

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

DUSA PHARMACEUTICALS INC  
Form 10-Q  
August 11, 2004

FORM 10-Q  
UNITED STATES  
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, 2004

OR

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

Commission file number 0-19777

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

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

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

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

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

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

Yes  No

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY  
PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

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

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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16,855,697 shares as of August 10, 2004

PART I.

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

|   | JUNE 30,<br>2004<br>(UNAUDITED)<br>----- |
|---|--|
| <b>ASSETS</b>   |  |
| <b>CURRENT ASSETS</b>   |  |
| Cash and cash equivalents   | \$ 30,057,306                            |
| United States government securities   | 25,767,385                               |
| Accrued interest receivable   | 444,137                                  |
| Accounts receivable   | 766,178                                  |
| Inventory   | 891,280                                  |
| Prepays and other current assets  | 1,087,983                                |
|   | -----                                    |
| TOTAL CURRENT ASSETS  | 59,014,269                               |
| Restricted cash   | 139,847                                  |
| United States government securities   | -  |
| Property and equipment, net   | 3,772,582                                |
|   | -----                                    |
| <b>TOTAL ASSETS</b>   | <b>\$ 62,926,698</b>                     |
|   | =====                                    |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>   |  |
| <b>CURRENT LIABILITIES</b>  |  |
| Accounts payable  | \$ 413,662                               |
| Accrued payroll   | 658,527                                  |
| Other accrued expenses  | 1,518,544                                |
| Current maturities of long-term debt  | -  |
| Deferred revenue  | 323,939                                  |
|   | -----                                    |
| TOTAL CURRENT LIABILITIES   | 2,914,672                                |
| Long-term debt, net of current maturities   | -  |
|   | -----                                    |
| <b>TOTAL LIABILITIES</b>  | <b>\$ 2,914,672</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: |  |
| 16,827,122 (2003: 13,966,247) shares of common stock, no par  | \$ 124,523,928                           |
| Additional paid-in capital  | 2,256,339                                |
| Accumulated deficit   | (67,507,522)                             |
| Accumulated other comprehensive income  | 739,281                                  |

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|  |                              |
|--|------------------------------|
| TOTAL SHAREHOLDERS' EQUITY                 | -----<br>60,012,026<br>----- |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | \$ 62,926,698<br>=====       |

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<br>JUNE 30,<br>(UNAUDITED) |                        | SIX MONTHS ENDED<br>JUNE 30,<br>(UNAUDITED) |                        |
|---|---|------------------------|---|------------------------|
|   | -----<br>2004<br>-----                        | -----<br>2003<br>----- | -----<br>2004<br>-----                      | -----<br>2003<br>----- |
| REVENUES  |   |                        |   |                        |
| Product sales   | \$ 2,176,028                                  | \$ 147,275             | \$ 3,431,713                                | \$ 290                 |
| OPERATING COSTS   |   |                        |   |                        |
| Cost of product sales and royalties                     | 1,068,711                                     | 824,027                | 1,894,716                                   | 1,577                  |
| Research and development                                | 1,577,294                                     | 1,448,600              | 3,265,060                                   | 2,964                  |
| Marketing and sales                                     | 1,699,145                                     | 532,978                | 3,066,603                                   | 1,063                  |
| General and administrative                              | 2,402,546                                     | 1,679,750              | 4,577,793                                   | 3,155                  |
| TOTAL OPERATING COSTS                                   | 6,747,696                                     | 4,485,355              | 12,804,172                                  | 8,760                  |
| LOSS FROM OPERATIONS                                    | (4,571,668)                                   | (4,338,080)            | (9,372,459)                                 | (8,470)                |
| OTHER INCOME  |   |                        |   |                        |
| Interest income, net                                    | 375,581                                       | 526,964                | 774,718                                     | 1,093                  |
| NET LOSS  | \$ (4,196,087)                                | \$ (3,811,116)         | \$ (8,597,741)                              | \$ (7,377)             |
| BASIC AND DILUTED NET LOSS PER<br>COMMON SHARE          | \$ (.25)                                      | \$ (.27)               | \$ (.55)                                    | \$                     |
| WEIGHTED AVERAGE NUMBER OF<br>COMMON SHARES OUTSTANDING | 16,727,111                                    | 13,932,424             | 15,764,792                                  | 13,912                 |

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

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|  | SIX MONTHS ENDED JUNE<br>2004<br>(UNAUDITED) | 2003<br>(UNAUDITED) |
|--|--|---------------------|
|  | -----  | -----               |
| CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES  |  |                     |
| Net loss   | \$ (8,597,741)                               | \$ (7,377,000)      |
| 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 | 51,986                                       | 47,000              |
| Depreciation and amortization expense  | 896,372                                      | 610,000             |
| Issuance of common stock to consultants  | 240,753                                      | 75,000              |
| Changes in other assets and liabilities impacting cash flows from operations:                                      |  |                     |
| Restricted cash  | (634)  |                     |
| Accrued interest receivable  | 89,659                                       | 85,000              |
| Accounts receivable  | (536,695)                                    | (62,000)            |
| Inventory  | (178,449)                                    | 151,000             |
| Prepays and other current assets   | (87,570)                                     | 237,000             |
| Accounts payable   | (445,619)                                    | (230,000)           |
| Accrued payroll and other accrued expenses   | 218,314                                      | (741,000)           |
| Deferred revenue   | 194,039                                      | 61,000              |
|  | -----  | -----               |
| NET CASH USED IN OPERATING ACTIVITIES  | (8,155,585)                                  | (7,143,000)         |
|  | -----  | -----               |
| CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES  |  |                     |
| Proceeds from maturing United States government securities   | 7,000,000                                    | 8,000,000           |
| Purchases of property and equipment  | (417,465)                                    | (172,000)           |
|  | -----  | -----               |
| NET CASH PROVIDED BY INVESTING ACTIVITIES  | 6,582,535                                    | 7,827,000           |
|  | -----  | -----               |
| CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES  |  |                     |
| Issuance of common stock   | 28,462,500                                   |                     |
| Stock offering costs   | (200,202)                                    |                     |
| Proceeds from exercise of options  | 591,076                                      |                     |
| Payments of long-term debt   | (1,517,500)                                  | (135,000)           |
|  | -----  | -----               |
| NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES  | 27,335,874                                   | (135,000)           |
|  | -----  | -----               |
| NET INCREASE IN CASH AND CASH EQUIVALENTS  | 25,762,824                                   | 548,000             |
|  | -----  | -----               |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD   | 4,294,482                                    | 6,926,000           |
|  | -----  | -----               |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD   | \$ 30,057,306                                | \$ 7,474,000        |
|  | =====  | =====               |

