

DUSA PHARMACEUTICALS INC

Form 10-Q

November 10, 2011

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549  
FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended: September 30, 2011**

**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: 001-31533**

**DUSA PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

New Jersey  
(State of Other Jurisdiction of  
Incorporation or Organization)

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

25 Upton Drive, Wilmington, MA  
(Address of Principal Executive Offices)

01887  
(Zip Code)

(978) 657-7500

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 months (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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 9, 2011, the registrant had 24,649,364 shares of Common Stock, no par value per share, outstanding.



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|   | <b>September<br/>30,<br/>2011</b> | <b>December 31,<br/>2010</b> |
|---|-----------------------------------|------------------------------|
| <b>ASSETS</b>   |                                   |                              |
| <b>CURRENT ASSETS</b>   |                                   |                              |
| Cash and cash equivalents   | \$ 23,301,191                     | \$ 8,884,402                 |
| Marketable securities   | 1,116,215                         | 10,762,559                   |
| Accounts receivable, net of allowance for doubtful accounts of \$50,000 and \$60,000 in 2011 and 2010, respectively   | 2,231,374                         | 3,311,467                    |
| Inventory   | 2,967,131                         | 2,165,220                    |
| Prepaid and other current assets  | 754,289                           | 1,344,062                    |
| <b>TOTAL CURRENT ASSETS</b>   | <b>30,370,200</b>                 | <b>26,467,710</b>            |
| Restricted cash   | 175,587                           | 174,753                      |
| Property, plant and equipment, net  | 1,521,601                         | 1,582,777                    |
| Deferred charges and other assets   | 61,902                            | 68,099                       |
| <b>TOTAL ASSETS</b>   | <b>\$ 32,129,290</b>              | <b>\$ 28,293,339</b>         |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY</b>  |                                   |                              |
| <b>CURRENT LIABILITIES</b>  |                                   |                              |
| Accounts payable  | \$ 1,017,419                      | \$ 162,742                   |
| Accrued compensation  | 960,489                           | 2,243,997                    |
| Other accrued expenses  | 2,723,889                         | 2,348,838                    |
| Deferred revenue  |                                   | 712,338                      |
| <b>TOTAL CURRENT LIABILITIES</b>  | <b>4,701,797</b>                  | <b>5,467,915</b>             |
| Deferred revenue  | 908,578                           | 1,917,237                    |
| Warrant liability   | 1,698,769                         | 1,203,553                    |
| Other liabilities   | 161,822                           | 181,153                      |
| <b>TOTAL LIABILITIES</b>  | <b>7,470,966</b>                  | <b>8,769,858</b>             |
| <b>COMMITMENTS AND CONTINGENCIES (NOTE 13)</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: 24,649,364 and 24,239,365 shares of common stock, no par, at September 30, 2011 and December 31, 2010, respectively | 151,985,400                       | 151,703,468                  |
| Additional paid-in capital  | 10,283,724                        | 9,399,434                    |

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|   |               |               |
|---|---------------|---------------|
| Accumulated deficit                       | (137,644,010) | (141,656,600) |
| Accumulated other comprehensive income    | 33,210        | 77,179        |
| <br>                                      |               |               |
| TOTAL SHAREHOLDERS EQUITY                 | 24,658,324    | 19,523,481    |
| <br>                                      |               |               |
| TOTAL LIABILITIES AND SHAREHOLDERS EQUITY | \$ 32,129,290 | \$ 28,293,339 |

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**

|  | <b>Three-months ended<br/>September 30,</b> |                   | <b>Nine-months ended<br/>September 30,</b> |                     |
|--|---|-------------------|--|---------------------|
|  | <b>2011</b>                                 | <b>2010</b>       | <b>2011</b>                                | <b>2010</b>         |
| Product revenues   | \$ 9,447,918                                | \$ 8,015,546      | \$ 30,292,804                              | \$ 25,430,363       |
| Cost of product revenues                                   | 1,536,581                                   | 1,627,782         | 4,891,140                                  | 5,228,075           |
| <b>GROSS MARGIN</b>  | <b>7,911,337</b>                            | <b>6,387,764</b>  | <b>25,401,664</b>                          | <b>20,202,288</b>   |
| Operating costs:   |   |                   |  |                     |
| Research and development                                   | 1,307,054                                   | 1,283,771         | 3,739,472                                  | 3,643,849           |
| Marketing and sales  | 3,352,535                                   | 2,792,780         | 10,614,332                                 | 9,544,564           |
| General and administrative                                 | 2,323,072                                   | 2,208,898         | 7,335,106                                  | 6,919,128           |
| Gain on sale of assets                                     |   |                   | (750,000)                                  |                     |
| <b>TOTAL OPERATING COSTS</b>                               | <b>6,982,661</b>                            | <b>6,285,449</b>  | <b>20,938,910</b>                          | <b>20,107,541</b>   |
| <b>INCOME FROM OPERATIONS</b>                              | <b>928,676</b>                              | <b>102,315</b>    | <b>4,462,754</b>                           | <b>94,747</b>       |
| Gain (loss) on change in fair value of warrants            | 2,569,154                                   | (130,674)         | (495,216)                                  | (486,964)           |
| Other income   | 9,065                                       | 61,183            | 45,052                                     | 188,752             |
| <b>NET INCOME (LOSS)</b>                                   | <b>\$ 3,506,895</b>                         | <b>\$ 32,824</b>  | <b>\$ 4,012,590</b>                        | <b>\$ (203,465)</b> |
| <b>BASIC NET INCOME (LOSS) PER COMMON SHARE</b>            | <b>\$ 0.14</b>                              | <b>\$ 0.00</b>    | <b>\$ 0.16</b>                             | <b>\$ (0.01)</b>    |
| <b>DILUTED NET INCOME (LOSS) PER COMMON SHARE</b>          | <b>\$ 0.13</b>                              | <b>\$ 0.00</b>    | <b>\$ 0.15</b>                             | <b>\$ (0.01)</b>    |
| <b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING, BASIC</b>   | <b>24,649,364</b>                           | <b>24,209,215</b> | <b>24,492,137</b>                          | <b>24,173,399</b>   |
| <b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING, DILUTED</b> | <b>26,442,251</b>                           | <b>24,658,844</b> | <b>26,385,140</b>                          | <b>24,173,399</b>   |

See the accompanying Notes to the Condensed Consolidated Financial Statements.



**Table of Contents****DUSA PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

|  | <b>Nine-months ended<br/>September 30,</b> |                     |
|--|--|---------------------|
|  | <b>2011</b>                                | <b>2010</b>         |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>  |  |                     |
| Net income (loss)  | \$ 4,012,590                               | \$ (203,465)        |
| Adjustments to reconcile net income (loss) to net cash provided by operating activities: |  |                     |
| Accretion of premiums and discounts on marketable securities                             | (13,288)                                   | 5,236               |
| Share-based compensation   | 884,290                                    | 920,755             |
| Depreciation and amortization  | 332,254                                    | 295,020             |
| Loss on change in fair value of warrants   | 495,216                                    | 486,964             |
| Gain on sale of assets   | (750,000)                                  |                     |
| Deferred revenues recognized   | (1,720,997)                                | (1,077,933)         |
| Changes in other assets and liabilities impacting cash flows from operations:            |  |                     |
| Accounts receivable  | 1,080,093                                  | 177,480             |
| Inventory  | (801,911)                                  | (99,330)            |
| Prepaid and other assets   | 595,970                                    | 625,652             |
| Accounts payable, accrued compensation and other accrued expenses                        | (53,780)                                   | (513,474)           |
| Other liabilities  | (19,331)                                   | (43,001)            |
| <b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>   | <b>4,041,106</b>                           | <b>573,904</b>      |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>  |  |                     |
| Purchases of marketable securities   | (1,499,337)                                | (12,742,296)        |
| Proceeds from maturities and sales of marketable securities                              | 11,115,000                                 | 10,885,000          |
| Proceeds from sale of assets   | 750,000                                    |                     |
| Restricted cash  | (834)                                      | (332)               |
| Purchases of property, plant and equipment   | (271,078)                                  | (128,896)           |
| <b>NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>                               | <b>10,093,751</b>                          | <b>(1,986,524)</b>  |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>  |  |                     |
| Stock option exercises   | 515,689                                    | 25,993              |
| Settlements of restricted stock for tax withholding obligations                          | (233,757)                                  | (42,490)            |
| <b>NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES</b>                               | <b>281,932</b>                             | <b>(16,497)</b>     |
| <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>                              | <b>14,416,789</b>                          | <b>(1,429,117)</b>  |
| <b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>                                  | <b>8,884,402</b>                           | <b>7,613,378</b>    |
| <b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>  | <b>\$ 23,301,191</b>                       | <b>\$ 6,184,261</b> |



**Table of Contents****DUSA PHARMACEUTICALS, INC.****NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)****1) BASIS OF PRESENTATION**

The Condensed Consolidated Balance Sheet as of September 30, 2011, the Condensed Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2011 and 2010, and the Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2011 and 2010 of DUSA Pharmaceuticals, Inc. (the Company or DUSA ) have been prepared in accordance with accounting principles generally accepted in the United States of America ( U.S. GAAP ). 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 U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements should be read in conjunction with the Consolidated Financial Statements and Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission. The Condensed Consolidated Balance Sheet as of December 31, 2010 included herein was derived from the audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require disclosure. Subsequent events have been evaluated through the date of issuance of these financial statements.

**2) NEW ACCOUNTING PRONOUNCEMENTS**

In June 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-05, *Comprehensive Income (Topic 220)* (ASU 2011-05). This newly issued accounting standard (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in shareholders equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this ASU do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income nor do the amendments affect how earnings per share is calculated or presented. This ASU is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011, which for the Company means January 1, 2012. As this accounting standard only requires enhanced disclosure, the adoption of this standard will not impact the Company s financial position or results of operations.

In May 2011, the FASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). This newly issued accounting standard clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This ASU is effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011, which for the Company means January 1, 2012. The Company does not expect that adoption of this standard will have a material impact on our financial position or results of operations.

**3) FINANCIAL INSTRUMENTS***Fair Value Measurements*

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, financial instruments are categorized based on a hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted market prices in active markets for identical assets or liabilities. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data. Level 2 consists of financial instruments that are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency in the determination of value. The Company accesses publicly available market activity from third-party databases and credit ratings of the issuers of the securities it holds to corroborate the data used in the fair value calculations obtained from its primary pricing source. The Company also takes into account credit rating changes, if any, of the securities or recent marketplace activity.

Level 3: Unobservable inputs that are not corroborated by market data. Level 3 is comprised of financial instruments whose fair value is estimated based on internally developed models or methodologies utilizing significant inputs that are generally less readily observable. We initially recorded the warrant liability at its fair value using the Black-Scholes option-pricing model and revalue it at each reporting date until the warrants are exercised or expire. The fair value of the warrants is subject to significant fluctuation based on changes in our stock price, expected volatility, remaining contractual life and the risk-free interest rate.

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The Company's cash equivalents and marketable securities are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices, or broker dealer quotations and matrix pricing compiled by third party pricing vendors, respectively, which are based on third party pricing sources with reasonable levels of price transparency. The Company's investments are valued based on a market approach in which all significant inputs are observable or can be derived from or corroborated by observable market data such as interest rates, yield curves, and credit risk.

The following table presents the Company's financial instruments recorded at fair value in the Condensed Consolidated Balance Sheet, classified according to the three categories described above:

|  | Carrying Value | Fair Value Measurements at September 30, 2011 |               |              |
|--|----------------|---|---------------|--------------|
|  |                | (Level 1)                                     | (Level 2)     | (Level 3)    |
| <b>Assets</b>                              |                |   |               |              |
| Cash and cash equivalents                  | \$ 23,301,000  | \$ 23,301,000                                 | \$            | \$           |
| United States government-backed securities | 576,000        |   | 576,000       |              |
| Corporate securities                       | 540,000        |   | 540,000       |              |
| Total assets at fair value                 | \$ 24,417,000  | \$ 23,301,000                                 | \$ 1,116,000  | \$           |
| <b>Liabilities</b>                         |                |   |               |              |
| Warrant liability                          | 1,699,000      |   |               | 1,699,000    |
| Total liabilities at fair value            | \$ 1,699,000   | \$  | \$            | \$ 1,699,000 |
|  | Carrying Value | Fair Value Measurements at December 31, 2010  |               |              |
|  |                | (Level 1)                                     | (Level 2)     | (Level 3)    |
| <b>Assets</b>                              |                |   |               |              |
| Cash and cash equivalents                  | \$ 8,884,000   | \$ 8,884,000                                  | \$            | \$           |
| United States government-backed securities | 9,985,000      |   | 9,985,000     |              |
| Corporate securities                       | 778,000        |   | 778,000       |              |
| Total assets at fair value                 | \$ 19,647,000  | \$ 8,884,000                                  | \$ 10,763,000 | \$           |
| <b>Liabilities</b>                         |                |   |               |              |
| Warrant liability                          | 1,204,000      |   |               | 1,204,000    |
| Total liabilities at fair value            | \$ 1,204,000   | \$  | \$            | \$ 1,204,000 |

The Company reviewed the level classifications of its investments at September 30, 2011 compared to December 31, 2010 and determined that there were no significant transfers between levels in the nine-month period ended September 30, 2011.

