

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

DUSA PHARMACEUTICALS INC  
Form 10-Q  
August 12, 2003

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 June 30, 2003

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  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.

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13,955,247 shares as of August 8, 2003

PART I.

ITEM 1. FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	JUNE 30,	
	2003	
	(UNAUDITED)	
	-----	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 7,613,837	\$
United States government securities	37,400,520	
Accrued interest receivable	614,205	
Accounts receivable	99,131	
Inventory	1,036,987	
Prepays and other current assets	678,245	
	-----	
TOTAL CURRENT ASSETS	47,442,925	
Property and equipment, net	4,792,083	
	-----	
<b>TOTAL ASSETS</b>	<b>\$ 52,235,008</b>	<b>\$</b>
	=====	
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 322,596	\$
Accrued payroll	394,032	
Other accrued expenses	1,374,295	
Current maturities of long-term debt	270,000	
Deferred revenue	66,150	
	-----	
TOTAL CURRENT LIABILITIES	2,427,073	
Long-term debt, net of current maturities	1,382,500	
	-----	
<b>TOTAL LIABILITIES</b>	<b>3,809,573</b>	
	-----	
<b>COMMITMENTS AND CONTINGENCIES (NOTE 10)</b>		
<b>SHAREHOLDERS' EQUITY</b>		
Capital Stock		
Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding: 13,943,581 (2002: 13,887,612) shares of common stock, no par.	95,602,686	
Additional paid-in capital	2,015,586	
Accumulated deficit	(51,460,016)	
Accumulated other comprehensive income	2,267,179	
	-----	
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>48,425,435</b>	
	-----	

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TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY \$ 52,235,008  
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See the accompanying Notes to the Condensed Consolidated Financial Statements.

2

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	THREE MONTHS ENDED JUNE 30, (UNAUDITED)	
	2003	2002
REVENUES		
Product sales and rental income	\$ 147,275	\$ 55,658
Research grant and milestone revenue	-	495,834
Research revenue earned under collaborative agreements	-	878,486
TOTAL REVENUES	147,275	1,429,978
OPERATING COSTS		
Cost of product sales and royalties	824,027	776,533
Research and development	1,448,600	3,374,905
Marketing and sales	532,978	-
General and administrative	1,679,750	1,501,008
TOTAL OPERATING COSTS	4,485,355	5,652,446
LOSS FROM OPERATIONS	(4,338,080)	(4,222,468)
OTHER INCOME		
Interest income, net	526,964	784,902
NET LOSS	\$ (3,811,116)	\$ (3,437,566)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (.27)	\$ (.25)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	13,932,424	13,869,297

See the accompanying Notes to the Condensed Consolidated Financial Statements.

3

DUSA PHARMACEUTICALS, INC.

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## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	SIX MONTHS EN 2003 (UNAUDITED) -----
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES	
Net loss	\$ (7,377,089)
Adjustments to reconcile net loss to net cash used in operating activities	
Amortization of premiums and accretion of discounts on United States government securities available for sale, net	47,096
Depreciation and amortization expense	610,504
Amortization of deferred revenue	-
Issuance of common stock to consultants	75,000
Changes in other assets and liabilities impacting cash flows from operations:	
Accrued interest receivable	85,459
Accounts receivable	(62,411)
Receivable under co-development program	-
Inventory	151,672
Prepays and other current assets	237,459
Deferred charges	-
Accounts payable	(230,295)
Accrued payroll and other accrued expenses	(741,300)
Deferred revenue	61,050
	-----
NET CASH USED IN OPERATING ACTIVITIES	(7,142,855)
	-----
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES	
Purchases of United States government securities	-
Proceeds from maturing United States government securities	8,000,000
Purchases of property and equipment	(172,904)
	-----
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	7,827,096
	-----
CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES	
Proceeds from long-term debt	-
Payments of long-term debt	(135,000)
	-----
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	(135,000)
	-----
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	549,241
	-----
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	7,064,596
	-----
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 7,613,837
	=====

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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### NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of June 30, 2003, Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2003 and 2002, and Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2003 and 2002 of DUSA Pharmaceuticals, Inc. (the "Company" or "DUSA") have been prepared in accordance with accounting principles generally accepted in the United States of America. These condensed consolidated financial statements are unaudited but include all normal recurring adjustments, which management of the Company believes to be necessary for fair presentation of the periods presented. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full year.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. These condensed consolidated financial statements should be read in conjunction with the Company's December 31, 2002 audited consolidated financial statements and notes thereto. Certain amounts for 2002 have been reclassified to conform to the current year presentation. Such reclassifications had no impact on the net loss or shareholders' equity for any period presented.

