share, and $4,632,000, or $0.34 per share, for the three and nine-month periods ended September 30, 2001, as compared to a net loss of $1,614,000, or $0.12 per share, and $4,295,000, or $0.33 per share, for the three and nine-month periods ended September 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. As previously reported, management expects DUSA s net loss for 2001 to be between $6 million and $7 million.

Liquidity and Capital Resources

We are in a strong cash position to continue to expand our research and development activities for our Levulan® PDT/PD platform. Our total assets were approximately $78,677,000 at September 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 nine months of 2001.

As of September 30, 2001, we had inventory of approximately $2,051,000, representing finished goods 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 $2,662,000, 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 last three months of 2001 and 2002 in order to acquire equipment for the manufacture of the Kerastick® for either a back up second source of supply or the development of our own manufacturing capabilities. As of September 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 September 30, 2001, we had accounts receivable of $131,000, representing net sales associated with product sales, compared to $915,000 at the end of 2000. In addition, based on our Marketing, Development and Supply agreement with Schering AG, a receivable of $1,795,000 has been recorded during the current quarter for reimbursable research and development costs and certain costs associated with restructuring the supply agreement with our Kerastick® manufacturer. As of December 31, 2000, we recorded a co-development receivable of $723,000.

As of September 30, 2001, we had current liabilities of $2,205,000, compared to $2,837,000 as of December 31, 2000. Since our inception, we have had no long-term debt.

We invest our cash in United States government securities, which are classified as available for sale. As of September 30, 2001, we held securities with an aggregate cost of approximately $57,891,000 and a current aggregate market value of $60,670,000, resulting in a net unrealized gain on securities available for sale of $2,779,000, 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

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$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 4.39% to 6.91% and maturity dates ranging from October 1, 2001 to August 15, 2006.

We believe that we have sufficient capital resources to proceed with our current development program for Levulan® 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 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. However, no such transaction is imminent. 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 September 30, 2001, we had deferred revenues of approximately $23,349,000, 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 $22,808,000, and the deferral of $540,000 of BLU-U® 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® 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 and the opportunities available.

As of September 30, 2001, we had 54 full-time employees. We expect that we will continue to hire more employees as commercialization of Levulan® 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®, 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 Pronouncements

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

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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 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 September 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 will have to be competitive

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with other AK products reimbursement levels and that the proposed reimbursement fees will allow the therapy to gain acceptance, the goal of reducing cost of product sales, timing of royalties on Kerastick® sales and recognition of revenue on BLU-U® 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 - 5.

None.

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

a) i) Exhibit 10 (a) Amendment to Marketing, Development and Supply Agreement between the Company and Schering AG, dated September 26, 2001, 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.

ii) Exhibit 10 (b) Master Service Agreement with Therapeutics, Inc. dated as of October 4, 2001, 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.

b) (i) Form 8-K dated and filed on July 17, 2001 reporting the Registrant s conference call with shareholders on research and development program advancements.

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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: November 7, 2001 By:/s/John E. Mattern

John E. Mattern
Vice President, Finance, and Chief Financial Officer
(Chief Financial and Chief Accounting Officer)