The table below includes a rollforward of the balance sheet amounts for the three and nine-month periods ended September 30, 2011 and 2010 for the warrant liability, which is classified as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable parameters to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable components, observable components (that is, components that are actively quoted and can be validated to external sources).

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)  
Three-Months Ended September 30, 2011**

|                   | <b>Fair Value</b>              | <b>Total<br/>Unrealized<br/>Gain<br/>Recognized<br/>in<br/>Statement<br/>Of<br/>Operations</b> | <b>Purchases,<br/>Sales,<br/>Issuances,<br/>Settlements,<br/>net</b> | <b>Transfers<br/>In<br/>and/or<br/>Out<br/>of<br/>Level<br/>3</b> | <b>Fair Value<br/>at<br/>September<br/>30,<br/>2011</b> | <b>Change in<br/>Unrealized<br/>Gains in<br/>2011</b> |
|-------------------|--------------------------------|--|--|---|---|---|
|                   | <b>at<br/>July 1,<br/>2011</b> |  |  |   |   |   |
| Warrant Liability | \$ 4,268,000                   | \$ (2,569,000)   | \$   | \$  | \$ 1,699,000  | \$ (2,569,000)  |

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**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)  
Three-Months Ended September 30, 2010**

|                   | <b>Fair Value<br/>at<br/>July 1,<br/>2010</b> | <b>Total<br/>Unrealized<br/>Loss<br/>Recognized<br/>in<br/>Statement<br/>Of<br/>Operations</b> | <b>Purchases,<br/>Sales,<br/>Issuances,<br/>Settlements,<br/>net</b> | <b>Transfers<br/>In<br/>and/or<br/>Out of<br/>Level<br/>3</b> | <b>Fair Value<br/>at<br/>September<br/>30,<br/>2010</b> | <b>Change in<br/>Unrealized<br/>Losses in<br/>2011</b> |
|-------------------|---|--|--|---|---|--|
| Warrant Liability | \$ 1,169,000                                  | \$ 131,000   | \$   | \$  | \$ 1,300,000  | \$ 131,000   |

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)  
Nine-Months Ended September 30, 2011**

|                   | <b>Fair Value<br/>at<br/>January 1,<br/>2011</b> | <b>Total<br/>Unrealized<br/>Loss<br/>Recognized<br/>in<br/>Statement<br/>Of<br/>Operations</b> | <b>Purchases,<br/>Sales,<br/>Issuances,<br/>Settlements,<br/>net</b> | <b>Transfers<br/>In<br/>and/or<br/>Out of<br/>Level<br/>3</b> | <b>Fair Value<br/>at<br/>September<br/>30,<br/>2011</b> | <b>Change in<br/>Unrealized<br/>Losses in<br/>2011</b> |
|-------------------|--|--|--|---|---|--|
| Warrant Liability | \$ 1,204,000                                     | \$ 495,000   | \$   | \$  | \$ 1,699,000  | \$ 495,000   |

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)  
Nine-Months Ended September 30, 2010**

|                   | <b>Fair<br/>Value at<br/>January<br/>1,<br/>2010</b> | <b>Total<br/>Unrealized<br/>Loss<br/>Recognized<br/>in<br/>Statement<br/>Of<br/>Operations</b> | <b>Purchases,<br/>Sales,<br/>Issuances,<br/>Settlements,<br/>net</b> | <b>Transfers<br/>In<br/>and/or<br/>Out of<br/>Level<br/>3</b> | <b>Fair Value<br/>at<br/>September<br/>30,<br/>2010</b> | <b>Change in<br/>Unrealized<br/>Losses in<br/>2011</b> |
|-------------------|--|--|--|---|---|--|
| Warrant Liability | \$ 813,000   | \$ 487,000   | \$   | \$  | \$ 1,300,000  | \$ 487,000   |

*Marketable Securities*

The Company's marketable securities consist of the following:

**September 30, 2011**  
**Gross Gross**

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|  | <b>Amortized<br/>Cost</b> | <b>Unrealized<br/>Gains</b> | <b>Unrealized<br/>Losses</b> | <b>Fair<br/>Value</b> |
|--|---------------------------|-----------------------------|------------------------------|-----------------------|
| United States government-backed securities | \$ 554,000                | \$ 22,000                   | \$                           | \$ 576,000            |
| Corporate securities                       | 529,000                   | 11,000                      |                              | 540,000               |
| <b>Total marketable securities</b>         | <b>\$ 1,083,000</b>       | <b>\$ 33,000</b>            | <b>\$</b>                    | <b>\$ 1,116,000</b>   |

|  |                           | <b>December 31, 2010</b>              |  |                       |
|--|---------------------------|---------------------------------------|--|-----------------------|
|  | <b>Amortized<br/>Cost</b> | <b>Gross<br/>Unrealized<br/>Gains</b> | <b>Gross<br/>Unrealized<br/>Losses</b> | <b>Fair<br/>Value</b> |
| United States government-backed securities | \$ 9,954,000              | \$ 34,000                             | \$ (3,000)                             | \$ 9,985,000          |
| Corporate securities                       | 732,000                   | 46,000                                |  | 778,000               |
| <b>Total marketable securities</b>         | <b>\$ 10,686,000</b>      | <b>\$ 80,000</b>                      | <b>\$ (3,000)</b>                      | <b>\$ 10,763,000</b>  |

The Company amortizes or accretes the premiums and discounts paid for the securities into interest income over the period to maturity of the securities. The decrease in net unrealized gains on such securities for the nine-month periods ended September 30, 2011 and 2010 was \$44,000 and \$111,000, respectively, which has been recorded in accumulated other comprehensive income and is reported as part of shareholders' equity in the Condensed Consolidated Balance Sheets. Realized losses on sales of marketable securities were \$0 for the nine-



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month periods ended September 30, 2011 and 2010. As of September 30, 2011, current yields range from 4.27% to 6.36% and maturity dates range from October 2011 to January 2013.

*Common Stock Warrants*

Upon issuance of the warrants on October 29, 2007, the Company recorded the warrant liability at its initial fair value of \$1,950,000. Warrants that are classified as a liability are revalued at each reporting date until the warrants are exercised or expire with changes in the fair value reported in the Company's Condensed Consolidated Statements of Operations as gain or loss on fair value of warrants. Non-cash gains (losses) for the three and nine-month periods ended September 30, 2011 were \$2,569,000 and (\$495,000), respectively, compared with (\$131,000) and (\$487,000), respectively, for the comparable 2010 periods. At September 30, 2011 and December 31, 2010, the aggregate fair value of these warrants was \$1,699,000 and \$1,204,000, respectively. Assumptions used for the Black-Scholes option-pricing models in determining the fair value as of September 30, 2011 and December 31, 2010 are as follows:

|                                    | <b>September<br/>30,<br/>2011</b> | <b>December<br/>31,<br/>2010</b> |
|------------------------------------|-----------------------------------|----------------------------------|
| Expected volatility                | 62.5%                             | 81%                              |
| Remaining contractual term (years) | 1.6                               | 2.3                              |
| Risk-free interest rate            | 0.25%                             | 0.7%                             |
| Expected dividend yield            | 0%                                | 0%                               |
| Common stock price                 | \$ 3.70                           | \$ 2.45                          |

**4) CONCENTRATIONS**

The Company invests cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. The Company manages the credit risk associated with its investments in marketable securities by investing in U.S. government securities and investment grade corporate bonds. The Company's exposure to credit risk relating to its accounts receivable is limited. To manage credit risk in accounts receivable, the Company performs regular credit evaluations of its customers and provides allowances for potential credit losses, when applicable. At September 30, 2011, there were no customers representing over 10% of the Company's accounts receivable balance. The Company is dependent upon sole-source suppliers for a number of its products. There can be no assurance that these suppliers will be able to meet the Company's future requirements for such products or parts or that they will be available at favorable terms. Any extended interruption in the supply of any such products or parts or any significant price increase could have a material adverse effect on the Company's operating results in any given period.

**5) INVENTORY**

Inventory consisted of the following:

|                         | <b>September<br/>30,<br/>2011</b> | <b>December 31,<br/>2010</b> |
|-------------------------|-----------------------------------|------------------------------|
| Finished goods          | \$ 1,398,000                      | \$ 907,000                   |
| BLU-U® evaluation units | 105,000                           | 129,000                      |
| Work in process         | 432,000                           | 371,000                      |
| Raw materials           | 1,032,000                         | 758,000                      |
| <br>                    |                                   |                              |
| Total                   | \$ 2,967,000                      | \$ 2,165,000                 |

BLU-U® commercial light sources placed in physicians' offices for an initial evaluation period are included in inventory until all revenue recognition criteria are met. The Company amortizes the cost of the evaluation units during the evaluation period to cost of goods sold using an estimated life of three years to approximate its net realizable value.

**6) OTHER ACCRUED EXPENSES**

Other accrued expenses consisted of the following:

|  | <b>September<br/>30,<br/>2011</b> | <b>December<br/>31,<br/>2010</b> |
|--|-----------------------------------|----------------------------------|
| Research and development costs           | \$ 216,000                        | \$ 231,000                       |
| Marketing and sales costs                | 176,000                           | 195,000                          |
| Reserve for sales returns and allowances | 238,000                           | 125,000                          |
| Other product related costs              | 878,000                           | 798,000                          |
| Legal and other professional fees        | 495,000                           | 308,000                          |
| Due to former Sirius shareholders        | 246,000                           | 232,000                          |
| Employee benefits                        | 326,000                           | 298,000                          |
| Other expenses                           | 149,000                           | 162,000                          |
| <br>                                     |                                   |                                  |
| Total                                    | \$ 2,724,000                      | \$ 2,349,000                     |

**Table of Contents****7) SHARE-BASED COMPENSATION**

Total share-based compensation expense, related to all of the Company's share-based awards, recognized for the three and nine-month periods ended September 30, 2011 and 2010 included the following line items:

|                                  | <b>Three-months ended</b> |                  | <b>Nine-months ended</b> |                  |
|----------------------------------|---------------------------|------------------|--------------------------|------------------|
|                                  | <b>September</b>          | <b>September</b> | <b>September</b>         | <b>September</b> |
|                                  | <b>30,</b>                | <b>30,</b>       | <b>30,</b>               | <b>30,</b>       |
|                                  | <b>2011</b>               | <b>2010</b>      | <b>2011</b>              | <b>2010</b>      |
| Cost of product revenues         | \$ 14,000                 | \$ 11,000        | \$ 39,000                | \$ 38,000        |
| Research and development         | 39,000                    | 29,000           | 106,000                  | 94,000           |
| Marketing and sales              | 57,000                    | 37,000           | 164,000                  | 83,000           |
| General and administrative       | 202,000                   | 356,000          | 575,000                  | 706,000          |
| Share-based compensation expense | \$ 312,000                | \$ 433,000       | \$ 884,000               | \$ 921,000       |

*Incentive And Non-qualified Stock Options*

The weighted-average estimated fair values of employee stock options granted during the three and nine-month periods ended September 30, 2011 were \$2.85 and \$2.89 per share, respectively, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

|  | <b>Three-months</b>       | <b>Nine-months</b> |
|--|---------------------------|--------------------|
|  | <b>ended</b>              | <b>ended</b>       |
|  | <b>September 30, 2011</b> |                    |
| Expected volatility                          | 78.72%                    | 77.21%             |
| Risk-free interest rate                      | 1.29%                     | 2.22%              |
| Expected dividend yield                      | 0%                        | 0%                 |
| Expected life-directors and officers (years) | 5.94                      | 5.94               |
| Expected life-non-officer employees (years)  | 5.58                      | 5.58               |

A summary of stock option activity for the nine-month period ended September 30, 2011 is as follows:

|   |           | <b>Weighted</b> | <b>Average</b>     | <b>Aggregate</b> |
|---|-----------|-----------------|--------------------|------------------|
|   |           | <b>Average</b>  | <b>Remaining</b>   | <b>Intrinsic</b> |
|   |           | <b>Exercise</b> | <b>Contractual</b> | <b>Value</b>     |
|   |           | <b>Price</b>    | <b>Term</b>        |                  |
|   |           |                 | <b>(Years)</b>     |                  |
| Outstanding, beginning of period, January 1, 2011 | 3,064,050 | \$ 4.09         |                    | \$               |
| Options granted                                   | 150,300   | \$ 4.37         |                    |                  |
| Options forfeited                                 | (25,037)  | \$ 2.34         |                    |                  |
| Options expired                                   | (101,500) | \$ 13.45        |                    |                  |
| Options exercised                                 | (273,338) | \$ 1.89         |                    |                  |
| Outstanding, end of period                        | 2,814,475 | \$ 3.99         | 4.12               | \$ 3,488,000     |
| Exercisable, end of period                        | 1,839,314 | \$ 5.08         | 3.57               | \$ 1,674,000     |

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Options vested and expected to vest, end of period      2,695,728      \$    4.08      4.07      \$ 3,287,000

*Unvested Shares Of Common Stock*

A summary of unvested shares of common stock activity for the nine-month periods ended September 30, 2011 and 2010 is as follows:

|                                   | <b>2011</b> | <b>2010</b> |
|-----------------------------------|-------------|-------------|
| Outstanding, beginning of period, | 586,000     | 393,250     |
| Shares granted                    | 506,000     | 308,000     |
| Shares vested                     | (191,250)   | (115,250)   |
| Outstanding, end of period        | 900,750     | 586,000     |

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|  | <b>2011</b> | <b>2010</b> |
|--|-------------|-------------|
| Weighted average grant date fair value of shares vested during period    | \$ 1.88     | \$ 1.41     |
| Weighted average grant date fair value of shares granted during period   | \$ 4.42     | \$ 1.65     |
| Weighted average grant date fair value of unvested shares, end of period | \$ 3.08     | \$ 1.52     |
| Weighted average remaining years to vest                                 | 2.73        | 2.90        |

At September 30, 2011 total unrecognized estimated compensation cost related to non-vested common shares was \$2,212,000, which is expected to be recognized over a weighted average period of 2.73 years. At September 30, 2011 total unrecognized estimated compensation cost related to stock options was \$924,000 which is expected to be recognized over a weighted average period of 2.16 years.