2) UNITED STATES GOVERNMENT SECURITIES 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 June 30, 2003, ranging from 3.96% to 7.13% and maturity dates ranging from August 15, 2003 to February 15, 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.

3) INVENTORY

Inventory consisted of the following:

	JUNE 30, 2003 (UNAUDITED)	DECEMBER 31, 2002	
	-----	-----	
Finished goods	\$ 860,968	\$ 1,047,941	
Raw materials	176,019	140,718	
	-----	-----	
	\$ 1,036,987	\$ 1,188,659	
	=====	=====	

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### 4) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	JUNE 30, 2003 (UNAUDITED)	DECEMBER 31, 2002
	-----	-----
Research and development costs	\$ 252,382	\$ 473,543
Marketing and sales costs	146,351	-
Product related costs	70,951	463,340
License milestone	-	500,000
Legal and other professional fees	583,259	297,966
Employee benefits	193,674	207,833
Other accrued expenses	127,678	127,468
	-----	-----
	\$ 1,374,295	\$ 2,070,150
	=====	=====

### 5) SHAREHOLDERS' EQUITY

On June 15, 2003, the Company granted compensation of \$50,000 to Therapeutics, Inc., a clinical research organization, pursuant to an agreement for services. This compensation was issued in July 2003 and was comprised of 11,666 shares of common stock valued at \$35,000 and \$15,000 of cash. The Company recorded the total value of the compensation in the current quarter as part of research and development costs in the Condensed Consolidated Statements of Operations.

On May 2, 2003, the Company granted a total of 32,750 shares of unregistered common stock, without par value, to two outside consultants as compensation for services. These shares were valued at approximately \$75,000 and were recorded as part of research and development costs in the Condensed Consolidated Statements of Operations.

On March 13, 2003, the Company issued 23,219 shares of restricted common stock at a closing price of \$1.599 per share to its Chief Executive Officer, reflecting payment of the after-tax portion of his 2002 bonus compensation.

### 6) MARKETING AND SALES

As a result of the termination of the Company's marketing and development collaboration with its former marketing partner in September 2002, the Company commenced certain marketing and sales initiatives in 2003 associated with having full rights and responsibilities of its product. In addition, the Company has reassigned resources that were previously functioning in research and development roles to its marketing and sales function. Prior to the Company's termination of its marketing and development collaboration, all rights and activities associated with marketing and sales of its products were solely the responsibility of its former partner. Activities included in

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marketing and sales expense for 2003 consist of trade show expenses, advertising, personnel and other resources assigned to marketing and sales activities, and other marketing and promotional activities. All such costs are expensed as incurred.

### 7) ACCOUNTING FOR STOCK BASED COMPENSATION

Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation," addresses the financial accounting and reporting standards for stock or other equity-based compensation arrangements. The Company has elected to continue to use the intrinsic value-based method to account for employee stock option awards under the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and to provide disclosures based on the fair value method in the Notes to the Consolidated Financial Statements as permitted by SFAS No. 123. Stock or other equity-based compensation for non-employees must be accounted for under the fair value-based method as required by SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and other related interpretations. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost is recognized and charged to operations over the service period, which is generally the vesting period.

7

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Had the Company used the fair value method to measure compensation, the Company's pro forma net loss and pro forma net loss per common share for the three and six months ending June 30, 2003 and 2002 would have been as follows:

	THREE MONTHS ENDED JUNE 30, (UNAUDITED)		SIX MONTHS JUNE (UNAUDITED)
	2003	2002	2003
<b>NET LOSS</b>			
As reported	\$ (3,811,116)	\$ (3,437,566)	\$ (7,377,089)
Stock-based compensation recorded	75,000	50,000	75,000
Effect on net loss if fair value method had been used	(618,712)	(1,402,906)	(1,205,921)
Proforma	\$ (4,354,828)	\$ (4,790,472)	\$ (8,508,010)
<b>BASIC AND DILUTED NET LOSS PER COMMON SHARE</b>			
As reported	\$ (.27)	\$ (.25)	\$ (.53)
Stock-based compensation recorded	.01	-	.01
Effect on net loss per common share if fair value method had been used	(.05)	(.10)	(.09)

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Proforma	\$ ( .31)	\$ ( .35)	\$ ( .61)
	=====	=====	=====

8) BASIC AND DILUTED NET LOSS PER COMMON SHARE

Basic and diluted net loss per common share are 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 Condensed Consolidated Statements of Operations, as the effect would be antidilutive. For the periods ended June 30, 2003 and 2002, such potentially dilutive securities totaling approximately 2,705,000 and 2,751,000 shares, respectively, have been excluded from the computation of diluted net loss per common share.