NON-CASH TRANSACTION

The Company issued 135,000 shares of its common stock in a private placement at \$11.00 per share as commission and non-refundable retainer to the placement agent on March 2, 2004, and an additional 20,250 shares on April 14, 2004 with respect to the exercise of the additional investment rights, for a total value of \$1,707,750.

See the accompanying Notes to the Condensed Consolidated Financial Statements.

## 1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of June 30, 2004, Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2004 and 2003, and Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2004 and 2003 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, 2003 audited consolidated financial statements and notes thereto. Certain amounts for 2003 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, 2004, ranging from 3.70% to 7.59% and maturity dates ranging from July 15, 2004 to September 24, 2007.

Accumulated other comprehensive income consists of net unrealized gains 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,<br>2004<br>(UNAUDITED) | DECEMBER 31,<br>2003 |
|-----------------|---------------------------------|----------------------|
|                 | -----                           | -----                |
| Finished goods  | \$347,876                       | \$582,382            |
| Work in process | 396,852                         | -                    |
| Raw materials   | 146,552                         | 130,449              |
|                 | -----                           | -----                |
|                 | \$891,280                       | \$712,831            |
|                 | =====                           | =====                |

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### 4) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

|                                   | JUNE 30,<br>2004<br>(UNAUDITED) | DECEMBER 31,<br>2003 |
|-----------------------------------|---------------------------------|----------------------|
|                                   | -----                           | -----                |
| Research and development costs    | \$ 49,736                       | \$ 184,912           |
| Marketing and sales costs         | 216,649                         | 113,020              |
| Product related costs             | 342,627                         | 144,826              |
| Legal and other professional fees | 565,654                         | 359,747              |
| Employee benefits                 | 178,117                         | 189,051              |
| Other expenses                    | 165,761                         | 170,583              |
|                                   | -----                           | -----                |
|                                   | \$1,518,544                     | \$1,162,139          |
|                                   | =====                           | =====                |

### 5) LONG-TERM DEBT

In May 2002, DUSA entered into a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility and borrowed \$1,900,000. Based on the terms of the Note, at June 30th of each year DUSA could 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. DUSA repaid the outstanding loan balance in June 2004. The security interest in approximately \$3,000,000 of the Company's United States government securities that were pledged as collateral to secure the loan was released.

### 6) SHAREHOLDERS' EQUITY

On February 27, 2004, the Company completed a private placement of 2,250,000 shares of its common stock at a purchase price of \$11.00 per share, resulting in gross proceeds of \$24,750,000. The closing date of the private placement was March 2, 2004. The Company also granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at \$11.00 per share. These additional investment rights were exercised on April 14, 2004, resulting in additional gross proceeds of \$3,712,500. Offering costs incurred as of June 30, 2004 in connection with the placement were \$1,907,952, of which \$1,707,750 consisted of the placement agent's commission and non-refundable retainer paid in the form of 135,000 shares of common stock calculated at the offering price and an additional 20,250 shares issued with respect to the exercise of the additional investment rights.

On March 18, 2004, the Company granted a total of 30,000 fully vested options to three consultants on its Medical Advisory Board as compensation for services. These options were valued at \$240,753 in accordance with the fair value-based method as required by Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure," 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,"

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and recorded as part of research and development costs in the Condensed Consolidated Statement of Operations.

### 7) ACCOUNTING FOR STOCK BASED COMPENSATION

SFAS No. 123, as amended by SFAS No. 148, 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, as amended by SFAS No. 148. Under the intrinsic value method, compensation expense, if any, is recognized for the difference between the exercise price of the option and the fair value of the underlying common stock as of a measurement date. The measurement date is the time when both the number of shares and the exercise price is known. 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, as amended by SFAS No. 148, and EITF No. 96-18, 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 measurement date, which is generally the grant date. The resulting compensation cost is recognized and charged to operations over the service period, which is generally the vesting period.