**8) BASIC AND DILUTED NET INCOME (LOSS) PER SHARE**

Basic net income (loss) per common share is based on the weighted-average number of common shares outstanding during each period. Diluted net income (loss) is based on the weighted-average shares outstanding and any contingently issuable shares. The net outstanding shares are adjusted for the dilutive effect of shares issuable upon the assumed conversion of the Company's common stock equivalents, which consist of outstanding stock options, warrants and unvested shares of common stock.

|   | <b>Three-months ended</b>         |                                   | <b>Nine-months ended</b>          |                                   |
|---|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
|   | <b>September<br/>30,<br/>2011</b> | <b>September<br/>30,<br/>2010</b> | <b>September<br/>30,<br/>2011</b> | <b>September<br/>30,<br/>2010</b> |
| Weighted average common shares outstanding-basic            | 24,649,364                        | 24,209,215                        | 24,492,137                        | 24,173,399                        |
| Stock options, warrants and unvested shares of common stock | 1,792,887                         | 449,629                           | 1,893,003                         |                                   |
| Weighted average common shares outstanding-diluted          | 26,442,251                        | 24,658,844                        | 26,385,140                        | 24,173,399                        |

The following stock options were not included in weighted average diluted common shares outstanding because they are anti-dilutive:

|                                 | <b>Three-months ended</b>         |                                   | <b>Nine-months ended</b>          |                                   |
|---------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
|                                 | <b>September<br/>30,<br/>2011</b> | <b>September<br/>30,<br/>2010</b> | <b>September<br/>30,<br/>2011</b> | <b>September<br/>30,<br/>2010</b> |
| Stock options                   | 902,000                           | 2,934,000                         | 894,000                           | 3,173,000                         |
| Warrants                        |                                   | 1,395,000                         |                                   | 1,395,000                         |
| Unvested shares of common stock | 42,000                            | 375,000                           | 14,000                            | 586,000                           |
| Total                           | 944,000                           | 4,704,000                         | 908,000                           | 5,154,000                         |

**9) SEGMENT REPORTING**

The Company has two reportable segments: Photodynamic Therapy (PDT) Drug and Device Products and Non-Photodynamic Therapy (Non-PDT) Products. Operating segments are defined as components of the Company for

which separate financial information is available to manage resources and evaluate performance regularly by the chief operating decision maker. The table below presents the revenues, costs of revenues and gross margins attributable to these reportable segments for the periods presented. The Company does not allocate research and development, selling and marketing and general and administrative expenses to its reportable segments, because these activities are managed at a corporate level.

|                                      | <b>Three-months ended</b> |                  | <b>Nine-months ended</b> |                   |
|--------------------------------------|---------------------------|------------------|--------------------------|-------------------|
|                                      | <b>September</b>          | <b>September</b> | <b>September</b>         | <b>September</b>  |
|                                      | <b>30,</b>                | <b>30,</b>       | <b>30,</b>               | <b>30,</b>        |
|                                      | <b>2011</b>               | <b>2010</b>      | <b>2011</b>              | <b>2010</b>       |
| <b>REVENUES</b>                      |                           |                  |                          |                   |
| PDT drug and device product revenues | \$ 9,374,000              | \$ 7,837,000     | \$ 30,027,000            | \$ 24,544,000     |
| Non-PDT product revenues             | 74,000                    | 179,000          | 266,000                  | 886,000           |
| <b>Total revenues</b>                | <b>9,448,000</b>          | <b>8,016,000</b> | <b>30,293,000</b>        | <b>25,430,000</b> |

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|  | <b>Three-months ended</b> |                  | <b>Nine-months ended</b> |                  |
|--|---------------------------|------------------|--------------------------|------------------|
|  | <b>September</b>          | <b>September</b> | <b>September</b>         | <b>September</b> |
|  | <b>30,</b>                | <b>30,</b>       | <b>30,</b>               | <b>30,</b>       |
|  | <b>2011</b>               | <b>2010</b>      | <b>2011</b>              | <b>2010</b>      |
| <b>COSTS OF REVENUES</b>                     |                           |                  |                          |                  |
| PDT drug and device cost of product revenues | 1,398,000                 | 1,305,000        | 4,472,000                | 4,348,000        |
| Non-PDT cost of product revenues             | 139,000                   | 323,000          | 419,000                  | 880,000          |
| Total cost of revenues                       | 1,537,000                 | 1,628,000        | 4,891,000                | 5,228,000        |
| <b>GROSS MARGIN</b>                          |                           |                  |                          |                  |
| PDT drug and device product gross margin     | 7,976,000                 | 6,532,000        | 25,555,000               | 20,196,000       |
| Non-PDT gross margin                         | (65,000)                  | (144,000)        | (153,000)                | 6,000            |
| Total gross margin                           | \$ 7,911,000              | \$ 6,388,000     | \$ 25,402,000            | \$ 20,202,000    |

During the three and nine-month periods ended September 30, 2011 and 2010, the Company derived revenues from the following geographies based on the location of the customer (as a percentage of revenues):

|               | <b>Three-months ended</b> |                  | <b>Nine-months ended</b> |                  |
|---------------|---------------------------|------------------|--------------------------|------------------|
|               | <b>September</b>          | <b>September</b> | <b>September</b>         | <b>September</b> |
|               | <b>30,</b>                | <b>30,</b>       | <b>30,</b>               | <b>30,</b>       |
|               | <b>2011</b>               | <b>2010</b>      | <b>2011</b>              | <b>2010</b>      |
| United States | 83%                       | 89%              | 93%                      | 94%              |
| Canada        | 1%                        | 2%               | 1%                       | 2%               |
| Korea         | 16%                       | 1%               | 6%                       | 1%               |
| Latin America | %                         | 8%               | %                        | 3%               |
| Total         | 100%                      | 100%             | 100%                     | 100%             |

**10) COMPREHENSIVE INCOME (LOSS)**

For the three and nine-month periods ended September 30, 2011 and 2010, comprehensive loss consisted of the following:

|  | <b>Three-months ended</b> |                  | <b>Nine-months ended</b> |                  |
|--|---------------------------|------------------|--------------------------|------------------|
|  | <b>September</b>          | <b>September</b> | <b>September</b>         | <b>September</b> |
|  | <b>30,</b>                | <b>30,</b>       | <b>30,</b>               | <b>30,</b>       |
|  | <b>2011</b>               | <b>2010</b>      | <b>2011</b>              | <b>2010</b>      |
| NET INCOME (LOSS)  | \$ 3,507,000              | \$ 33,000        | \$ 4,013,000             | \$ (203,000)     |
| Change in net unrealized gains on marketable securities available-for-sale | (16,000)                  | (36,000)         | (44,000)                 | (111,000)        |

|                             |              |            |              |              |
|-----------------------------|--------------|------------|--------------|--------------|
| COMPREHENSIVE INCOME (LOSS) | \$ 3,491,000 | \$ (3,000) | \$ 3,969,000 | \$ (314,000) |
|-----------------------------|--------------|------------|--------------|--------------|

## 11) SIGNIFICANT PRODUCT AGREEMENTS

### *Daewoong Agreement*

In the third quarter of 2011, the Company terminated its Marketing, Distribution and Supply Agreement, dated January 4, 2007, as amended, as of January 10, 2007, September 8, 2008 and June 20, 2011 with Daewoong Pharmaceutical, Co., LTD. and DNC Daewoong Derma & Plastic Surgery Network Company (collectively Daewoong ). The Company sent notice of termination of the agreement on August 31, 2011 based on DUSA's contractual right to unilaterally terminate the agreement as a result of certain regulatory milestones that were not achieved. As a result of the termination, the Company has recorded \$1,379,000 of revenues that were previously deferred, comprised of deferred drug shipments of \$301,000 and the unamortized balance of milestone payments of \$1,078,000, and has recorded \$71,000 of costs of revenues that were previously deferred. For the three and nine-month periods ended September 30, 2011 the Daewoong termination resulted in the recognition of \$1,308,000 of income from operations.

### *Stiefel Agreement*

In the third quarter of 2010, the Company gave notice to Stiefel Laboratories, Inc. ( Stiefel ) terminating the parties Marketing, Distribution and Supply Agreement, dated January 12, 2006, as amended, as of September 26, 2007. The termination of this Agreement, which had appointed Stiefel as the Company's exclusive marketing and distribution partner for the Company's product, the Levula® Kerastick®, in Latin America, resulted in the acceleration of the recognition of deferred revenues of \$555,000, comprised of deferred drug shipments of \$87,000 and the



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unamortized balance of milestone payments of \$468,000, and the acceleration of deferred cost of revenues of \$42,000. For the three and nine-month periods ended September 30, 2010 the Stiefel termination resulted in the recognition of \$513,000 of income from operations.

*Photocure Agreement*

On May 30, 2006, the Company entered into a patent license agreement under which the Company granted Photocure ASA a non-exclusive license under the patents the Company licenses from PARTEQ for ALA esters. In addition, the Company granted a non-exclusive license to Photocure for its existing formulations of Hexvix® and Metvix® (known in the U.S. as Metvixia®) for any patent the Company owns now or in the future.

Photocure is obligated to pay the Company royalties on sales of its ester products to the extent they are covered by the Company's patents in the U.S. and certain other territories. As part of the agreement, Photocure paid the Company a prepaid royalty in the amount of \$1,000,000 in 2006. Revenues recognized pursuant to the Photocure Agreement have not been material to date. The balance of the prepaid royalty under the Photocure Agreement is included in deferred revenues in the accompanying Condensed Consolidated Balance Sheets.

**12) INCOME TAXES**

There is no provision for income taxes due to the utilization of operating loss carryforwards for which a full valuation allowance had been provided. As of December 31, 2010, the Company had net operating loss carryforwards remaining of approximately \$91,504,000 and tax credit carryforwards of approximately \$1,759,000 for Federal tax purposes. These amounts expire at various times through 2030. We have concluded that it is not more-likely-than-not that the Company's deferred tax assets will be realized and therefore have provided a full valuation allowance against the deferred tax assets at September 30, 2011 and December 31, 2010. In concluding that it is not more-likely-than-not that the Company's deferred tax assets will be realized, the Company evaluated both positive and negative evidence regarding the future realization of these assets. This evaluation requires the Company to make difficult, subjective and complex judgments regarding its projections of taxable income and the amount and expiration dates of its net operating loss carryforwards and other deferred tax assets. In forming its conclusion as to whether the deferred tax assets are more likely than not to be realized, the Company has considered its historical cumulative profit and loss position, adjusted for non-recurring items, its sources of future taxable income and the projected stability of those sources. However, in future periods it is reasonably possible that the Company may release all or a portion of its valuation allowance if operations continue to improve.

Based on an Internal Revenue Code (IRC) Section 382 study performed, we determined that we have experienced prior ownership changes, as defined under IRC Section 382, with the most recent change in ownership occurring in 2007 (the 2007 Ownership Change). Our utilization of the NOL carryforwards generated prior to the 2007 Ownership Change are subject to an annual limitation of approximately \$3.0 million per year for the first five years after the ownership change. We estimate that we will be able to utilize approximately \$54.3 million of our current net operating losses, provided that sufficient income is generated and no further ownership changes were to occur. However, it is reasonably possible that a future ownership change, which could be the result of transactions involving our common stock that are outside of our control (such as sales by existing shareholders), could occur during 2011 or thereafter. Future ownership changes could further restrict our utilization of our net operating losses and tax credits, reducing or eliminating the benefit of such net operating losses and tax credits. If such future ownership changes were to occur, it is a possibility that the Company could be required to pay federal income taxes in the near-term.

**13) COMMITMENTS AND CONTINGENCIES****Business Acquisition**

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius Laboratories, Inc. ( Sirius ). The Company agreed to pay additional consideration in future periods to the former Sirius shareholders based upon the achievement of total cumulative sales milestones for the Sirius products over the period beginning with the closing of the acquisition and ending December 31, 2011, according to an amendment to the parties' agreement.