8

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

9) COMPREHENSIVE LOSS

For the three and six months ended June 30, 2003 and 2002, comprehensive loss consisted of the following:

	THREE MONTHS ENDED JUNE 30, (UNAUDITED)		SIX MONTHS ENDED JUNE 30, (UNAUDITED)	
	2003	2002	2003	2002
NET LOSS	\$ (3,811,116)	\$ (3,437,566)	\$ (7,377,089)	\$ (6,377,089)
Net change in unrealized gains (losses) on United States securities available for sale	(120,333)	838,459	(367,331)	
COMPREHENSIVE LOSS	\$ (3,931,449)	\$ (2,599,107)	\$ (7,744,420)	\$ (6,377,089)

10) COMMITMENTS AND CONTINGENCIES

Legal Matters - On April 12, 2002, the Company received notice that one of the patents licensed to the Company by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario was challenged by PhotoCure ASA. PhotoCure ASA has filed a lawsuit in Australia alleging that Australian Patent No. 624985, which is one of the patents relating to the Company's 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University has assigned the Australian patent to the Company so that DUSA may participate directly in this litigation. The Company has filed an answer setting forth its defenses and a related countersuit alleging that certain activities of PhotoCure and its marketing partner, Galderma S.A., infringe the patent. The case is in its earliest stages so the Company is unable to predict the outcome at this time.



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In March 2003, the Company received notice that its Dutch patent was being formally challenged by an anonymous agent, and DUSA filed a formal response to the opposition. In May 2003, a hearing was held in the Dutch Patent Office with both the anonymous agent and the Company presenting technical arguments pertaining to the validity of the Dutch patent. A final ruling by the Dutch patent board is expected later in 2003. The potential impact of a challenge in The Netherlands is minimal; however, the Company does plan to defend its patent at this time.

9

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

### 11) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In December 2002, the EITF reached conclusion on EITF Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." This consensus provides guidance in determining when a revenue arrangement with multiple deliverables should be divided into separate units of accounting, and, if separation is appropriate, how the arrangement consideration should be allocated to the identified accounting units. The provisions of EITF No. 00-21 are effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company will evaluate any new arrangements into which it enters in accordance with this EITF.

### 12) SUBSEQUENT EVENT

In March 2003, the Company completed the facility qualification, process validation, and drug product stability testing, and submitted an NDA supplement to the FDA, with respect to its manufacturing facility in Wilmington, Massachusetts. In May 2003, the FDA completed its inspection of the facility and, on July 14, 2003, the Company received approval from the FDA to manufacture the Levulan(R) Kerastick(R) at its Wilmington facility.

10

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

### OVERVIEW

DUSA is a pharmaceutical company engaged primarily in the research, development, and marketing of a drug named 5-aminolevulinic acid, or ALA, used in combination with appropriate light devices in order to detect or treat a variety of medical conditions. The trademark for our brand of ALA is Levulan(R). When Levulan(R) is used and followed with exposure to light to produce a therapeutic effect, the technology is called photodynamic therapy, or PDT. When Levulan(R) is used and followed with exposure to light to detect medical conditions, the technology is called photodetection, or PD. Our 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 unit. Our products are used together to provide PDT for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp.

We have primarily devoted our resources to funding research and development in order to advance the Levulan(R) PDT/PD technology platform and, as a result, we have experienced significant operating losses. As of June 30,

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2003, we had an accumulated deficit of approximately \$51,460,000. Achieving our goal of becoming a profitable operating company is dependent upon the market penetration of our products, acceptance of our therapy by the medical and consumer constituencies, and our ability to develop new products. We believe that as doctors become more familiar with the benefits of Levulan(R) PDT for actinic keratoses, and improved reimbursement for physicians is attained, more widespread adoption of our therapy should occur over time. In addition, we are aware that some physicians have been using Levulan(R) with light devices manufactured by other companies and for uses other than our FDA-approved use. While we are not permitted to market our products for so-called "off-label" uses, these activities could also positively affect adoption of our products and increase sales.

We expect to continue to incur operating losses until our first products successfully penetrate the market. As a result of the termination of our former dermatology collaboration arrangement in 2002, we reevaluated our expenses and are minimizing research and development and related general and administrative expenditures that are not directly related to our core objectives for 2003. At this time, we are focusing primarily on increasing the sales of our approved products, on implementing our development program, and on seeking a partner to help develop and market Levulan(R) PDT for the treatment of dysplasia in patients with Barrett's esophagus. As of June 30, 2003, our staff included 42 full-time employees as compared to 43 at the end of 2002, who support all of our activities, including marketing, production, maintenance, customer support, and financial operations for our products, as well as the research and development programs for dermatology and internal indications. We expect to increase our staff during the second half of 2003 as we focus on marketing activities and customer support associated with our AK products. While our financial position is strong, we cannot predict when product sales along with interest income may offset the cost of these efforts.