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As described above, the Company uses the intrinsic value method to measure compensation expense associated with grants of stock options to employees. 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, 2004 and 2003 would have been as follows:

|  | THREE MONTHS ENDED<br>JUNE 30,<br>(UNAUDITED) |                | SIX MO<br>JU<br>(UN |
|--|---|----------------|---------------------|
|  | 2004  | 2003           | 2004                |
| <b>NET LOSS</b>  |   |                |                     |
| As reported  | \$ (4,196,087)                                | \$ (3,811,116) | \$ (8,597,741)      |
| Effect on net loss if fair value method had been used                  | (779,453)                                     | (543,712)      | (1,496,598)         |
| Proforma   | \$ (4,975,540)                                | \$ (4,354,828) | \$ (10,094,339)     |
| <b>BASIC AND DILUTED NET LOSS PER COMMON SHARE</b>                     |   |                |                     |
| As reported  | \$ (.25)                                      | \$ (.27)       | \$ (.55)            |
| Effect on net loss per common share if fair value method had been used | (.05)   | (.04)          | (.09)               |
| Proforma   | \$ (.30)                                      | \$ (.31)       | \$ (.64)            |

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### 8) BASIC AND DILUTED NET LOSS PER COMMON SHARE

Basic net loss per common share is based on the weighted average number of shares outstanding during each period. Stock options and warrants are not included in the computation of the weighted average number of shares outstanding for dilutive net loss per common share during each of the periods presented in the Condensed Consolidated Statements of Operations, as the effect would be antidilutive. For the periods ended June 30, 2004 and 2003, such potentially dilutive securities totaling approximately 3,083,000 and 2,705,000 shares, respectively, have been excluded from the computation of diluted net loss per common share.

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### COMPREHENSIVE LOSS

For the three and six months ended June 30, 2004 and 2003, comprehensive loss consisted of the following:

|   | THREE MONTHS ENDED<br>JUNE 30,<br>(UNAUDITED) |               | SIX MONTHS ENDED<br>JUNE 30,<br>(UNAUDITED) |               |
|---|---|---------------|---|---------------|
|   | 2004  | 2003          | 2004  | 2003          |
| NET LOSS  | \$(4,196,087)                                 | \$(3,811,116) | \$(8,597,741)                               | \$(7,370,000) |
| Change in net unrealized gains on United States securities available for sale | (568,750)                                     | (120,333)     | (716,409)                                   | (360,000)     |
| COMPREHENSIVE LOSS  | \$(4,764,837)                                 | \$(3,931,449) | \$(9,314,150)                               | \$(7,730,000) |

### 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 being challenged by PhotoCure ASA. PhotoCure ASA 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, was invalid. As a consequence of this action, Queen's University assigned the Australian patent to the Company so that DUSA could participate directly in this litigation. The Company filed a response 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 final hearing in the Federal Court of Australia was held in April 2004, and a decision is expected in late 2004. Each party has the right to appeal within approximately one month following the Court's decision. The Company is unable to predict the outcome of the case at this time.

In December 2003, the Company was served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland alleging that DUSA's BLU-U(R) caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint names Berlex Laboratories, Inc., a subsidiary of the Company's former marketing partner, as another defendant. The



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case has been removed to the U.S. District Court for the Eastern District of Michigan Southern Division. The damages are unspecified. The Company has filed its answer denying the claims, and Berlex has requested indemnification from the Company under the terms of the Company's former agreement with Schering AG, Berlex's parent. Currently, the Company has declined to indemnify Berlex. While it is not possible to predict or determine the outcome of this action, the Company believes that the costs associated with all such matters will not have a material adverse effect on its

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consolidated financial position or liquidity, but could possibly be material to the consolidated results of operations in any one period to the extent costs are not covered by DUSA's insurance.

### 11) THIRD-PARTY CANADIAN MARKETING AND DISTRIBUTION AGREEMENT

On March 31, 2004, DUSA signed an exclusive Canadian marketing and distribution agreement for the Kerastick(R) and BLU-U(R) with Coherent-AMT Inc. ("Coherent"), a leading Canadian medical device and laser distribution company. Coherent began marketing the BLU-U(R) for moderate inflammatory acne in April 2004 and the Kerastick(R) for the treatment of non-hyperkeratotic actinic keratoses, or AKs, in June 2004, following receipt of the applicable regulatory approval from Health Canada. The agreement has a three-year term, which can be automatically renewed for additional one-year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. In addition, during the initial three-year term, either party may terminate the agreement earlier by providing formal written notice of its intention to do so at least 90 days in advance of each anniversary of the effective date, or in the event that the other party shall have materially breached any of its obligations in the agreement. DUSA recognizes product sales when Coherent sells the Kerastick(R) and the BLU-U(R) to the end-user, as the price is fixed and final at that point.

### 12) AMENDED/RESTATED PURCHASE AND SUPPLY AGREEMENT

On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation ("NBC"), the manufacturer of its BLU-U(R) light source. This agreement provides for the elimination of certain exclusivity clauses, permits DUSA to order on a purchase order basis without minimums, and other modifications of the original agreement providing both parties greater flexibility related to the development and manufacture of light sources, and the associated technology within the field of PDT. DUSA paid \$110,000 to NBC upon execution of the agreement which will be amortized over the remaining term of the agreement, expiring November 5, 2008.

## 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, which is 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 products, which were launched in September 2000 in the United States, are

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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. In addition, DUSA received market

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clearance from the United States Food and Drug Administration ("FDA") in September 2003 to market the BLU-U(R) without Levulan(R) for the treatment of moderate inflammatory acne vulgaris.

Marketing and sales activities since the October 2003 launch of our sales force have resulted in significant additional expenses; however, the impact on sales has been positive. Kerastick(R) unit sales to end-users were 17,910 for the three months ended June 30, 2004, including 1,908 sold by Coherent-AMT, our Canadian marketing and distribution partner. This compared to 12,054 Kerastick(R) units sold during the three months ended March 31, 2004 and 1,914 during the three months ended June 30, 2003, neither of which included any Canadian sales. The number of BLU-U(R) units placed in doctors' offices during the quarter also increased significantly, by 241, to 775 units, including 58 placed in Canada, compared with 534 in place at March 31, 2004 and 323 in physician offices at June 30, 2003.