If the remaining sales milestones are attained, additional consideration will be paid in either common stock or cash, at the Company's sole discretion. The remaining cumulative sales milestones and related consideration are, as follows:

**Additional**

| <b>Cumulative Sales Milestone:</b> | <b>Consideration:</b> |
|------------------------------------|-----------------------|
| \$35.0 million                     | \$1.0 million         |
| \$45.0 million                     | \$1.0 million         |
| Total                              | \$2.0 million         |

**Third Amendment to Merger Agreement**

In April 2009, the Company and the former shareholders of Sirius entered into a letter agreement providing for the consent of the former Sirius shareholders to the Amendment to the License Agreement with River s Edge Pharmaceuticals, LLC, a release, and the Third Amendment to the Merger Agreement, dated as of December 30, 2005, by and among the DUSA Pharmaceuticals, Inc., Sirius and the shareholders of Sirius. Pursuant to the Merger Agreement prior to this amendment, the Company agreed to pay additional consideration after

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the closing of the merger to the former shareholders of Sirius based upon the attainment of pre-determined total cumulative sales milestones for the products acquired from Sirius over the period ending 50 months from the date of the March 2006 closing of the original Merger Agreement. Pursuant to the agreements entered into in April 2009, the Company agreed to extend the Milestone Termination Date from 50 months from the date of the closing of the original Merger Agreement until December 31, 2011 and to include in the definition of Net Sales in the Merger Agreement payments which the Company may receive from the divestiture of Sirius products. The Third Amendment to the Merger Agreement also removes the Company's obligation to market the Sirius products according to certain previously required standards and allows the Company to manage all business activities relating to the products acquired from Sirius without further approval from the former Sirius shareholders. In April 2009 the Company paid to the former Sirius shareholders, on a pro rata basis, \$100,000. In addition, in the event that the \$1,000,000 milestone payment that would become due to the former Sirius shareholders under the Merger Agreement if cumulative Net Sales of the Sirius products reach \$35,000,000 is not, in fact, triggered by December 31, 2011, then the Company has agreed to pay \$250,000 to the former Sirius shareholders on a pro rata basis on or before January 6, 2012. The present value of the guaranteed \$250,000 milestone payment, or \$246,000, is included in other accrued expenses in the accompanying Condensed Consolidated Balance Sheets.

The Company has not accrued amounts for any other potential contingencies as of September 30, 2011.

The Company is involved in legal matters arising in the ordinary course of business. Although the outcome of these matters cannot presently be determined, management does not expect that the resolution of these matters will have a material effect on the Company's financial position or results of operation.

**Lease Arrangements**

The Company leases its facilities under operating leases. The Company's lease arrangements have terms which expire through 2014. For the nine-month periods ended September 30, 2011 and 2010, total rent expense under operating leases was approximately \$266,000 and \$290,000, respectively. Future minimum payments under lease arrangements at September 30, 2011 are as follows:

| <b>Years Ending December 31,</b> | <b>Operating<br/>Lease<br/>Obligations</b> |
|----------------------------------|--|
| 2011                             | \$ 96,000                                  |
| 2012                             | 389,000                                    |
| 2013                             | 396,000                                    |
| 2014                             | 367,000                                    |
| <br>Total                        | <br>\$ 1,248,000                           |

**14) GAIN ON SALE OF ASSETS**

On June 30, 2011 the Company entered into an Asset Purchase Agreement with Acella Pharmaceuticals, LLC ( Acella ) pursuant to which the Company sold to Acella U.S. Patent No. 6,979,468 covering Nicomide<sup>®</sup>, together with the trademarks Nicomide<sup>®</sup> and Nicomide-T<sup>®</sup>, and related domain names (the Divested Assets ). The Divested Assets, which had a book value of \$0, were sold for cash consideration of \$750,000, all of which was paid at the closing. The Company ceased selling Nicomide<sup>®</sup> in June, 2008. The agreement includes customary representations, warranties and covenants for a transaction of this type.

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

When you read this section of this report, it is important that you also read the financial statements and related notes included elsewhere in this report. This section contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those we anticipate in these forward-looking statements for many reasons, including the factors described below and in the section entitled "Risk Factors."

We are a vertically integrated dermatology company that is developing and marketing Levulan<sup>®</sup> PDT and other products for common skin conditions. Our marketed products include Levulan<sup>®</sup> Kerastick<sup>®</sup> 20% Topical Solution with PDT, the BLU-U<sup>®</sup> brand light source, and ClindaReach<sup>®</sup>.

We devote most of our resources to advancing the development and marketing of our Levulan<sup>®</sup> PDT technology platform. In addition to our marketed products, our drug, Levulan<sup>®</sup> brand of aminolevulinic acid HCl, or ALA, in combination with light, has been studied in a broad range of medical conditions. When Levulan<sup>®</sup> is used and followed with exposure to light to treat a medical condition, it is known as Levulan<sup>®</sup> PDT. The Kerastick<sup>®</sup> is our proprietary applicator that delivers Levulan<sup>®</sup>. The BLU-U<sup>®</sup> is our patented light device.

The Levulan<sup>®</sup> Kerastick<sup>®</sup> 20% Topical Solution with PDT and the BLU-U<sup>®</sup> were launched in the United States, or U.S., in September 2000 for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. In addition, in September 2003 we received clearance from the United States Food and Drug Administration, or FDA, to market the BLU-U<sup>®</sup> without Levulan<sup>®</sup> PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

We are marketing Levulan<sup>®</sup> PDT under an exclusive worldwide license of patents, many of which have expired, and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to our BLU-U<sup>®</sup> device and methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA<sup>®</sup>, DUSA Pharmaceuticals, Inc.<sup>®</sup>, Levulan<sup>®</sup>, Kerastick<sup>®</sup>, BLU-U<sup>®</sup>, ClindaReach<sup>®</sup>, Meted<sup>®</sup>, and Psoriacap<sup>®</sup> are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Other trademark applications are pending.

We are responsible for manufacturing our Levulan<sup>®</sup> Kerastick<sup>®</sup> and for the regulatory, sales, marketing, and customer service and other related activities for all of our products, including our Levulan<sup>®</sup> Kerastick<sup>®</sup>.

Sirius Laboratories, Inc., or Sirius, a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. We merged with Sirius in March 2006. In the second quarter of 2011, we sold the patent that covers Nicomide<sup>®</sup>, the key product which we acquired from Sirius, together with the trademarks, Nicomide<sup>®</sup> and Nicomide-T<sup>®</sup>, and related domain names to Acella Pharmaceuticals, LLC for \$750,000 in cash. The entire purchase price was paid at the closing of the transaction.

**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, 2010. 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. Other than noted below, there have been no other changes to our critical accounting policies in the nine-month period ended September 30, 2011.

***Changes in Critical Accounting Policies******Income Taxes***

Prior to 2010, we had historically incurred domestic operating losses from both a financial reporting and tax return standpoint. We establish valuation allowances if it appears more likely than not that our deferred tax assets will not be realized. In concluding that it is not more-likely-than-not that our deferred tax assets will be realized, we have evaluated both positive and negative evidence regarding the future realization of these assets. This evaluation requires us to make difficult, subjective and complex judgments regarding our projections of taxable income and the amount and expiration dates of our net operating loss carryforwards and other deferred tax assets. In forming our conclusions

as to whether the deferred tax assets are more likely than not to be realized we considered our historical cumulative profit and loss position, adjusted for non-recurring items, the sources of our future taxable income and the projected stability of those sources. We have historically established valuation allowances against all of our net deferred tax assets because of our history of generating operating losses and restrictions on the use of certain items.

**RESULTS OF OPERATIONS THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2011 VERSUS SEPTEMBER 30, 2010**

**REVENUES** Total revenues for the three- and nine-month periods ended September 30, 2011 were \$9,448,000 and \$30,293,000, respectively, as compared to \$8,016,000 and \$25,430,000 in 2010, and were comprised of the following:

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|   | Three-months ended<br>September 30, |              |                         | Nine-months ended<br>September 30, |               | INCREASE/<br>(DECREASE) |
|---|-------------------------------------|--------------|-------------------------|------------------------------------|---------------|-------------------------|
|   | 2011                                | 2010         | INCREASE/<br>(DECREASE) | 2011                               | 2010          |                         |
| LEVULAN®<br>KERASTICK®<br>PRODUCT<br>REVENUES       |                                     |              |                         |                                    |               |                         |
| United States                                       | \$ 7,314,000                        | \$ 6,678,000 | \$ 636,000              | \$ 26,639,000                      | \$ 21,837,000 | \$ 4,802,000            |
| Canada  | 89,000                              | 153,000      | (64,000)                | 272,000                            | 379,000       | (107,000)               |
| Korea (1)   | 1,516,000                           | 109,000      | 1,407,000               | 1,720,000                          | 322,000       | 1,398,000               |
| Latin America (2)                                   |                                     | 602,000      | (602,000)               |                                    | 778,000       | (778,000)               |
| Subtotal Levulan®<br>Kerastick® product<br>revenues | 8,919,000                           | 7,542,000    | 1,377,000               | 28,631,000                         | 23,316,000    | 5,315,000               |
| BLU-U®<br>PRODUCT<br>REVENUES                       |                                     |              |                         |                                    |               |                         |
| United States                                       | 455,000                             | 295,000      | 160,000                 | 1,396,000                          | 1,223,000     | 173,000                 |
| Canada  |                                     |              |                         |                                    | 5,000         | (5,000)                 |
| Subtotal BLU-U®<br>product revenues                 | 455,000                             | 295,000      | 160,000                 | 1,396,000                          | 1,228,000     | 168,000                 |
| TOTAL PDT<br>PRODUCT<br>REVENUES                    | 9,374,000                           | 7,837,000    | 1,537,000               | 30,027,000                         | 24,544,000    | 5,483,000               |
| NON-PDT<br>PRODUCT<br>REVENUES                      | 74,000                              | 179,000      | (105,000)               | 266,000                            | 886,000       | (620,000)               |
| TOTAL<br>REVENUES                                   | \$ 9,448,000                        | \$ 8,016,000 | \$ 1,432,000            | \$ 30,293,000                      | \$ 25,430,000 | \$ 4,863,000            |

- 1) The three-and nine-month periods ended September 30, 2011, include the acceleration of deferred revenues of \$1,379,000, comprised of deferred drug shipments of \$301,000 and the unamortized balance of milestone payments of \$1,078,000, related to the termination of our Asia Pacific distribution agreement with Daewoong Pharmaceutical Co., LTD. and Daewoong Derma & Plastic Surgery Network Company, or Daewoong, in the third quarter of 2011.

- 2) The three- and nine-month periods ended September 30, 2010, include the acceleration of deferred revenues of \$555,000, comprised of deferred drug shipments of \$87,000 and the unamortized balance of milestone payments of \$468,000, related to the termination of our Latin American distribution agreement with Stiefel Laboratories, Inc., or Stiefel, in the third quarter of 2010.

For the three- and nine-month periods ended September 30, 2011, total PDT product revenues, comprised of revenues from our Kerastick® and BLU-U® products, were \$9,374,000 and \$30,027,000, respectively. This represents an increase of \$1,537,000, or 20%, and \$5,483,000, or 22%, over the comparable 2010 totals of \$7,837,000 and \$24,544,000, respectively. The incremental revenues on a year-to-date basis was driven primarily by increased Kerastick® and BLU-U® revenues in the United States and the acceleration of deferred revenues related to the termination of our Asia Pacific distribution agreement with Daewoong.

For the three- and nine-month periods ended September 30, 2011, Kerastick® revenues were \$8,919,000, and \$28,631,000, respectively, representing a \$1,377,000, or 18%, and \$5,315,000, or 23%, increase over the comparable 2010 totals of \$7,542,000, and \$23,316,000, respectively. Kerastick® unit sales to end-users were 54,258 and 195,177, for the three- and nine-month periods ended September 30, 2011, respectively, including on a year-to-date basis, 188,754 sold in the United States, 2,838 units sold in Canada and 3,585 sold in Korea. This represents an increase from 53,724 and 176,924 Levulan® Kerastick® units sold in the three- and nine-month periods ended September 30, 2010, respectively, including on a year-to-date basis, 167,910 sold in the United States, 4,014 units sold in Canada, 3,228 sold in Korea and 1,772 sold in Latin America. Our overall average net selling price for the Kerastick® increased to \$138.82 per unit for the first nine months of 2011 from \$126.64 per unit for the first nine months of 2010. Our average net selling price for the Kerastick® in the United States increased to \$141.12 per unit in 2011 from \$129.71 per unit in 2010. Our average net selling price for the Kerastick® includes sales made directly to our end-user customers, as well as sales made to our international distributors. The increase in 2011 Kerastick® revenues was driven mainly by an increase in sales volumes in the United States as well as an increase in our overall average unit selling price and the acceleration of deferred revenues of \$1,379,000, comprised of deferred drug shipments of \$301,000 and the unamortized balance of milestone payments of \$1,078,000, related to the termination of our Asia Pacific distribution agreement with Daewoong in the third quarter of 2011, while in the third quarter of 2010 we accelerated the recognition of \$555,000 of deferred revenues related to the termination of our Latin American distribution agreement with Stiefel.