11

As we continue to evaluate our corporate governance policies in light of the Sarbanes-Oxley Act of 2002, DUSA's Board of Directors determined that the Chairman of the Board and Chief Executive Officer positions should be held by two persons, rather than one. Therefore, in June, 2003, the Board of Directors appointed one of its independent directors, Mr. Jay Haft, as the Company's Chairman. Simultaneously, our Controller, Peter Chakoutis, was appointed as the Company's Principal Accounting Officer.

MANUFACTURING FACILITY APPROVAL - In March 2003, DUSA completed the facility qualification, process validation, and drug product stability testing, and submitted an NDA supplement to the FDA with respect to our manufacturing facility in Wilmington, Massachusetts. The FDA completed its inspection of the facility in May 2003 and, on July 14, 2003, DUSA received approval from the FDA to manufacture the Levulan(R) Kerastick(R) at our Wilmington facility.

510(k) FDA FILING - On June 10, 2003, DUSA submitted a Section 510(k) premarket notification application to the FDA for treatment of mild to moderate acne with our BLU-U(R) light, without Levulan(R), based on an equivalency comparison to other manufacturers approved commercial light units. DUSA anticipates a response from the FDA later in 2003.

### CRITICAL ACCOUNTING POLICIES

Our accounting policies are disclosed in Note 2 to the Notes to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2002. Since not all of these accounting policies require management to make difficult, subjective or complex judgments or estimates, they

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are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting policies with our Audit Committee. We consider the following policies and estimates to be critical to our financial statements.

REVENUE RECOGNITION - Revenues on product sales of the Kerastick(R) are recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred, and there is reasonableness of collection. Research revenue previously earned under collaborative agreements consisted of non-refundable research and development funding from our former dermatology collaboration partner. Research revenue generally compensated us for a portion of our agreed-upon research and development expenses and was recognized as revenue at the time the research and development activities were performed under the terms of the related agreements and when no future performance obligations existed. Milestone or other up-front payments are typically recorded as deferred revenue upon receipt and recognized as earned, generally on a straight-line basis over the term of an agreement. Although we make every effort to assure the reasonableness of our estimates, significant unanticipated changes in our estimates due to business, economic, or industry events could have a material impact on our results of operations.

INVENTORY - Inventories are stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Inventories are continually reviewed for slow moving, obsolete and excess items. Inventory items identified as slow-moving are evaluated to determine if an

12

adjustment is required. Additionally, our industry is characterized by regular technological developments that could result in obsolete inventory. Although we make every effort to assure the reasonableness of our estimates, any significant unanticipated changes in demand, technological development, or significant changes to our business model could have a significant impact on the value of our inventory and our results of operations. We use sales projections to estimate the appropriate level of inventory that should remain on the Consolidated Balance Sheet. Management believes that the recorded inventory value is reasonable in light of our current sales forecasts. Should we be unable to achieve the forecasted sales, additional adjustments may be recorded to cost of goods sold.

VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS - We review long-lived assets, comprised of property, plant and equipment for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Factors considered important which could trigger an impairment review include significant changes relative to: (i) projected future operating results; (ii) the use of the assets or the strategy for the overall business; (iii) business collaborations; and (iv) industry, business, or economic trends and developments. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. When it is determined that the carrying value of long-lived or intangible assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, the asset is written down to its estimated fair value on a discounted cash flow basis. In 2002 and again as of June 30, 2003, we concluded that the termination of our former dermatology collaboration arrangement in September 2002 and current business events have not caused any impairment to our manufacturing facility. At June 30, 2003, our total property, plant and equipment had a carrying value of \$4,792,000, including \$2,663,000 associated with our manufacturing facility, and we had no intangible assets recorded as of that date.

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STOCK-BASED COMPENSATION - We have elected to continue to use the intrinsic value-based method to account for employee stock option awards under the provisions of Accounting Principles Board Opinion No. 25, and to provide disclosures based on the fair value method in the Notes to the Consolidated Financial Statements as permitted by Statement of Financial Accounting Standards ("SFAS") No. 123. Stock or other equity-based compensation for non-employees is accounted for under the fair value-based method as required by SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and other related interpretations. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost is recognized and charged to operations over the service period, which, in the case of stock options, is generally the vesting period. As we utilize stock and stock options as one means of compensating employees, consultants, and others, a change in accounting for stock-based compensation would, under certain circumstances, result in a material effect on our results of operations, but would not affect cash flow.