Although the costs related to the addition of our sales force and related marketing activities are currently greater than the gross margin generated from the increased sales, we are encouraged with the ongoing increases in sales. We are continuing our efforts to penetrate the market through expanding our sales coverage in key geographic locations. As of June 30, 2004, we reached our second quarter target of 16 sales representatives and area managers. Since then, we decided to increase the size of our direct sales force to approximately 23 during 2004, and as of August 10, 2004, the sales force total stood at 21. We expect to continue to incur operating losses until sales of our products increase substantially above the current levels. At this time, our core objectives include focusing on increasing sales in the United States, conducting clinical trials to treat acne vulgaris and photodamaged skin, which, if successful, could lead to additional regulatory approvals, and making plans to advance development of Levulan(R) PDT for the treatment of dysplasia in patients with Barrett's esophagus. In addition, we continue to support independent investigator trials to advance research in the use and applicability of Levulan(R) PDT for indications in dermatology.

On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation ("NBC"), the manufacturer of its BLU-U(R) light source. This agreement eliminated certain exclusivity clauses, permits DUSA to order on a purchase order basis without minimums, and made other modifications to the original agreement providing both parties greater flexibility related to the development and manufacture of light sources, and the associated technology within the field of PDT. DUSA paid \$110,000 to NBC upon execution of the agreement which will be amortized over the remaining term of the agreement, expiring November 5, 2008. As of June 30, 2004, DUSA had 775 BLU-U(R) light sources placed in physician's offices with approximately 160 light units remaining in inventory. This declining level of remaining inventory is due to the higher than anticipated demand for the BLU-U(R) during the first six months of 2004. The Company is evaluating its options with respect to ordering more BLU-U(R) light units, and/or developing alternative light sources. We could experience a backlog once our current BLU-U(R) inventory is depleted, so until a new supply of light sources is available, BLU-U(R) revenues are expected to be limited by supply constraints. In addition, growth of Kerastick(R) units could be adversely affected by limited BLU-U(R) sales, though we believe this effect should not be significant.

On February 24, 2004, DUSA reacquired the rights to the aminolevulinic acid (Levulan(R)) technology for Canada held by Draxis Health Inc. ("Draxis"), DUSA's former parent. These rights were initially assigned to Draxis in 1991 at the time of the original licensing of the patents underlying our Levulan(R) PDT platform from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario. DUSA and Draxis terminated the assignment and DUSA agreed to pay to Draxis an upfront fee and an ongoing royalty on sales of the Levulan(R) Kerastick(R) in Canada over a five year term. In addition, on March 31, 2004 DUSA signed an exclusive marketing and distribution agreement for Canada with Coherent-AMT, a leading Canadian medical device and laser distribution company. Coherent-AMT began marketing the BLU-U(R) for moderate inflammatory acne upon entering our agreement and the Kerastick(R) in June 2004 for the treatment of non-hyperkeratotic actinic keratoses, or AKs, following receipt of regulatory approval from Health Canada.

In February 2004, DUSA commenced commercial production of the Levulan(R) Kerastick(R) at its Wilmington, Massachusetts manufacturing facility. Production continued during the current quarter based upon the anticipated demand for the Kerastick(R). During the current quarter, we commenced the distribution of the initial commercial product produced at our manufacturing facility.

On February 27, 2004, DUSA entered into definitive agreements with certain institutional and other accredited investors for the private placement of 2,250,000 shares of its common stock at a purchase price of \$11.00 per share, resulting in gross proceeds to DUSA of \$24,750,000. The closing date of the private placement was March 2, 2004. DUSA also issued Additional Investment Rights providing the investors with the right to purchase up to an aggregate of an additional 337,500 shares of common stock at \$11.00 per share. All of the Additional Investment Rights were exercised on April 14, 2004. Offering costs incurred as of June 30, 2004 in connection with the placement were \$1,908,000, of which \$1,708,000 consisted of the placement agent's commission and non-refundable retainer paid in the form of 135,000 shares of common stock and an additional 20,250 shares issued with respect to the exercise of the Additional Investment Rights, all of which were calculated at the offering price. DUSA will use the proceeds from the sale of the securities to expand its sales force and for general working capital purposes, including research and development activities.

DUSA has devoted its resources primarily to fund 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, 2004, we had an accumulated deficit of approximately \$67,508,000. Achieving our goal of becoming a profitable operating company is dependent upon acceptance of our therapy by the medical and consumer constituencies and our ability to develop new products.

DUSA has continued to support efforts to improve reimbursement levels to physicians. Some physicians have suggested that current reimbursement levels still do not fully reflect the required efforts to routinely employ our therapy in their practices. We believe that this issue has adversely affected the economic competitiveness of our products with other AK therapies and has hindered the adoption of our therapy. However, we continue to work to educate the major private insurance carriers about our AK therapy, and as of June 30, 2004, several major private insurers have approved coverage. We believe that due to these efforts, along with our education and marketing programs,

and increased interest in other uses for our products, more widespread adoption by the medical community will occur over time.

We have been encouraged by the positive response from many physicians and patients who have used our therapy, but we recognize that we have to continue to demonstrate the clinical value of our unique therapy, and the related product benefits as compared to other well-established conventional therapies, in order for the medical community to accept our products on a large scale. While our financial position is strong, we cannot predict when product sales may offset the costs associated with these efforts. We are aware that some physicians have been using Levulan(R) with the BLU-U(R), and with light devices manufactured by other companies, 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 are positively affecting the sales of our products.