For the three- and nine-month periods ended September 30, 2011, BLU-U® revenues were \$455,000 and \$1,396,000, respectively, representing a \$160,000, or 54%, and \$168,000, or 14%, increase over the comparable 2010 totals of \$295,000 and \$1,228,000, respectively. On a year-to-date basis in the United States BLU-U® revenues increased 14% overall resulting primarily from an increase in our overall average selling price. In the three- and nine-month periods ended September 30, 2011, there were 61 and 181 units sold, respectively, versus 39 and 179 units

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sold, respectively, in the comparable 2010 periods. All of the units sold in both years were sold in the United States, except for one that was sold in Canada in the first quarter of 2010. For the first nine months of 2011, our average net selling price for the BLU-U® increased to \$7,526 from \$6,679 in 2010. The average net selling price of the BLU-U® increased, in part, due to incentive discounting in the prior year in advance of the introduction of our new upgraded unit, which was launched in April 2010. Our BLU-U® evaluation program allows customers to take delivery for a limited number of BLU-U® units for a period of up to four months for private practitioners and up to one year for hospital clinics, before we require a purchase decision. At September 30, 2011, there were approximately 25 units in the field pursuant to this evaluation program, compared to 26 units in the field at December 31, 2010. The units are classified as inventory in the financial statements and are being amortized during the evaluation period to cost of goods sold using an estimated life for the equipment of three years.

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. We are aware that physicians are using Levulan® with the BLU-U® using short incubation times, and 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, we believe that these activities are positively affecting the sales of our products.

Non-PDT product revenues reflect the revenues generated by the products acquired as part of our acquisition of Sirius. Total Non-PDT product revenues for the three- and nine-month periods ended September 30, 2011 were \$74,000 and \$266,000, respectively, compared to \$179,000 and \$886,000, respectively for the comparable 2010 periods. In 2011, the substantial majority of the Non-PDT product revenues were from sales of ClindaReach®. In 2010, the substantial majority of the Non-PDT product revenues were from sales of ClindaReach® and royalties received from River s Edge Pharmaceuticals, LLC, or River s Edge, from sales of the AVAR® product line. Royalties from our license of the AVAR® product line with River s Edge ceased during the fourth quarter of 2010 pursuant to the terms of our agreement with River s Edge.

The increase in our total revenues for the three and nine-month periods ended September 30, 2011 compared with the comparable periods in 2010 results primarily from increased Kerastick® and BLU-U® revenues in the United States and the acceleration of deferred revenues of \$1,379,000, comprised of deferred drug shipments of \$301,000 and the unamortized balance of milestone payments of \$1,078,000, related to the termination of our Asia Pacific distribution agreement with Daewoong in the third quarter of 2011, while in the third quarter of 2010 we accelerated the recognition of \$555,000 of deferred revenues related to the termination of our Latin American distribution agreement with Stiefel.

During 2011, our PDT segment revenues in the United States grew as a result of increased demand for our product. We intend to announce an annual price increase in the fourth quarter of each year, which will become effective on January 1 of the following year. This strategy is likely to have a positive impact on sales in the fourth quarter of each year. Although we expect continued growth in our PDT segment revenues, we are susceptible to the uncertain economic conditions, particularly with our customer base in the U.S. and internationally where our product lacks reimbursement, and to increased competition particularly from Metvixia® and Allumera . Galderma, S.A., a large dermatology company, holds a non-exclusive license from us to Metvixia®, which was transferred to Galderma by Photocure ASA, our original licensee. This product received FDA approval for treatment of AKs in July 2004 and this product is directly competitive with our Levulan® Kerastick® product. While we are entitled to royalties on net sales of Metvixia®, Galderma has considerably more resources than we have, which could significantly hamper our ability to maintain or increase our market share. Metvixia® is commercially available in the U.S.; however, product revenues have not been significant to date. Also, in June 2011 Photocure announced the commercial launch of an ALA ester-based product, Allumera , as a cosmetic, which could cause disruption in the marketplace. In addition, Leo Pharma, a Danish corporation that acquired Peplin in 2010, has announced that in 2012 it will be launching PEP005 for the treatment of AKs. These products could negatively impact the market penetration of our PDT products. Our ability to maintain profitability on a quarterly basis may be affected by fluctuations in the demand for our products caused by both seasonal changes, such as when patient visits slow during summer months, and the timing of pricing changes, which may impact the purchasing patterns of our customers.



In addition, we expect our Non-PDT product revenues for the full year 2011 to be reduced from 2010 levels since the AVAR<sup>®</sup> royalty period ended during the fourth quarter of 2010. During the second quarter of 2011, we entered into an Asset Purchase Agreement with Acella Pharmaceuticals, LLC, or Acella, pursuant to which we sold to Acella U.S. Patent No. 6,979,468 covering Nicomide<sup>®</sup>, together with the trademarks Nicomide<sup>®</sup> and Nicomide-T<sup>®</sup>, and related domain names. These assets were sold for cash consideration of \$750,000, all of which was paid at the closing of the transaction. We ceased selling Nicomide<sup>®</sup> in June 2008. We continue to consider other strategic transactions for the remaining Non-PDT asset portfolio we acquired from Sirius. If such a transaction were to occur, it is at least possible that we would become obligated under the next cumulative sales milestone as described further in Footnote 13 to the Notes to the Condensed Consolidated Financial Statements.

Also see the section entitled *Risk Factors We May Not Achieve Profitability On A Quarterly Basis Unless We Can Successfully Market And Sell Higher Quantities Of Our Products.*

*Cost of Product Revenues* Cost of product revenues for the three- and nine-month periods ended September 30, 2011 were \$1,537,000 and \$4,891,000 as compared to \$1,628,000 and \$5,228,000 in the comparable periods in 2010. A summary of the components of cost of product revenues and royalties is provided below:

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|   | THREE-MONTHS ENDED SEPTEMBER 30, |              |                         |
|---|----------------------------------|--------------|-------------------------|
|   | 2011                             | 2010         | INCREASE/<br>(DECREASE) |
| <b>Levulan® Kerastick® cost of product revenues and royalties</b>   |                                  |              |                         |
| Direct and indirect Levulan® Kerastick® product costs   | \$ 628,000                       | \$ 713,000   | \$ (85,000)             |
| Royalty and supply fees (1)   | 307,000                          | 275,000      | 32,000                  |
| <br>  |                                  |              |                         |
| Subtotal Levulan® Kerastick® cost of product revenues and royalties   | \$ 935,000                       | \$ 988,000   | \$ (53,000)             |
| <br>  |                                  |              |                         |
| <b>BLU-U® cost of product revenues</b>  |                                  |              |                         |
| Direct BLU-U® product costs   | \$ 245,000                       | \$ 151,000   | \$ 94,000               |
| Other BLU-U® product costs including internal costs assigned to support products; as well as, costs incurred to ship and install the BLU-U® in physicians offices | 218,000                          | 166,000      | 52,000                  |
| <br>  |                                  |              |                         |
| Subtotal BLU-U® cost of product revenues  | \$ 463,000                       | \$ 317,000   | \$ 146,000              |
| <br>  |                                  |              |                         |
| TOTAL PDT COST OF REVENUES AND ROYALTIES  | \$ 1,398,000                     | \$ 1,305,000 | \$ 93,000               |
| <br>  |                                  |              |                         |
| Non-PDT drug cost of product revenues and royalties   | \$ 139,000                       | \$ 323,000   | \$ (184,000)            |
| <br>  |                                  |              |                         |
| TOTAL COST OF REVENUES AND ROYALTIES  | \$ 1,537,000                     | \$ 1,628,000 | \$ (91,000)             |
| <br>  |                                  |              |                         |
|   | NINE-MONTHS ENDED SEPTEMBER 30,  |              |                         |
|   | 2011                             | 2010         | INCREASE/<br>(DECREASE) |
| <b>Levulan® Kerastick® cost of product revenues and royalties</b>   |                                  |              |                         |
| Direct and indirect Levulan® Kerastick® product costs   | \$ 2,066,000                     | \$ 2,175,000 | \$ (109,000)            |
| Royalty and supply fees (1)   | 1,081,000                        | 891,000      | 190,000                 |
| <br>  |                                  |              |                         |
| Subtotal Levulan® Kerastick® cost of product revenues and royalties   | \$ 3,147,000                     | \$ 3,066,000 | \$ 81,000               |
| <br>  |                                  |              |                         |
| <b>BLU-U® cost of product revenues</b>  |                                  |              |                         |
| Direct BLU-U® product costs   | \$ 727,000                       | \$ 663,000   | \$ 64,000               |
|   | 598,000                          | 619,000      | (21,000)                |

Other BLU-U<sup>®</sup> product costs including internal costs assigned to support products; as well as, costs incurred to ship and install the BLU-U<sup>®</sup> in physicians offices

|  |              |              |              |
|--|--------------|--------------|--------------|
| Subtotal BLU-U <sup>®</sup> cost of product revenues | \$ 1,325,000 | \$ 1,282,000 | \$ 43,000    |
| TOTAL PDT COST OF REVENUES AND ROYALTIES             | \$ 4,472,000 | \$ 4,348,000 | \$ 124,000   |
| Non-PDT drug cost of product revenues and royalties  | \$ 419,000   | \$ 880,000   | \$ (461,000) |
| TOTAL COST OF REVENUES AND ROYALTIES                 | \$ 4,891,000 | \$ 5,228,000 | \$ (337,000) |

1) Royalty and supply fees reflect amounts paid to our licensor, PARTEQ, and amortization of an upfront fee and royalties paid to Draxis Health Inc. on sales of Levulan<sup>®</sup> Kerastick<sup>®</sup> in Canada.

*Margins* Total gross margins for the three- and nine-month periods ended September 30, 2011 were \$7,911,000 and \$25,402,000, respectively, as compared to \$6,388,000 and \$20,202,000 for the comparable 2010 periods, as shown below:

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|  | THREE-MONTHS ENDED<br>SEPTEMBER 30, |            |                     |            | INCREASE/<br>(DECREASE) |
|--|-------------------------------------|------------|---------------------|------------|-------------------------|
|  | 2011                                |            | 2010                |            |                         |
| Levulan <sup>®</sup> Kerastick <sup>®</sup> gross margin | \$ 7,984,000                        | 90%        | \$ 6,554,000        | 87%        | \$ 1,430,000            |
| BLU-U <sup>®</sup> gross margin                          | (8,000)                             | (2)%       | (22,000)            | (7)%       | 14,000                  |
| Total PDT product gross margin                           | \$ 7,976,000                        | 85%        | \$ 6,532,000        | 83%        | \$ 1,444,000            |
| Total Non-PDT drug gross margin                          | (65,000)                            | (87)%      | (144,000)           | (81)%      | \$ 79,000               |
| <b>TOTAL GROSS MARGIN</b>                                | <b>\$ 7,911,000</b>                 | <b>84%</b> | <b>\$ 6,388,000</b> | <b>80%</b> | <b>\$ 1,523,000</b>     |

|  | NINE-MONTHS ENDED<br>SEPTEMBER 30, |            |                      |            | INCREASE/<br>(DECREASE) |
|--|------------------------------------|------------|----------------------|------------|-------------------------|
|  | 2011                               |            | 2010                 |            |                         |
| Levulan <sup>®</sup> Kerastick <sup>®</sup> gross margin | \$ 25,484,000                      | 89%        | \$ 20,250,000        | 87%        | \$ 5,234,000            |
| BLU-U <sup>®</sup> gross margin                          | 71,000                             | 5%         | (54,000)             | (4)%       | 125,000                 |
| Total PDT product gross margin                           | \$ 25,555,000                      | 85%        | \$ 20,196,000        | 82%        | \$ 5,359,000            |
| Total Non-PDT drug gross margin                          | (153,000)                          | (58)%      | 6,000                | 1%         | \$ (159,000)            |
| <b>TOTAL GROSS MARGIN</b>                                | <b>\$ 25,402,000</b>               | <b>84%</b> | <b>\$ 20,202,000</b> | <b>79%</b> | <b>\$ 5,200,000</b>     |

Kerastick<sup>®</sup> gross margins for the three and nine-month periods ended September 30, 2011 were 90% and 89%, respectively, versus 87% for both comparable periods in 2010. The margin improvement for 2011 on a year-to-date basis is attributable to increased U.S. sales volumes, an increase in our overall average selling price, and the acceleration of deferred revenues related to the termination of our distribution agreement with Daewoong. The Daewoong termination resulted in the recognition of \$1,308,000 of gross margin, while in the third quarter of 2010 the Stiefel termination resulted in the recognition of \$513,000 of gross margin.

Our long-term goal is to achieve higher gross margins on Kerastick<sup>®</sup> sales. We believe that we can achieve improved gross margins on our Kerastick<sup>®</sup> from further volume growth and price increases in the United States.

BLU-U<sup>®</sup> margins for the three and nine-month periods ended September 30, 2011 were (2%) and 5%, respectively, versus (7%) and (4%) for the comparable 2010 periods. The increase in gross margin is the result of an increase in our average selling price. It is important for us to sell BLU-U<sup>®</sup> units in an effort to drive Kerastick<sup>®</sup> sales volumes and accordingly, we may sell BLU-U units at low profit margins.