13

### RESULTS OF OPERATIONS

REVENUES - Total revenues for the three and six months ended June 30, 2003 were \$147,000 and \$291,000, as compared to \$1,430,000 and \$2,755,000 during the comparable 2002 periods. Revenues for 2003 were comprised entirely of product sales reflecting direct Kerastick(R) sales to physicians as compared to \$56,000 and \$106,000 of product sales in the three and six months ended June 30, 2002. The increase in 2003 product sales revenue results from DUSA's receipt of 100% of revenues on Kerastick(R) units sold to end-users primarily through our distributor, Moore Medical Corporation, as compared to approximately 30% of the net sales that we received as a royalty under our former collaboration agreement during 2002. Product sales for the comparable three and six-month 2002 periods also included rental income on the BLU-U(R) in the amount of \$2,000 and \$21,000, respectively, which we did not receive in 2003 due to a change in the marketing strategy of the BLU-U(R). Total revenues for the three and six month periods in 2002 also included research grant and milestone revenues of \$496,000 and \$992,000, and research and development reimbursement of \$878,000 and \$1,658,000 that we earned under our collaboration agreement with our former marketing and development partner.

As of June 30, 2003, 323 BLU-U(R) units were in place in physicians offices, down slightly from 324 units at March 31, 2003 and 329 units at December 31, 2002. Kerastick(R) sales to end-users were 1,914 and 3,756 for the three and six months ended June 30, 2003, as compared to 2,202 and 4,002 for the comparable 2002 periods. Management believes this decrease in 2003 and continued low level of end-user sales is partly attributable to the transition of marketing responsibilities from our former partner, including our focus on developing an infrastructure to support marketing activities and implementation of our own marketing strategy. See "Marketing and Sales."

14

COST OF PRODUCT SALES AND ROYALTIES - Cost of product sales and royalties for the three and six months ended June 30, 2003 were \$824,000 and \$1,577,000, respectively, as compared to \$777,000 and \$1,455,000 in 2002. A summary of the components of cost of product sales and royalties is provided

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below:

THREE MONTHS ENDED JUNE 30, (UNAUDITED)				SIX MONTHS ENDED JUNE 30, (UNAUDITED)
2003	2002	INCREASE (DECREASE)		2003
\$ 620,000	\$ 331,000	\$ 289,000	Product costs including internal costs (e.g. customer service, quality assurance, purchasing, and other product support operations) assigned to support products (1)	\$ 1,183,000
71,000	186,000	(115,000)	Costs incurred to ship, install and service the BLU-U(R) in physicians offices	117,000
114,000	96,000	18,000	Depreciation on BLU-U(R) light units	241,000
19,000	16,000	3,000	Royalty and supply fees (2)	36,000
-	91,000	(91,000)	Net underutilization costs (3)	-
-	57,000	(57,000)	Deferred charges amortization (4)	-
\$ 824,000	\$ 777,000	\$ 47,000	Total cost of product sales and royalties	\$ 1,577,000

- 1) Includes costs to support DUSA's manufacturing facility, including the submission of the FDA supplement.
- 2) Royalty and supply fees are paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario.
- 3) Underutilization costs commenced in 2001 and were fully amortized as of December 31, 2002 based on agreements with our third-party manufacturers due to orders falling below certain previously anticipated levels.
- 4) Deferred charges amortization reflects consideration paid by us in 2000 to amend our Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan(R). Such deferred charges were fully amortized in 2002.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs for the three and six month periods ended June 30, 2003 were \$1,449,000 and \$2,965,000, as compared to \$3,375,000 and \$6,472,000 in the comparable 2002 periods. This lower level of research and development costs in 2003 is attributable to the absence of costs for co-sponsored projects that were developed in collaboration in 2002 and previously reimbursed to us by our former marketing partner. Co-

sponsored projects included Phase I/II studies using Levulan(R) PDT in the treatment of persistent plantar warts and onychomycosis (nail fungus). These

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projects have been delayed as we concentrate on increasing sales, and implementing a new dermatology development program focused on indications that use our approved Kerastick(R). Based on market research that was completed during the quarter, we have decided to move forward with Phase II studies for use of Levulan(R) PDT in acne and photo-damaged skin rather than pursuing a broad area actinic keratoses (BAAK) treatment at this time, as we do not believe this indication would have a major impact on sales. We have also submitted a Section 510(k) premarket notification application to the FDA for use of the BLU-U(R), without Levulan(R) PDT, to treat mild to moderate acne. The development program also includes completing an FDA-mandated Phase IV long-term AK tracking study, which should be completed in 2003, and funding of various investigator studies involving the Kerastick(R). This strategy should keep us in a strong financial position as we continue to implement activities to increase revenues from the current approved products for AKs.