As of June 30, 2004, DUSA's staff included 56 full-time employees and 2 part-time employees as compared to 50 full-time employees and 1 part-time employee at the end of 2003. These include marketing and sales, production, maintenance, customer support, and financial operations personnel, as well as those who support research and development programs for dermatology and internal indications. We expect to continue to increase our staff in 2004 as we focus on sales, marketing activities and customer support associated with our AK products, and research and development programs for dermatology and internal indications.

#### 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, 2003. Since all of these accounting policies do not require management to make difficult, subjective or complex judgments or estimates, they 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 are recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred, and there is reasonableness of collection. Product sales made through distributors who have a general right of return of product have been recorded as deferred revenue until the product is sold by our distributors to the end user. 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. Cost is determined using the first-in, first-out method. Inventories are continually reviewed for slow moving, obsolete or excess items. Inventory items identified as slow-moving are evaluated to determine if an 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

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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 Condensed Consolidated Balance Sheet. Management believes that the level of remaining Kerastick(R) inventory is reasonable in light of our current sales forecasts. However, if we do not order more BLU-U(R) units from our supplier or develop an alternative BLU-U(R) light device, we could experience a shortage of these light devices.

**VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS** - We review long-lived assets 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. If 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. At June 30, 2004, our total property, plant and equipment had a carrying value of \$3,773,000, including \$2,048,000 associated with our manufacturing facility, which received FDA approval in July 2003 and began inventory production in February 2004. We had no intangible assets recorded as of June 30, 2004 and December 31, 2003.

**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 Condensed Consolidated Financial Statements as permitted by Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure". 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 could, under certain circumstances, result in an adverse material effect on our results of operations, but would not affect cash flows.

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### RESULTS OF OPERATIONS

**REVENUES** - Total revenues for the three and six months ended June 30, 2004 were \$2,176,000 and \$3,432,000, respectively, as compared to \$147,000 and \$291,000 in the same periods in 2003, and were comprised of the following:

THREE MONTHS ENDED

SIX MONTHS ENDED

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|   | JUNE 30,<br>(UNAUDITED) |           | JUNE 30,<br>(UNAUDITED) |           |
|---|-------------------------|-----------|-------------------------|-----------|
|   | 2004                    | 2003      | 2004                    | 2003      |
| PRODUCT SALES REVENUES                  |                         |           |                         |           |
| Direct Kerastick(R) sales to physicians | \$1,304,000             | \$147,000 | \$2,200,000             | \$299,000 |
| BLU-U(R) sales to physicians            | 872,000                 | -         | 1,232,000               | -         |
| Total product sales                     | \$2,176,000             | \$147,000 | \$3,432,000             | \$299,000 |

The increase in 2004 product sales reflects sales to physicians of 17,910 and 29,964 Kerastick(R) units for the three and six months ended June 30, 2004, respectively, as compared to 1,914 and 3,756 Kerastick(R) units for the comparable 2003 periods. The increase in product revenues also reflects an increase in the BLU-U(R) units placed in physician's offices to 775 units as of June 30, 2004, up from 406 units at December 31, 2003.

On March 31, 2004, DUSA signed an exclusive marketing and distribution agreement for the Kerastick(R) and BLU-U(R) in Canada with Coherent-AMT Inc. ("Coherent"), a leading Canadian medical device and laser distribution company. Following receipt of regulatory approval from Health Canada, Coherent began marketing the BLU-U(R) for moderate inflammatory acne in April 2004, and the Kerastick(R) for the PDT treatment of non-hyperkeratotic actinic keratoses, or AKs, in June 2004. DUSA recognizes product sales when Coherent sells the Kerastick(R) and/or the BLU-U(R) to the end-user, as the price is fixed and final at that point. Product sales for the three and six months ended June 30, 2004 included 1,908 Kerastick(R) units and 58 BLU-U(R) units placed in Canada, and representing revenue of \$100,000 and \$183,000, respectively.

The increase of both Kerastick(R) and BLU-U(R) sales in the United States is a result of the efforts of our sales force, which we launched in October 2003, and includes sales generated at dermatology conferences including the American Academy of Dermatology ("AAD") annual meeting in February 2004, which is the largest and most prestigious annual dermatology conference. In addition, the increase in BLU-U(R) placements is caused, in part, by our ability to sell the BLU-U(R) to physicians as a stand alone device for the treatment of moderate inflammatory acne vulgaris since September 2003, following FDA clearance.

Although the level of Kerastick(R) sales to end-users for 2004 is higher than the level in the prior year, Kerastick(R) sales must continue to increase significantly in order for DUSA to become profitable. To reach that goal, we have increased our sales force's geographic reach, and we will continue to participate in medical conferences throughout the year. Due to the potential for elective

procedures to decline during the summer months, we do not expect sales for the third quarter of 2004 to increase at the same rate that we experienced during the last three quarters. In addition, we do not expect to generate the same level of sales from conferences as we did in the first two fiscal quarters. However, due to the increasing number of sales representatives, and the increasing acceptance of our therapy, we do expect that sales levels will increase during the fourth quarter of 2004 and in 2005. See "Results of

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Operations-Marketing and Sales Costs".