Non-PDT drug gross margins reflect the gross margin generated by the products acquired as part of our merger with Sirius. Total Non-PDT drug gross margins for the three and nine-month periods ended September 30, 2011 were (87)% and (58)%, respectively, compared to (81)% and 1%, respectively, in the comparable prior year periods. Non-PDT cost of goods sold for 2010 includes a charge of \$48,000, net of insurance recoveries of \$273,000, related to a shipment of ClindaReach<sup>®</sup> that was lost while in-transit to us.

*Research and Development Costs* Research and development costs for the three and nine-month periods ended September 30, 2011 were \$1,307,000 and \$3,739,000 as compared to \$1,284,000 and \$3,644,000 in the comparable 2010 periods. The increase in 2011 on a year-to-date basis compared to 2010 was due primarily to increased spending related to the addition of employees.

An exploratory DUSA-sponsored clinical trial designed to study the broad area application and/or short drug incubation, or BASDI, method of using the Levulan<sup>®</sup> Kerastick<sup>®</sup> will be initiated at 10 clinical trial sites. DUSA expects that approximately 220 study subjects will be enrolled in this trial. The protocol objectives are to compare the safety and efficacy of various incubation times (1, 2 or 3 hours) of Levulan<sup>®</sup> plus BLU-U<sup>®</sup> PDT versus vehicle plus BLU-U<sup>®</sup> for the treatment of multiple actinic keratoses of the face or scalp and to investigate the potential for reduction in AK occurrence in the treatment areas. In addition to the BASDI clinical trial for the treatment of AKs of the face and scalp, a pilot DUSA-sponsored clinical trial designed to study the BASDI method of using the Levulan<sup>®</sup> Kerastick for the treatment of AKs on extremities will also be initiated at 3 clinical trial sites. DUSA expects that approximately 64 study subjects will be enrolled in this study. The objective of the study is to determine and compare the safety and efficacy of ALA-PDT versus vehicle PDT on AKs of the upper extremities, and to evaluate the effect of occlusion on the safety and efficacy of ALA-PDT, using blue light after a three hour incubation period. We are planning on initiating both studies in the fourth quarter of 2011 and therefore, expect research and development costs to increase in the fourth quarter of 2011 relative to the first three quarters. We also expect research and development expense for the full year 2011 to be increased from the prior year. We expect that the total cost of the trials will be approximately \$2.8 million over the terms of the trials.

*Marketing and Sales Costs* Marketing and sales costs for the three and nine-month periods ended September 30, 2011 were \$3,353,000 and \$10,614,000, respectively, as compared to \$2,793,000 and \$9,545,000 for the comparable 2010 periods. These costs consisted primarily of

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expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling \$2,701,000 and \$7,812,000 for the three and nine-month periods ended September 30, 2011, compared to \$2,260,000 and \$7,044,000 in the comparable periods in 2010. The increase in spending in 2011 in this category is due to increased headcount. The remaining expenses consisted of tradeshow, miscellaneous marketing and outside consultants totaling \$652,000 and \$2,802,000 for the three and nine-month periods ended September 30, 2011, compared to \$533,000 and \$2,501,000 for the comparable 2010 periods. The increase in this category on a year to date basis is due primarily to an increase in expenditures related to sales training and promotional materials. We expect marketing and sales costs for the full year 2011 to increase over 2010 levels, but to decrease as a percentage of revenues.

*General and Administrative Costs* General and administrative costs for the three and nine-month periods ended September 30, 2011 were \$2,323,000 and \$7,335,000, respectively, as compared to \$2,209,000 and \$6,919,000 for the comparable 2010 periods. The increase in 2011 is due to an increase in compensation related charges, partially offset by a decrease in professional services fees. General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period. For the full year 2011, we expect general and administrative costs to increase compared with 2010, but to decrease as a percentage of revenues.

*Gain on Sale of Assets* In the second quarter of 2011 we entered into an Asset Purchase Agreement with Acella pursuant to which we sold to Acella U.S. Patent No. 6,979,468 covering Nicomide<sup>®</sup>, together with the trademarks Nicomide<sup>®</sup> and Nicomide-T<sup>®</sup>, and related domain names. These assets, which had a book value of \$0, were sold for cash consideration of \$750,000, all of which was paid at the closing of the transaction. We ceased selling Nicomide<sup>®</sup> in June, 2008.

*Gain (Loss) on Change in Fair Value of Warrants* The warrants issued to investors in connection with the October 29, 2007 private placement were recorded initially at fair value and are marked to market each reporting period. The non-cash gains (losses) during the three and nine-month periods ended September 30, 2011 were \$2,569,000 and (\$495,000), respectively. The change in the fair value of the warrants is primarily due to changes in our stock price, our stock's historical volatility and the length of time remaining prior to expiration.

*Other Income, Net* Other income for the three and nine-month periods ended September 30, 2011, decreased to \$9,000 and \$45,000, respectively, from \$61,000 and \$189,000 during the comparable 2010 periods. The decrease is generally due to decreased returns on our investments.

*Income Taxes* There is no provision for income taxes due to the utilization of operating loss carryforwards for which a full valuation allowance had been provided. As of December 31, 2010, we had net operating loss carryforwards remaining of approximately \$91,504,000 and tax credit carryforwards of approximately \$1,759,000 for Federal tax purposes. These amounts expire at various times through 2030. We have concluded that it is not more-likely-than-not that our deferred tax assets will be realized and therefore have provided a full valuation allowance against the deferred tax assets at September 30, 2011 and December 31, 2010. In concluding that it is not more-likely-than-not that our deferred tax assets will be realized, we have evaluated both positive and negative evidence regarding the future realization of these assets. This evaluation requires us to make difficult, subjective and complex judgments regarding our projections of taxable income and the amount and expiration dates of our net operating loss carryforwards and other deferred tax assets. In forming our conclusion as to whether the deferred tax assets are more likely than not to be realized, we have considered our historical cumulative profit and loss position, adjusted for non-recurring items, our sources of future taxable income and the projected stability of those sources.

Based on an Internal Revenue Code, or IRC, Section 382 study performed, we determined that we have experienced prior ownership changes, as defined under IRC Section 382, with the most recent change in ownership occurring in 2007. Our utilization of the NOL carryforwards generated prior to the 2007 ownership change are subject to an annual limitation of approximately \$3.0 million per year for the first five years after the ownership change. We estimate that we will be able to utilize approximately \$54.3 million of our current net operating losses, provided that sufficient income is generated and no further ownership changes were to occur. However, it is reasonably possible that a future ownership change, which could be the result of transactions involving our common stock that are outside of our control (such as sales by existing shareholders), could occur during 2011 or thereafter. Future ownership changes could further restrict our utilization of our net operating losses and tax credits, reducing or eliminating the benefit of

such net operating losses and tax credits. If such future ownership changes were to occur, it is a possibility that the Company could be required to pay federal income taxes in the near-term.

*Net Income (Loss)* For the three and nine-month periods ended September 30, 2011, our net income was \$3,507,000, or \$0.13 per diluted share, and \$4,013,000, or \$0.15 per diluted share, respectively, as compared to \$33,000, or \$0.00 per share, and (\$203,000), or (\$0.01) per share for the comparable 2010 periods. The increase in our net income, or decrease in our net loss, is attributable to the reasons discussed above.

#### **LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2011, we had approximately \$24,417,000 of total liquid assets, comprised of \$23,301,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$1,116,000. We believe that our liquidity will be sufficient to meet our cash requirements for at least the next twelve months. As of September 30, 2011, our marketable securities had a weighted average yield to maturity of 4.94% and maturity dates ranging from October 2011 to January 2013. Our net cash provided by operations for the nine-month period ended September 30, 2011 was \$4,041,000 versus \$574,000 in the comparable prior year period. The year-over-year increase in cash from operations is primarily attributable to an increase in our net income, or decrease in our net loss, partially offset by an increase in deferred revenues recognized and a gain on sale of assets; as well as, year-over-year improvements in changes to working capital. Improvements in changes in accounts receivable and accounts payable, accrued compensation and other accrued expenses were partially offset by an increase in our use of cash for inventory. As of September 30, 2011 working capital (total current assets minus total current liabilities) was \$25,668,000, as compared to \$21,000,000 as

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of December 31, 2010. Total current assets increased by \$3,902,000 during the nine-month period ended September 30, 2011, due primarily to increases in cash and cash equivalents and inventory, partially offset by decreases in marketable securities, accounts receivable and prepaid and other current asset. Total current liabilities decreased by \$766,000 during the same period due primarily to decreases in accrued compensation and the current portion of deferred revenues, partially offset by increases in accounts payable and other accrued expenses. In response to the instability in the financial markets, we regularly review our marketable securities holdings, and have invested primarily in securities of the U.S. government and its agencies.

Since our inception, we have generated significant losses while we have conducted preclinical and clinical trials, engaged in research and development and dedicated resources to the commercialization of our products. We have also incurred significant losses from the impairment of assets acquired in the acquisition of Sirius. We have funded our operations primarily through public offerings, private placements of equity securities and payments received under our collaboration agreements, and more recently, with positive cash flow from operations. We expect to incur significant additional research and development and other costs including costs related to preclinical studies and clinical trials. Our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any of our existing or future products to be marketed by us or our collaborators may exceed revenues in the future, which may result in future losses from operations.

We may expand or enhance our business in the future by using our resources to acquire by license, purchase or other arrangements, additional businesses, new technologies, or products in the field of dermatology. In 2011 to date and in 2010 we focused primarily on increasing the sales of the Levulan<sup>®</sup> Kerastick<sup>®</sup> and the BLU-U<sup>®</sup>. If we are unable to maintain profitability or positive cash flow from operations, we may reduce our headcount or reduce spending in other areas. We may also seek to raise funds through financing transactions. We cannot predict whether financing will be available at all or on reasonable terms.

As part of our merger with Sirius, as amended, we agreed to pay additional consideration to the former shareholders of Sirius in future periods, based upon the attainment of pre-determined total cumulative sales milestones for the Sirius products over the period ending December 31, 2011. The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments which may be paid in cash or shares, as we may determine, are as follows:

|                             |                           |
|-----------------------------|---------------------------|
| Cumulative Sales Milestone: | Additional Consideration: |
| \$35.0 million              | \$1.0 million             |
| \$45.0 million              | \$1.0 million             |
| Total                       | \$2.0 million             |

In April 2009, we entered into the Third Amendment to the Merger Agreement, or Third Amendment. As part of the consideration for entering into the Third Amendment and related documents, we have guaranteed a payment of \$250,000 in January 2012 to the former Sirius shareholders if the \$35,000,000 sales milestone is not triggered.

We have no off-balance sheet financing arrangements.

**Contractual Obligations and Other Commercial Commitments*****Perrigo Pharmaceuticals Company***

On October 21, 2005, the former Sirius entered into a supply agreement with L. Perrigo Company, or Perrigo, for the exclusive manufacture and supply of a proprietary device/drug kit designed by Sirius pursuant to an approved abbreviated new drug application, or ANDA, owned by Perrigo. The agreement, which covers our ClindaReach<sup>®</sup> product, was assigned to us as part of the Sirius merger, and has been assigned by Perrigo to its affiliate, Perrigo Pharmaceuticals Company. During the fourth quarter of 2010, the parties executed an amendment to the agreement, which extends the initial term of the agreement through December 31, 2011, subject to certain rights to early termination. Perrigo's affiliate is entitled to royalties on net sales of the product, including certain minimum royalties. For calendar year 2011, the minimum annual royalty is \$250,000, subject to pro-rata in the event that the agreement



is terminated early.

***Merger With Sirius Laboratories, Inc.***

In March 2006, we closed our merger to acquire all of the common stock of Sirius Laboratories Inc. in exchange for cash and common stock worth up to \$30,000,000. Of the up to \$30,000,000, up to \$5,000,000, (\$1,500,000 of which would be paid in cash, and \$3,500,000 of which would be paid in cash or common stock) may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. With the launch of ClindaReach<sup>®</sup>, we were obligated to make a cash payment of \$500,000 to the former shareholders of Sirius. Also, as a consequence of the decision not to launch the product under development with another third party and pursuant to the terms of the merger agreement with Sirius, we paid \$250,000 on a pro rata basis to the former Sirius shareholders. Similarly, with our decision in early 2008 not to develop a third product from a list of product candidates acquired as part of the merger, another \$250,000 was paid on a pro rata basis to the former Sirius shareholders. The payments for ClindaReach<sup>®</sup> and the other two product decisions satisfy our obligations for the \$1,500,000 portion of the purchase price mentioned above. In the third quarter of 2008, the first of the pre-determined total cumulative sales milestones for Sirius products was achieved, and accordingly, we made a cash payment of \$1,500,000 to the former Sirius shareholders in consideration of the milestone achievement.

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Pursuant to the agreements we entered into in April 2009, including a third amendment to the merger agreement, an amendment to a license agreement with River s Edge and a release, we agreed to extend the milestone termination date from 50 months from the date of the closing of the merger until December 31, 2011 and to include in the definition of net sales in the merger agreement payments which we may receive from the divestiture of Sirius products by December 31, 2011. This amendment to the merger agreement also removes our obligation to market the Sirius products according to certain previously required standards and allows us to manage all business activities relating to the products acquired from Sirius without further approval from the former Sirius shareholders.