We have also been conducting Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett's esophagus. Results of the high-grade dysplasia (HGD) study as of January 2003, with 12 months of follow-up data in 4 patients, and 6 months in 1 patient, showed a continued complete ablation of high-grade dysplasia. The treatment has been well tolerated, with no occurrence of strictures (circumferential scarring), and no signs of mucosal overgrowth. In addition, in preparation for a pre-pivotal Phase II clinical trial, we are preparing to carry out a small single-center pilot Phase II clinical trial using DUSA's new proprietary light delivery device for the treatment of high grade dysplasia. However, we do not plan to fund the pre-pivotal Phase II or III clinical trials for this indication on our own, and are soliciting potential partners for this indication, with the goal of completing a partnership during 2003. Despite these efforts, there can be no assurance that we will be able to consummate any collaboration, or whether we will be able to obtain terms acceptable to us.

MARKETING AND SALES COSTS - Marketing and sales costs for the three and six month periods ended June 30, 2003 were \$533,000 and \$1,063,000, respectively. In the prior year, there were no marketing and sales expenses incurred directly by us as all rights and activities associated with marketing and sales of our products were the sole responsibility of our former partner. In late 2002, following the termination of our collaboration with our former marketing partner, we commenced marketing initiatives associated with having full rights and responsibilities for our products. In addition, as of January 1, 2003, we reassigned resources that were functioning in research and development roles to our marketing and sales function. In August 2003, DUSA hired a sales executive and is planning to hire a small, dedicated Levulan(R) PDT sales team to commence regional test marketing in late 2003. With success, DUSA plans to expand the sales force significantly in 2004.

GENERAL AND ADMINISTRATIVE COSTS - General and administrative costs for the three and six month periods ended June 30, 2003 were \$1,680,000 and \$3,155,000, respectively, as compared to \$1,501,000 and \$2,693,000 in comparable 2002 periods. These increases are attributable to higher legal expenses amounting to \$903,000 and \$1,586,000 during the current three and six month periods, as compared to \$396,000 and \$734,000 in the comparable 2002 periods, due primarily to

patent defense costs. Such patent defense issues are discussed below. It is expected that legal expenses will remain at elevated levels as long as the patent dispute continues. This higher legal expense level was offset, in part, by lower staffing costs in 2003, due primarily to employee separations during 2002.

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In April 2002, we received a copy of a notice issued by PhotoCure ASA to Queen's University at Kingston, Ontario, alleging that Australian Patent No. 624985, which is one of the patents licensed by PARTEQ to us, relating to 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University has assigned the Australian patent to us so that we may participate directly in this litigation. We have filed an answer setting forth our defenses and a related countersuit alleging that certain activities of PhotoCure and its marketing partner, Galderma S.A, infringe the patent. The case is in its earliest stages so we are unable to predict the outcome at this time.

In March 2003, we received notice that our Dutch patent is being formally challenged by an anonymous agent, and we filed a formal response to the opposition. In May 2003, a hearing was held in the Dutch Patent Office with both the anonymous agent and DUSA presenting technical arguments pertaining to the validity of the Dutch patent. A final ruling by the Dutch patent board is expected later in 2003. Although we believe that the potential impact of a challenge in The Netherlands would be minimal, we plan to defend our patent at this time.

INTEREST INCOME, NET - Interest income, net for the three and six month periods ended June 30, 2003 was \$527,000 and \$1,093,000, as compared to \$785,000 and \$1,559,000 in the comparable 2002 periods. These decreases were attributable to lower investable cash balances as we used cash to support our operating activities, and lower yields. Interest income will continue to decline as our investable cash balances are used to support our operating activities. During the three and six month periods ended June 30, 2003, we incurred interest expense of \$17,000 and \$34,000 on borrowings associated with the construction of our new Kerastick(R) manufacturing facility, which has been capitalized in property and equipment in the Condensed Consolidated Balance Sheet as of June 30, 2003. There was no interest incurred in the comparable 2002 periods.

NET LOSSES - For the three and six months ended June 30, 2003, the Company incurred net losses of \$3,811,000, or \$0.27 per share, and \$7,377,000, or \$0.53 per share, respectively, as compared to net losses of \$3,438,000, or \$0.25 per share, and \$6,305,000, or \$0.45 per share, for the comparable periods in 2002. These increased losses are due in part to the absence of research revenue from our former collaborative partner offset, in part, by savings realized through cost reductions. Such losses were within management's expectations, and are expected to continue unless sales of our first products increase significantly.

### LIQUIDITY AND CAPITAL RESOURCES

We are in a strong cash position to continue to increase Levulan(R) PDT marketing expenses, and fund our current research and development activities for our Levulan(R) PDT/PD platform. Our

17

total assets were \$52,235,000 as of June 30, 2003 compared to \$60,950,000 as of December 31, 2002. This decrease is primarily attributable to the funding of 2003 operating activities.