COST OF PRODUCT SALES AND ROYALTIES - Cost of product sales and royalties for the three and six months ended June 30, 2004 were \$1,069,000 and \$1,895,000, respectively, as compared to \$824,000 and \$1,577,000 in the comparable 2003 periods. A summary of the components of cost of product sales and royalties is provided below:

| THREE MONTHS ENDED JUNE 30,<br>(UNAUDITED) |           |                        | SI         |
|--|-----------|------------------------|------------|
| 2004                                       | 2003      | INCREASE<br>(DECREASE) | 2004       |
|  |           |                        |            |
| \$ 305,000                                 | \$697,000 | \$(392,000)            | \$ 700,00  |
| 346,000                                    | 37,000    | 309,000                | 579,00     |
| 354,000                                    | 71,000    | 283,000                | 516,00     |
| 64,000                                     | 19,000    | 45,000                 | 100,00     |
| \$1,069,000                                | \$824,000 | \$ 245,000             | \$1,895,00 |

- (1) The decrease in product costs for 2004 primarily reflects the capitalization of labor and overhead associated with the start of Kerastick(R) production in our facility. These costs were expensed in the prior year due to the absence of production.
- (2) Although there were direct BLU-U(R) product sales in 2004, there were no related direct BLU-U(R) product costs as these units had a zero book value due to inventory impairment charges recorded during 2002.
- (3) Royalty and supply fees include fees paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, and in 2004 amortization of an upfront fee and a royalty paid to Draxis, DUSA's former parent, on sales of the Levulan(R) Kerastick(R) in Canada.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs for the three and six month periods ended June 30, 2004 were \$1,577,000 and \$3,265,000, respectively, as compared to

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\$1,449,000 and \$2,965,000 in the same periods in 2003. These increases reflect the preparation work associated with initiating the Phase II photodamaged skin trial, protocol finalization for our acne trial, and the start of our Phase II pilot study for Barrett's esophagus offset, in part, by lower third-party expenditures for our FDA mandated Phase IV clinical study of the long-term efficacy of the Kerastick(R). This FDA mandated Phase IV study was completed in late 2003 and we incurred only limited costs to file the final report with the FDA in 2004. We have concentrated our dermatology development program on indications that use our approved Kerastick(R). Based on market research that was completed in 2003, we have moved forward with our Phase II clinical studies for use of Levulan(R) PDT in photodamaged skin and moderate to severe acne vulgaris. We initiated the photodamaged skin study during the second quarter of 2004 based on the Investigational New Drug application which was cleared by the FDA. Subject to ongoing discussions with the FDA, we expect to initiate a Phase II study on Levulan(R) PDT for the treatment of acne vulgaris during the third quarter of 2004. In addition, DUSA is evaluating whether to develop an alternative BLU-U(R) light device. We expect to incur total research and development costs of approximately \$6,500,000 to \$7,500,000 during 2004 due primarily to initiating these studies; however, this could increase by approximately \$2,000,000 if we decide to develop the new light source.

DUSA has also been following patients who completed Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett's esophagus. In preparation for new Phase II clinical trials, we have initiated a small single-center pilot Phase II clinical trial using DUSA's new proprietary endoscopic light delivery device for the treatment of high-grade dysplasia associated with Barrett's Esophagus. However, currently, we do not plan to fund other Phase II or III clinical trials for this indication on our own. Therefore, we are seeking a strategic partner or similar collaboration to advance the development of our treatment for Barrett's esophagus dysplasia. There can be no assurance that we will be able to consummate any collaboration on terms acceptable to us.

In addition, the current six month period includes compensation of \$241,000 for 30,000 fully vested stock options issued to three consultants for services.

**MARKETING AND SALES COSTS** - Marketing and sales costs for the three and six month periods ended June 30, 2004 were \$1,699,000 and \$3,067,000, respectively, as compared to \$533,000 and \$1,063,000 in the comparable periods in 2003. These increases were mainly attributable to the launch of our direct sales force in October 2003 and related marketing and sales activities. As of June 30, 2004, our sales force was comprised of 16 direct representatives and various independent representatives in key target markets. We anticipate that the level of marketing and sales expenses and related support functions will continue to increase during the remainder of 2004 as we expand our sales capacity.

**GENERAL AND ADMINISTRATIVE COSTS** - General and administrative costs for the three and six month periods ended June 30, 2004 were \$2,403,000 and \$4,578,000, respectively, as compared to \$1,680,000 and \$3,155,000 in the comparable periods in 2003. These increases were mainly attributable to higher legal expenses amounting to \$1,331,000 and \$2,531,000 during the current

three and six month periods, as compared to \$903,000 and \$1,586,000 in the



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comparable 2003 periods, due primarily to patent litigation costs.

In April 2002, DUSA 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 ALA technology, is invalid. As a consequence of this action, Queen's University assigned the Australian patent to us so that we could participate directly in this litigation. We 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 final hearing in the Federal Court of Australia was held in April 2004, and we expect that the Court's decision will be rendered in late 2004. We are unable to predict the outcome at this time. However, should PhotoCure prevail in either part of the case, i.e. the Court finds that (i) our patent is invalid, or (ii) the patent is valid, but PhotoCure's product does not infringe the patent, PhotoCure will be able to market its product in Australia. Each party has the right to appeal within approximately one month of the Court's decision.

In December 2003, DUSA was served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland alleging that DUSA's BLU-U(R) caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint names Berlex Laboratories, Inc., a subsidiary of our former marketing partner, as another defendant. The damages are unspecified. The case has been removed to the U.S. District Court, Eastern District of Michigan, Southern Division. We have filed our answer denying the claims. Berlex has requested indemnification from DUSA under the terms of the Company's former agreement with Schering AG, Berlex's parent. Currently, DUSA has declined to indemnify Berlex. While it is not possible to predict or determine the outcome of this action, we believe that the costs associated with all such matters will not have a material adverse effect on its consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one period to the extent costs are not covered by DUSA's insurance.

It is expected that legal expenses will decline during the second half of 2004 unless we enter into any additional significant legal activities, as we await a decision from the Court in Australia.