Also, in April 2009, we paid to the former Sirius shareholders, on a pro rata basis, \$100,000. In addition, in the event that the \$1,000,000 milestone payment that would become due to the former Sirius shareholders under the merger agreement if cumulative net sales of the Sirius products reach \$35,000,000 is not, in fact, triggered by December 31, 2011, then we have agreed to pay \$250,000 to the former Sirius shareholders on a pro rata basis on or before January 6, 2012. The present value of the guaranteed \$250,000 milestone payment, or \$246,000, is included in other accrued expenses in the accompanying Condensed Consolidated Balance Sheet as of September 30, 2011.

***PARTEQ Agreement***

We license certain patents underlying our Levulan<sup>®</sup> PDT systems under a license agreement with PARTEQ Research and Development Innovations, or PARTEQ. Under the agreement, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ patent rights, to make, have made, use and sell certain products, including ALA. The agreement covers certain use patent rights. When we sell our products directly, we have agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where we have a sublicensee, we will pay 6% and 4% when patent rights do and do not exist, respectively, on our net selling price less the cost of goods for products sold to the sublicensee, and 6% of payments we receive on sales of products by the sublicensee. We are also obligated to pay to PARTEQ 5% of any lump sum sublicense fees received, such as milestone payments, excluding amounts designated by the sublicensee for future research and development efforts.

For the years ended December 31, 2010, 2009 and 2008, actual royalties based on product sales were approximately \$1,331,000, \$1,019,000, and \$873,000, respectively. Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$96,000 as of September 30, 2011).

***National Biological Corporation Amended And Restated Purchase And Supply Agreement***

On December 7, 2010, we extended the term of the 2004 Amended and Restated Purchase and Supply Agreement with National Biological Corporation, or NBC, the primary manufacturer of our BLU-U<sup>®</sup> light source, until December 31, 2011. We have an option to further extend the term for an additional two years if we purchase a certain number of units. The parties agreed upon a tiered price schedule based on the volume of purchases and updated certain quality control provisions. All other terms and conditions of the 2004 agreement remain in effect. We are in negotiations with NBC to extend the term of this agreement.

***Sochinaz SA***

Under an agreement dated December 24, 1993, Sochinaz SA manufactures and supplies our requirements of Levulan<sup>®</sup> from its FDA approved facility in Switzerland. In 2009, our agreement was renewed until December 31, 2015 on substantially the same terms, albeit with a revised pricing schedule to cover the new term. While we can obtain alternative supply sources in certain circumstances, any new supplier would have to be GMP compliant and complete process development, validation and stability programs to become fully qualified by us and acceptable to FDA.

***Lease Agreements***

We have entered into a lease commitment for office space in Wilmington, Massachusetts. The minimum lease payments disclosed below include the non-cancelable terms of the leases.

***Research Agreements***

We have entered into various agreements for research projects and clinical studies. As of September 30, 2011, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$3,032,000. Included in this future payment is a master service agreement, effective June 15, 2001, with Therapeutics, Inc. for management services in connection with the clinical development of our products in the field of dermatology.

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The agreement was renewed on June 15, 2011 for a one year period and is renewable annually. Therapeutics is entitled to receive a bonus valued at \$50,000, in cash or stock at our discretion, upon each anniversary of the effective date.

Our contractual obligations and other commercial commitments to make future payments under contracts, including lease agreements, research and development contracts, manufacturing contracts, or other related agreements are as follows at September 30, 2011:

|                                 | Total        | 1 Yr or less | 2-3 Years    | 4-5 Years | After<br>5 |
|---------------------------------|--------------|--------------|--------------|-----------|------------|
| Operating lease obligations     | \$ 1,247,000 | \$ 387,000   | \$ 794,000   | \$ 66,000 | \$         |
| Purchase obligations (1, 2)     | 4,021,000    | 3,698,000    | 323,000      |           |            |
| Minimum royalty obligations (3) | 380,000      | 284,000      | 96,000       |           |            |
| Total obligations               | \$ 5,648,000 | \$ 4,369,000 | \$ 1,213,000 | \$ 66,000 | \$         |

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- 1) Research and development projects include various commitments including obligations for our study on a broad area application, short drug incubation method of using the Levulan® Kerastick®
- 2) In addition to the obligations disclosed above, we have contracted with Therapeutics, Inc., a clinical research organization, to manage the clinical development of our products in the field of dermatology. This organization has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from \$250,000 to \$1,250,000, depending on the regulatory phase of development of products under Therapeutics management.
- 3) Minimum royalty obligations relate to our agreements with PARTEQ and Perrigo described above. Rent expense incurred under these operating leases was approximately \$266,000 and \$290,000 for the nine-month periods ended September 30, 2011 and 2010, respectively.

**Recently Issued Accounting Guidance**

In June 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-05, *Comprehensive Income (Topic 220)* (ASU 2011-05). This newly issued accounting standard (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this ASU do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income nor do the amendments affect how earnings per share is calculated or presented. This ASU is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011, which for us means January 1, 2012. As this accounting standard only requires enhanced disclosure, the adoption of this standard will not impact our financial position or results of operations.

In May 2011, the FASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS* (ASU 2011-04). This newly issued accounting standard clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This ASU is effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011, which for us means January 1, 2012. We do not expect that adoption of this standard will have a material impact on our financial position or results of operations.

**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, we expect the overall net effect of inflation on our operations to be minimal.

**Forward-Looking Statements Safe Harbor**

This report, including the Management's Discussion and Analysis of Financial Condition and Results of Operations, contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 21E of the Securities Exchange Act of 1934 which represent our expectations or beliefs concerning future events, including, but not limited to our intention to announce a price increase on an annual basis in the fourth quarter of each year; our beliefs regarding reimbursement for our products and the effect of changes to reimbursement policies; our beliefs regarding the global credit and financial market conditions, the softness in the international markets, effects of inflation and the economic recovery; our beliefs regarding interest rate fluctuations; our beliefs concerning Non-PDT products revenues and the possible obligation to pay a sales milestone to former Sirius shareholders; our expectations regarding general and administrative costs; our beliefs regarding the sufficiency of our cash, cash equivalents and marketable securities, our liquidity and capital resource needs and our ability to be profitable each quarter; our expectations regarding potential for reduction of headcount, curtailment of variable expenses and the affect of fluctuations in the demand for our product; our beliefs regarding our ability to raise funds through financing

transactions and on reasonable terms and the impact of such future sales of securities; our beliefs regarding the outcome if some or all of our shares are sold into the public market over a short period of time; our beliefs regarding our research and development programs and expectations for costs thereof; our beliefs regarding regulatory approvals, filings and timelines, including but not limited to the future development of Levulan® and our expectations regarding the initiation of objectives and timing of our planned BASDI clinical trials; our expectations regarding our manufacturing facility or any facility of our contract manufacturers, including but not limited to expectations concerning manufacture of the BLU-U® in our facility; our beliefs regarding our manufacturing capabilities and impact on our business if problems arise; our beliefs regarding compliance with and changes to governmental laws and regulations; our beliefs concerning product liability and insurance thereof, safety procedures for hazardous materials and environmental compliance; our beliefs regarding the market for our products and our product candidates and the growth in our PDT segments revenues and beliefs regarding improved gross margins on the Kerastick® and low margins on BLU-U®; our beliefs regarding competitive products and their impact on our market share; our beliefs regarding off-label use; our expectations regarding the confidentiality of our proprietary information; our ability and intentions to obtain, secure, defend and enforce our patents and our beliefs regarding the financial impact thereof; our beliefs concerning patent disputes or patents issued to third parties and potential litigation and cost thereof; our beliefs regarding physicians' use of Allumer for the treatment of AKs and how such use may be infringing our patents; our beliefs regarding the impact of a third-party's regulatory compliance status and fulfillment of contractual obligations; our expectations regarding the adequacy and availability of insurance; our expectations regarding sales and marketing costs and efforts; our beliefs regarding the dependence on key

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personnel; our intention to pursue licensing, marketing, co-promotion, other arrangements, additional business or new technologies and our beliefs regarding collaborations; our beliefs regarding the impact of our rights plan; our beliefs regarding the volatility of our stock price and its impact on value of warrants and our Nasdaq Global Market listing; our beliefs regarding the financial impact of recent accounting standards; our conclusions on how our deferred tax assets will be realized in the future; our beliefs regarding Section 382 on our current and future NOLs and our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income and the impact of a future ownership change or change of control on the utilization by us of such NOLs and the possibility of payment of income tax in the near-term. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the timely development, FDA and foreign regulatory approval, and market acceptance of our products, environmental risks relating to our products, reliance on third-parties for the production, manufacture, sales and marketing of our products, the availability of products for acquisition and/or license on terms agreeable to us, sufficient sources of funds, the securities regulatory process, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by third-party payors, none of which can be assured. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK****Interest Rates**

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments in our investment portfolio. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our investments consist of United States government securities and high grade corporate bonds. All investments are carried at fair value, which approximates cost. In response to the instability in the global financial markets, we regularly review our marketable securities holdings, and have reduced or avoided investing in securities deemed to have increased risk.

As of September 30, 2011, the weighted average rate of return on our investments was 4.94%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of September 30, 2011, the fair market value of the portfolio would decline by approximately \$9,000. Declines in interest rates could, over time, reduce our interest income.

**Derivative Financial Instruments**

The warrants that we issued on October 29, 2007 in connection with the private placement of our common stock were determined to be derivative financial instruments and accounted for as a liability. These warrants are revalued on a quarterly basis with the change in value reflected in our earnings. We value these warrants using various assumptions, including the Company's stock price as of the end of each reporting period, the historical volatility of the Company's stock price, and risk-free interest rates commensurate with the remaining contractual term of the warrants. Changes in the Company's stock price or in interest rates would result in a change in the value of the warrants.

**ITEM 4. CONTROLS AND PROCEDURES**

We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, 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 September 30, 2011.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, DUSA's internal control over financial reporting.

**PART II OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS.**

None.

**ITEM 1A. RISK FACTORS**

Investing in our common stock is very speculative and involves a high degree of risk. You should carefully consider and evaluate all of the information in, or incorporated by reference in, this report. The following are among the risks we face related to our business, assets and operations. They are not the only ones we face. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of our common stock and you might lose all or part of your investment.

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This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. We use words such as anticipate, believe, expect, future and intend and similar expressions to identify forward-looking statements. Our actual business, financial condition and results of operations could differ materially from those anticipated in these forward-looking statements for many reasons, including the factors described below and elsewhere in this report. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this report.

**Risks Related To DUSA**

***Any Failure To Comply With Ongoing Governmental Regulations In The United States And Elsewhere Will Limit Our Ability To Market Our Products And Achieve Profitability On A Quarterly Basis.***

The manufacture and marketing of our products are subject to continuing FDA review as well as comprehensive regulation by the FDA and by state and local regulatory authorities. These laws require, among other things:

approval of manufacturing facilities, including adherence to good manufacturing and laboratory practices during production and storage,

controlled research and testing of some of these products even after approval,

control of marketing activities, including sales promotions, advertising and labeling, and

state permits for the sale and distribution of products manufactured in and out-of-state.

If we, or any of our contract manufacturers, fail to comply with these requirements, we may be limited in the jurisdictions in which we are permitted to sell our products. Additionally, if we or our manufacturers fail to comply with applicable regulatory approval requirements, a regulatory agency may:

send warning letters,

impose fines and other civil penalties on us,

seize our products,

suspend our regulatory approvals,

cease the manufacture of our products,

refuse to approve pending applications or supplements to approved applications filed by us,

refuse to permit exports of our products from the United States,

require us to recall products,

require us to notify physicians of labeling changes and/or product related problems,

impose restrictions on our operations, and/or

criminally prosecute us.

We and our manufacturers must continue to comply with current Good Manufacturing Practice regulations, or cGMP, and Quality System Regulations, or QSR, and equivalent foreign regulatory requirements. The cGMP and QSR requirements govern quality control and documentation policies and procedures. In complying with cGMP, QSR and foreign regulatory requirements, we and our third-party manufacturers will be obligated to expend time, money and effort in production, record keeping and quality control to assure that our products meet applicable specifications and



other requirements.

Manufacturing facilities are subject to ongoing periodic inspection by the FDA, including unannounced inspections. We cannot guarantee that our third-party supply sources, including our sole source supplier for the active ingredient in Levulan® and the component parts in the BLU-U®, or our own Kerastick® facility, will continue to meet all applicable FDA regulations. If we, or any of our manufacturers, fail to maintain compliance with FDA regulatory requirements, it would be time-consuming and costly to remedy the problem(s) or to qualify other sources. These consequences could have a significant adverse effect on our financial condition and operations. Additionally, if previously unknown problems with the product, a manufacturer or its facility are discovered in the future, changes in product labeling restrictions or withdrawal of the product from the market may occur. Any such problems could affect our ability to become profitable on an ongoing basis.

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Any significant interruption in our operation caused by FDA could have a negative effect on our revenues.