As of June 30, 2003 we had inventory of \$1,037,000 as compared to \$1,189,000 as of December 31, 2002, representing finished goods and raw materials. Also, as of June 30, 2003, we had net property, plant and equipment of \$4,792,000, as compared to \$5,230,000 as of December 31, 2002, representing costs associated with constructing our manufacturing facility, commercial light units in the field, and other property, plant and equipment. The decrease in net

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property, plant and equipment mainly reflects normal depreciation.

As of June 30, 2003, we had accounts receivable of \$99,000 as compared to \$37,000 as of December 31, 2002, representing net sales associated with Kerastick(R) sales.

As of June 30, 2003, we had current liabilities of \$2,427,000, as compared to \$3,375,000 as of December 31, 2002. In May 2002, we entered into a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of our manufacturing facility and borrowed \$1,900,000. As of June 30, 2003, the total outstanding loan balance was \$1,652,500, of which \$270,000 is current. Approximately \$3,000,000 of the Company's United States government securities are pledged as collateral to secure the loan. Prior to expiration of the 360-day LIBOR-based rate for each year of the loan, we can either continue to choose a LIBOR-based rate at that time, execute a one-time conversion to a fixed rate loan, or repay the loan balance. As of June 30, 2003, the interest rate on the Note was reduced to 2.755%. As this interest rate was lower than the yield being generated by each of our United States government securities, we decided to maintain the loan at this time.

We invest our excess cash in United States government securities, all of which are classified as available for sale. These securities had an aggregate cost of \$35,134,000, and a current aggregate market value of \$37,401,000 as of June 30, 2003, resulting in a net unrealized gain on securities available for sale of \$2,267,000, which has been included in shareholders' equity. As of December 31, 2002, government securities had an aggregate cost of \$43,180,000 and an aggregate market value of \$45,815,000, resulting in a net unrealized gain of \$2,635,000. 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. As of June 30, 2003, these securities had interest yields ranging from 3.96% to 7.13% and maturity dates ranging from August 15, 2003 to February 15, 2007. As of December 31, 2002, these securities had interest yields ranging from 3.95% to 7.21% and maturity dates ranging from January 21, 2003 to February 15, 2007.

We believe that we have sufficient capital resources to proceed with our current programs for Levulan(R) PDT, and to fund operations and capital expenditures for the foreseeable future, particularly with the current reduction in research and development spending. 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.

18

As a result of the termination of our former dermatology collaboration arrangement, we have reevaluated our operations and are minimizing research and development and related general and administrative expenditures that are not directly related to our core objectives for 2003. We are also implementing a development program focused on dermatology indications that use our approved Kerastick(R). See "Research and Development Costs."

We anticipate that the level of marketing and sales expense will increase with the hiring of a sales executive in August 2003, and a small targeted sales force over the balance of 2003. We may seek to expand or enhance our business by using resources to acquire by license, purchase or other arrangements, businesses, new technologies, or products, especially in PDT-related areas. For the balance of the year, we are focusing primarily on increasing the sales of the Levulan(R) Kerastick(R) and the BLU-U(R), and on seeking a partner to help develop and market Levulan(R) PDT for the treatment of



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dysplasia in patients with Barrett's esophagus.

We cannot accurately predict the level of revenues from sales of our products. In order to maintain and expand continuing research and development programs, we may need to raise additional funds through future corporate alliances, financings, or other sources, depending upon the amount of sales we receive.

### CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

There have been no material changes to our contractual obligations and other commercial commitments from those presented in our Annual Report on Form 10-K for the year ended December 31, 2002.

### RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In December 2002, the EITF reached conclusion on EITF Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." This consensus provides guidance in determining when a revenue arrangement with multiple deliverables should be divided into separate units of accounting, and, if separation is appropriate, how the arrangement consideration should be allocated to the identified accounting units. The provisions of EITF No. 00-21 are effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company will evaluate any new arrangements into which it enters in accordance with this EITF.

### INFLATION

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

19

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

We hold fixed income United States government securities that are subject to interest rate market risks. We do not believe that the risk is material at this time as we have apportioned our investments in short-term and long-term instruments with maturities, 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.

We currently have exposure to interest rate risk under a secured term loan promissory note which we issued to fund the construction of our manufacturing facility. This loan currently bears interest at a LIBOR-based rate, and calls for an annual renewal on June 30th of each year through June 30, 2009 to either the applicable LIBOR-based rate or a one-time conversion to a fixed rate loan. On June 30, 2003, the loan rate was reduced to the then current 360-day LIBOR-based rate of 2.755%. Our exposure to interest rate risk due to changes in LIBOR is not expected to be material.