OTHER INCOME, NET - Other income for the three and six month periods ended June 30, 2004 was \$376,000 and \$775,000, as compared to \$527,000 and \$1,093,000 in the comparable 2003 periods. These decreases were attributable to a reduction in our average investable cash balances during 2003 and early 2004, as we used cash to support our operating activities. With the addition of the proceeds from the private placement in March 2004, interest income will initially increase and then may decline, depending on the direction of interest rates and as our investable cash balances are used to support our operating activities. During the three and six month periods ended June 30, 2004, we incurred interest expense of \$9,000 and \$20,000 on borrowings associated with the construction of our Kerastick(R) manufacturing facility as compared to \$17,000 and \$34,000 in 2003, which was capitalized in property and equipment in the Condensed Consolidated Balance Sheet as of June 30, 2003.

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NET LOSSES - For the three and six months ended June 30, 2004, we incurred net losses of \$4,196,000, or \$0.25 per share, and \$8,598,000, or \$0.55 per share, respectively, as compared to net losses of \$3,811,000, or \$0.27 per share, and \$7,377,000, or \$0.53 per share, for the comparable periods in 2003. Net losses are expected to continue until product sales to physicians offset the cost of our sales force and marketing initiatives, and the costs for other

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business support functions.

### LIQUIDITY AND CAPITAL RESOURCES

DUSA is in a strong cash position to continue to fund increased Levulan(R) PDT sales and marketing expenses and current research and development activities for its Levulan(R) PDT/PD platform. At June 30, 2004, we had approximately \$55,965,000 of total cash resources comprised of \$30,057,000 of cash and cash equivalents, United States government securities totaling \$25,767,000, and restricted cash of \$140,000. All of our United States government securities are classified as available for sale. As of June 30, 2004, these securities had yields ranging from 3.70% to 7.59% and maturity dates ranging from July 15, 2004 to September 24, 2007.

On February 27, 2004, DUSA completed a private placement of 2,250,000 shares of its common stock at a purchase price of \$11.00 per share resulting in gross proceeds of \$24,750,000. We also granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at \$11.00 per share, which were exercised on April 14, 2004, resulting in additional proceeds of \$3,712,500. Offering costs incurred as of June 30, 2004 in connection with the placement were \$1,907,000, of which \$1,708,000 consisted of the placement agent's commission and non-refundable retainer paid in the form of 135,000 shares of common stock and an additional 20,250 shares issued with respect to the exercise of the additional investment rights all of which were calculated at the offering price.

As of June 30, 2004, working capital (total current assets minus total current liabilities) was \$56,100,000 as compared to \$33,838,000 as of December 31, 2003. Total current assets increased \$21,958,000 in 2004 due primarily to the gross proceeds received from the private placement of \$28,463,000, offset by the use of \$8,156,000 of cash and cash equivalents to support our operating activities.

As of June 30, 2004, DUSA had current liabilities of \$2,915,000, as compared to \$3,218,000 as of December 31, 2003. This decrease is due in part to the repayment of debt in June 2004 with proceeds from the private placement. 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. DUSA repaid the outstanding loan balance in June 2004. The security interest in approximately \$3,000,000 of our United States government securities that were being pledged as collateral to secure the loan was released.

DUSA believes that we have sufficient capital resources to proceed with its current programs for Levulan(R) PDT and to fund operations and capital expenditures for the foreseeable future. We have invested our funds in liquid investments so that we will have ready access to these cash reserves

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for funding our needs on a short-term and long-term basis.

DUSA may also seek to expand or enhance its business by using resources to acquire businesses, new technologies, or products, especially in dermatology-related areas. For the remainder of 2004, we are focusing primarily on increasing sales of the Levulan(R) Kerastick(R) and the BLU-U(R).

DUSA has no off-balance sheet financing arrangements other than its operating leases.

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### CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

In May 2002, DUSA entered into a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility and borrowed \$1,900,000. DUSA repaid the outstanding loan balance in June 2004. The security interest in approximately \$3,000,000 of our United States government securities that were being pledged as collateral to secure the loan was released.

On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation ("NBC"), the manufacturer of its BLU-U(R) light source. This agreement eliminated certain exclusivity clauses, permits the acquisition of light sources on a purchase order basis and made other modifications to the original agreement providing both parties greater flexibility related to the development and manufacture of light sources, and the associated technology within the field of PDT. DUSA paid \$110,000 to NBC upon execution of the agreement which will be amortized over the term of the agreement, expiring November 5, 2008.

### RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

There have been no recently issued accounting pronouncements that have a material impact on our financial reporting other than those presented in our Annual Report on Form 10-K for the year ended December 31, 2003.

### 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.

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### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES

#### ABOUT MARKET RISK

DUSA holds fixed income United States government securities that are subject to interest rate market risks. However, we do not believe that the risk is material as we make our investments in relatively short-term instruments 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.

### ITEM 4. CONTROLS AND PROCEDURES

DUSA carried out an evaluation, under the direction of its Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2004.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### FORWARD-LOOKING STATEMENTS

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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 outcome of litigation in Australia and Michigan and their respective potential impact on DUSA's financial condition, management's goal of becoming profitable, DUSA's current core objectives, intentions not to order additional BLU-Us(R), intention to launch an alternative light device for the treatment of acne and the costs related thereto, the use of proceeds from DUSA's sale of securities, beliefs regarding adoption of our therapy, expectations regarding rates of sales increases, expectations to pursue research of Barrett's Esophagus therapy, expectations for continuing operating losses, expectations for acquiring new businesses, technologies or products, expectations of inflation affecting operating costs, expectations of market risk affecting DUSA's investments, 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, expectations for increased marketing and sales costs, expectations regarding future levels of legal fees, expectations regarding levels of interest income and net losses, requirements of cash resources, and potential impact on conversion of government securities, 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 of our trials, the impact of competitive products and pricing, the

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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, 2003, none of which can be assured.