### ITEM 4. CONTROLS AND PROCEDURES

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Our management is responsible for the preparation, integrity and objectivity of the financial statements and other information presented in this report. Such financial statements have been prepared in accordance with generally accepted accounting principals and reflect certain estimates and adjustments by management. Our management maintains a system of internal accounting and disclosure controls, and procedures which management believes provide reasonable assurance that the transactions are properly recorded and our assets are protected from loss or unauthorized use.

The integrity of the accounting and disclosure systems are based on written policies and procedures, the careful selection and training of qualified financial personnel, a program of internal controls and direct management review. Our disclosure control systems and procedures are designed to ensure timely collection and evaluation of information subject to disclosure, to ensure the selection of appropriate accounting policies and to ensure compliance with our accounting policies and procedures. The Audit Committee is composed solely of independent directors and meets periodically with the independent auditors and management to discuss accounting, financial reporting, auditing and internal auditing matters. The independent auditors have direct and private access to the Audit Committee.

As of June 30, 2003, an evaluation was performed under the supervision and with the participation of our management, including the Chief Executive Officer/Chief Financial Officer, regarding the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our management, including the Chief Executive Officer/Chief Financial

20

Officer, believes that our disclosure controls and procedures are adequately designed to ensure that the information that we are required to disclose in this report has been accumulated and communicated to our management, including our Chief Executive Officer/Chief Financial Officer, as appropriate, to allow timely decisions regarding such required disclosure. There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to June 30, 2003.

### FORWARD-LOOKING STATEMENTS

This report, including the Management's Discussion and Analysis, contains various "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 which represent our expectations or beliefs concerning future events, including, but not limited to statements regarding management's goal of becoming profitable, beliefs regarding adoption of our therapy, expectations for continuing operating losses, expectations of increasing staff, timing of a response from FDA regarding the 510(k) application, effects of unanticipated changes in estimates, technology and forecasts, belief concerning reasonableness of inventory values, factors which could trigger impairment review, effect of an accounting change for stock-based compensation, beliefs concerning the decrease in revenues and decision not to pursue the BAAK indication, expectations for increased marketing and sales costs and elevated levels of legal fees, beliefs regarding The Netherlands patent litigation, expectations regarding levels of interest income and net losses, requirements of cash resources, and potential impact on conversion of government securities, need for additional funds for development, evaluation of transactions under new accounting pronouncements, inflation, market risks and controls and procedures. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results

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of our trials, the impact of competitive products and pricing, the FDA approval and market acceptance of our products, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by additional third-party payors, and other risks noted in our SEC filings from time to time, including our Form 10-K for the period ending December 31, 2002, none of which can be assured.

21

### PART II- OTHER INFORMATION

Items 1, 3, and 5.

None.

Item 2. Changes in Securities and Use of Proceeds.

- i) On May 2, 2003, DUSA issued 32,750 shares of unregistered common stock, without par value, to two outside consultants for compensation of services in reliance on Section 4(2) of the Securities Act of 1933, as amended.
- ii) On June 15, 2003, DUSA granted 11,666 shares of unregistered common stock, without par value, to an outside consultant for compensation of services in reliance on Section 4(2) of the Securities Act of 1933, as amended. Such shares were issued in July 2003.

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

Matters submitted to a vote of security holders of the Corporation at the Annual Meeting of Shareholders held June 19, 2003 included the election of five (5) directors and ratification of the selection of Deloitte and Touche LLP as the independent auditors for the Corporation for 2003.

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

	Votes Cast For -----	Votes Cast Against -----	Abstained -----	Broker Non-votes -----
D. Geoffrey Shulman	12,080,079	175,438	-0-	-0-
John H. Abeles	12,080,079	175,438	-0-	-0-
David Bartash	12,080,079	175,438	-0-	-0-
Richard C. Lufkin	12,080,079	175,438	-0-	-0-
Jay Haft	12,080,079	175,438	-0-	-0-

- b) Shareholders ratified the selection of Deloitte & Touche LLP as the independent auditors for the Corporation for 2003 as follows:

	Votes Cast For -----	Votes Cast Against -----	Abstained -----	Broker Non-votes -----
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Deloitte & Touche LLP

12,210,775

40,298

4,443

-0-

22

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

i) Exhibits

- a) Exhibit 31.1 - Sarbanes-Oxley Section 302(a) Certification.
- b) Exhibit 32.1 - Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- c) Exhibit 99.1 - Press Release dated August 12, 2003

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DUSA Pharmaceuticals, Inc.

By: /s/ D. Geoffrey Shulman

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D. Geoffrey Shulman  
President, Chief Executive Officer  
(Principal Executive Officer), and  
Chief Financial Officer (Principal  
Financial Officer)

Date: August 12, 2003

By: /s/ Peter M. Chakoutis

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Peter M. Chakoutis  
Controller (Principal Accounting  
Officer)

23