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### PART II - OTHER INFORMATION

Items 1, 3, and 5.

None.

Item 2. Changes in Securities and Use of Proceeds.

- i) February 2004 Private Placement - On February 27, 2004, DUSA entered into definitive agreements with certain new and existing institutional and other accredited investors for the private placement of 2,250,000 shares of our common stock at a purchase price of \$11.00 per share resulting in gross proceeds to DUSA of \$24,750,000. DUSA granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at \$11.00 per share which were exercised on April 14, 2004. Offering costs incurred as of June 30, 2004 in connection with the placement were \$1,907,952, of which \$1,707,750 consisted of the placement agent's commission and non-refundable retainer paid in the form of

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135,000 shares of common stock calculated at the offering price and an additional 20,250 shares issued with respect to the exercise of the additional investment rights. DUSA relied on Rule 506 promulgated under the Securities Act of 1933 in selling these shares. DUSA engaged in due diligence to confirm that all purchasers of the common stock were accredited investors.

DUSA will use the proceeds from the sale of the securities to expand its sales force and for general working capital purposes, including research and development activities.

### 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 10, 2004 included the election of six (6) directors, the ratification of the selection of Deloitte and Touche LLP as the independent auditors for the Corporation for 2004, and an amendment to the Omnibus Plan of 1996, as amended (the "Plan") to increase the number of shares available for Awards under the Plan.

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

|                     | Votes Cast<br>For<br>----- | Votes Cast<br>Against<br>----- | Abstained<br>----- | Broker<br>Non-vote<br>----- |
|---------------------|----------------------------|--------------------------------|--------------------|-----------------------------|
| D. Geoffrey Shulman | 13,813,026                 | 335,299                        | -0-                | -0-                         |
| John H. Abeles      | 13,830,526                 | 317,799                        | -0-                | -0-                         |
| David Bartash       | 13,813,026                 | 335,299                        | -0-                | -0-                         |
| Jay Haft            | 13,808,726                 | 339,599                        | -0-                | -0-                         |
| Richard C. Lufkin   | 13,813,026                 | 335,299                        | -0-                | -0-                         |
| Magnus Moliteus     | 13,830,526                 | 317,799                        | -0-                | -0-                         |

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- b) Shareholders ratified the selection of Deloitte & Touche LLP as the independent auditors for the Corporation for 2004 as follows:

|                       | Votes Cast<br>For<br>----- | Votes Cast<br>Against<br>----- | Abstained<br>----- | Broke<br>Non-vo<br>----- |
|-----------------------|----------------------------|--------------------------------|--------------------|--------------------------|
| Deloitte & Touche LLP | 14,127,204                 | 12,319                         | 8,802              | -0-                      |

- c) Shareholders ratified the amendment to the Plan increasing the number of shares reserved for issuance of Awards under the Plan from 2,753,328 to 3,343,874 shares as follows:

|  | Votes Cast<br>For<br>----- | Votes Cast<br>Against<br>----- | Abstained<br>----- | Broker<br>Non-vote<br>----- |
|--|----------------------------|--------------------------------|--------------------|-----------------------------|
|--|----------------------------|--------------------------------|--------------------|-----------------------------|

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7,463,716

1,809,700

-0-

-0-

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

#### i) Exhibits

- a) Exhibit 10(a) - Amended and Restated Purchase and Supply Agreement between Registrant and National Biological Corporation, effective as of June 21, 2004, portions of which have been omitted as confidential pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and Rule 406 of the Securities Act of 1933.
- b) Exhibit 31(a) - Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer.
- c) Exhibit 31(b) - Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
- d) Exhibit 32(a) - Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and
- e) Exhibit 32(b) - Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- f) Exhibit 99(a) - Press Release dated August 10, 2004

#### ii) Forms 8-K

- a) Form 8-K, dated April 14, 2004 and filed April 15, 2004, reporting sales results for the quarter ended March 31, 2004 and participation in the 2004 Annual Meeting of the American Society of Laser Medicine and Surgery in Dallas, Texas.
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- b) Form 8-K, dated and filed April 15, 2004, reporting that on April 14, 2004 DUSA received exercise notices relating to the exercise of additional investment rights to purchase 337,500 shares of its common stock at a price of \$11.00 per share.
  - c) Form 8-K, dated and filed May 4, 2004, reporting that DUSA's registration statement on Form S-3 with respect to the 2,587,500 shares issued to investors, and the 155,250 shares issued to the placement agent as commissions and non-refundable retainer, in connection with the recent private placement, was declared effective.
  - d) Form 8-K, dated and filed May 20, 2004, announcing (i) the initiation of a Phase II clinical study using DUSA's Levulan(R) Photodynamic Therapy for treatment of facial photodamage, and (ii) the filing of a Post-Effective Amendment to an existing Registration Statement on Form S-8 with the SEC.
  - e) Form 8-K, dated and filed June 8, 2004, reporting DUSA's

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initiation of a Phase II Pilot Study of Levulan PDT for the treatment of High-grade Dysplasia in Barrett's Esophagus.

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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.

By: /s/ D. Geoffrey Shulman

-----  
D. Geoffrey Shulman  
President and Chief Executive Officer  
(principal executive officer)

Date: August 10, 2004

By: /s/ Peter M. Chakoutis

-----  
Peter M. Chakoutis  
Vice President and Chief  
Financial Officer (principal  
financial officer) and Controller  
(principal accounting officer)

EXHIBIT INDEX

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