***We May Not Maintain Profitability On A Quarterly Basis Unless We Can Successfully Market And Sell Higher Quantities Of Our Products.***

*If A Competitive Product Is Successful Our Revenues Could Decline, And Our Ability To Maintain Profitability On A Quarterly Basis Could Be Delayed.*

Galderma, S.A., a large dermatology company, holds a non-exclusive license from us to Metvixia<sup>®</sup>, which was transferred to Galderma by Photocure ASA, our original licensee. This product received FDA approval for treatment of AKs in July 2004 and is directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product. While we are entitled to royalties on net sales of Metvixia<sup>®</sup>, Galderma has considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share and make it more difficult for us to achieve profitability on an ongoing basis. Metvixia's U.S. product revenues have not been significant to date. Also, Photocure launched an ALA ester-based product, Allumera, as a cosmetic, during the second quarter of 2011, which could cause disruption in the marketplace. In addition, Leo Pharma, a Danish corporation that acquired Peplin<sup>®</sup> in 2009, has announced that in 2012 it will be launching PEP005 for the treatment of AKs. These products could negatively impact the market penetration of our PDT products.

Our ability to be profitable on a quarterly basis may also be affected by fluctuations in the demand for our products caused by both seasonal changes, such as when patient visits slow during the summer months, and the timing of pricing changes, which may impact the purchasing patterns of our customers.

*If We Do Not Continue To Generate Positive Cash Flow, We May Need More Capital.*

We have approximately \$24,417,000 in cash, cash equivalents and marketable securities as of September 30, 2011. Our cash, cash equivalents and marketable securities should be sufficient for current operations for at least the next 12 months. Although we expect continued growth in our PDT segment revenues, we are susceptible to the uncertain economic conditions, particularly with increased competition from Metvixia<sup>®</sup> and Allumera. In addition, we expect our Non-PDT product revenues for 2011 to be reduced from 2010 levels since the AVAR<sup>®</sup> royalty period ended during the fourth quarter of 2010. If we are unable to continue to be profitable on an ongoing basis, we may have to reduce our headcount, curtail certain variable expenses, or raise funds through financing transactions.

***We Have Had Significant Cumulative Losses And May Have Losses In The Future.***

We reported net income (loss) of \$4,013,000 and (\$203,000) for the nine-month periods ended September 30, 2011 and 2010, respectively. Prior to 2010, we had a history of annual operating losses and we may incur losses in the future. We reported net income (loss) of \$2,703,000, (\$2,508,000) and (\$6,250,000) for the years ended December 31, 2010, 2009 and 2008, respectively. As of September 30, 2011, our accumulated deficit was approximately \$137,644,000. We expect to incur significant additional research and development and other costs including costs related to preclinical studies and clinical trials. Our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any of our existing or future products to be marketed by us or our distributors may exceed revenues in the future, which may result in future losses from operations.

***If We Cannot Maintain Or Improve Physician Reimbursement And/Or Convince More Private Insurance Carriers To Adequately Reimburse Physicians For Our Product, Sales May Suffer.***

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan<sup>®</sup> Kerastick<sup>®</sup> for AK therapy will be limited. While we continue to support efforts to improve reimbursement levels to physicians and are working with the major private insurance carriers to improve coverage for our therapy, if our efforts are not successful, broader adoption of our therapy and sales of our products could be negatively impacted. Although positive reimbursement changes related to AK were made over the last five years, some physicians still believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices.

If insurance companies do not cover our products, or government payors reduce the amounts of coverage or stop covering our products which are covered, our sales could be dramatically reduced.

***If Product Sales Do Not Continue to Increase, We May Not Be Able To Advance Development Of Other Potential Products As Quickly As We Would Like To, Which Would Delay The Approval Process And Marketing Of New Potential Products, If Approved.***

If we do not generate sufficient revenues from our approved products, we may be forced to delay or abandon our development program for programs we may wish to initiate. The pharmaceutical development and commercialization process is time consuming and costly, and any delays might result in higher costs which could adversely affect our financial condition and results of operations. Without sufficient product sales, we would need alternative sources of funding. There is no guarantee that adequate funding sources could be found to continue the development of our technology.

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***If We Are Unable To Obtain The Necessary Capital To Fund Our Operations, We Will Have To Delay Our Development Program And May Not Be Able To Complete Our Clinical Trials.***

We may need substantial additional funds to fully develop, manufacture, market and sell other potential products. We may obtain funds through other public or private financings, including equity financing, and/or through collaborative arrangements. We may also choose to license rights to third parties to commercialize products or technologies that we would otherwise have attempted to develop and commercialize on our own which could reduce our potential revenues. The availability of additional capital to us is uncertain. There can be no assurance that additional funding will be available to us on favorable terms, if at all. Any equity financing, if needed, would likely result in dilution to our existing shareholders, and debt financing, if available, would likely involve significant cash payment obligations and could include restrictive covenants that would adversely affect the operation of our business. Failure to raise capital, if needed, could materially adversely affect our clinical program, our financial condition, results of operations and cash flows.

***Global Credit And Financial Market Conditions May Affect Our Business.***

Sales of our products are dependent, in large part, on reimbursement from government health and administration authorities, private health insurers, distribution partners and other organizations. As a result of the global credit and financial market conditions, government authorities and private insurers may not satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenues.

Due to the tightening of global credit, there may be disruption or delay in the performance by our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including the active ingredient in Levulan<sup>®</sup> and key components of the BLU-U<sup>®</sup>, portions of our product manufacturing, conduct of clinical trials and the supply of raw materials. If such third parties are unable to satisfy their commitments to us, our business would be adversely affected.

***If The Economic Slowdown Adversely Affects Our Customer's Ability To Meet Our Payment Terms, Our Cash Flow Would Be Adversely Affected And Our Ability To Continue To Be Profitable Could Be Jeopardized.***

If our customers were unable to pay us or pay us on a timely basis for their purchases of our products, we may not be able to maintain profitability on a sustainable on-going basis, and our financial position, results of operations and cash flows could be negatively affected.

***We Have Only Three Therapies That Have Received Regulatory Approval Or Clearance, And We Cannot Predict Whether We Will Ever Develop Or Commercialize Any Other Levulan<sup>®</sup> Product Or Indications.***

*Potential Products Or PDT Indications Are In Early Stages Of Development And May Never Result In Any Additional Commercially Successful Products.*

Except for Levulan<sup>®</sup> PDT for AKs, the BLU-U<sup>®</sup> for acne, the ClindaReach<sup>®</sup> pledget and other products we acquired in our merger with Sirius, all of our other potential product candidates are being studied by independent investigators, or are at a very early stage of development, including the planning of our BASDI clinical studies. These candidates are subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

delays in product development, clinical testing or manufacturing,

unplanned expenditures in product development, clinical testing or manufacturing,

failure in clinical trials or failure to receive regulatory approvals,

emergence of superior or equivalent products,

inability to market products due to third-party proprietary rights, and

failure to achieve market acceptance.

We cannot predict how long the development of our investigational stage products will take or whether they will be medically effective. We cannot be sure that a successful market will continue to develop for our Levulan<sup>®</sup> drug technology.

*We Must Receive Separate Approval For Any Drug Or Medical Device Products Before We Can Sell Them Commercially In The United States Or Abroad.*

Any potential Levulan<sup>®</sup> product will require the approval of the FDA before it can be marketed in the United States. Before an application to the FDA seeking approval to market a new drug, called an NDA, can be filed, a product must undergo, among other things, extensive animal testing and human clinical trials. The process of obtaining FDA approvals can be lengthy, costly, and time-consuming. Following the acceptance of an NDA, the time required for regulatory approval can vary and is usually one to three years or more. The FDA may require

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additional animal studies and/or human clinical trials before granting approval. Our Levulan<sup>®</sup> PDT products are based on relatively new technology. To our knowledge, the FDA has approved only four drugs for use in photodynamic therapy, including Levulan<sup>®</sup>. This factor may lengthen the approval process. We face much trial and error and we may fail at numerous stages along the way.

We cannot predict whether we will obtain any other regulatory approvals. Data obtained from preclinical testing and clinical trials can be susceptible to varying interpretations which could delay, limit or prevent regulatory approvals. Future clinical trials may not show that Levulan<sup>®</sup> PDT is safe and effective for any new use we may study. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy.

***We Have Limited Patent Protection, And If We Are Unable To Protect Our Proprietary Rights, Competitors Might Be Able To Develop Similar Products To Compete With Our Products And Technology.***

Our ability to compete successfully depends, in part, on our ability to defend patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. We have no compound patent protection for our Levulan<sup>®</sup> brand of the compound ALA. Our basic ALA patents are for methods of detecting and treating various diseased tissues using ALA (or related compounds called precursors), in combination with light.

We own or exclusively license ALA patents and patent applications related to the following:

- methods of using ALA and its unique physical forms in combination with light to treat conditions such as AKs and acne,

- compositions and apparatus for those methods, and

- unique physical forms of ALA.

We also own patents covering our Kerastick<sup>®</sup> and BLU-U<sup>®</sup>, which also cover our AK therapy. However, other third parties may have blue light devices or drug delivery devices that do not infringe our patents.

The patents we license from PARTEQ, the licensor of our ALA patents, relating to methods of using ALA for detecting or treating disease, other than for acne and our approved indication for AKs of the face or scalp, started to expire in July 2009. The PARTEQ patent which covers our approved AK product expires in September 2013. With the newly allowed claims which issued on May 25, 2010, relating to use of our BLU-U<sup>®</sup>, we now have additional claims that relate to our AK product, and these will not expire until June 2019.

We have limited ALA patent protection outside the United States, which may make it easier for third parties to compete there. Our basic methods of treatment patents and applications have counterparts in only four foreign countries, and certain countries under the European Patent Convention. Even where we have patent protection, there is no guarantee that we will be able to enforce our patents. Additionally, enforcement of a given patent may not be practicable or an economically viable alternative. Some of the indications for which we may develop PDT therapies may not be covered by the claims in any of our existing patents. Even with the issuance of additional patents to us, other parties are free to develop other uses of ALA, including medical uses, and to market ALA for such uses, assuming that they have obtained appropriate regulatory marketing approvals. ALA in the chemical form has been commercially supplied for decades, and is not itself subject to patent protection. There are reports of third parties conducting clinical studies with ALA in countries outside the United States where PARTEQ does not have patent protection. In addition, a number of third parties are seeking patents for uses of ALA not covered by our patents. These other uses, whether patented or not, and the commercial availability of ALA, could limit the scope of our future operations because ALA products could come on the market which would not infringe our patents, but would compete with our Levulan<sup>®</sup> product even though they are marketed for different uses.

Metvixia<sup>®</sup> was approved by the FDA as a treatment of AKs in July 2004, and this ALA-derived product is directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product. While we are entitled to royalties on net sales of Metvixia, Galderma<sup>®</sup>, our licensee, has considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share. Metvixia's U.S. product revenues have not been significant to date. Physicians who use Allumera<sup>®</sup>, another ALA-derived product, for treatment of AKs, even though it is being marketed as a cosmetic product, may be infringing our patents.

While we attempt to protect our proprietary information as trade secrets through agreements with each employee, licensing partner, consultant, university, pharmaceutical company and agent, we cannot guarantee that these agreements will provide effective protection for our proprietary information. It is possible that all of the following issues could negatively impact our ability to be profitable:

these persons or entities might breach the agreements,

we might not have adequate remedies for a breach, and/or,

our competitors will independently develop or otherwise discover our trade secrets.

***Since We Now Operate The Only FDA Approved Manufacturing Facility For The Kerastick® And Continue To Rely Heavily On Sole Suppliers For The Manufacture Of Levulan®, The BLU-U®, ClindaReach®, And Meted®, Any Supply Or Manufacturing Problems Could Negatively Impact Our Sales.***

If we experience problems producing Levulan® Kerastick® units in our facility, or if any of our contract suppliers fail to supply our requirements for products or services, our business, financial condition and results of operations would suffer. Although we have received

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approval by the FDA to manufacture the BLU-U<sup>®</sup> and the Levulan<sup>®</sup> Kerastick<sup>®</sup> in our Wilmington, Massachusetts facility, at this time, with respect to the BLU-U<sup>®</sup>, we expect to utilize our own facility only as a back-up to our current third party manufacturers or for repairs.

Manufacturers and their subcontractors often encounter difficulties when commercial quantities of products are manufactured for the first time, or large quantities of products are manufactured, including problems involving:

- product yields,
- quality control,
- component and service availability,
- compliance with FDA regulations, and
- the need for further FDA approval if manufacturers make material changes to manufacturing processes and/or facilities.

We cannot guarantee that problems will not arise with production yields, costs or quality as we and our suppliers manufacture our products. Any manufacturing problems could delay or limit our supplies which would hinder our marketing and sales efforts. If our facility, any facility of our contract manufacturers, or any equipment in those facilities is damaged or destroyed, we may not be able to quickly or inexpensively replace it. Likewise, if there is quality or supply problems with any components or materials needed to manufacture our products, we may not be able to quickly remedy the problem(s). Any of these problems could cause our sales to suffer and could increase costs.

***Our Ability To Use Net Operating Loss Carryforwards And Tax Credit Carryforwards To Offset Future Taxable Income May Be Further Limited As A Result Of Past Or Future Transactions Involving Our Common Stock.***

Under Internal Revenue Code, or IRC, Section 382 the amount of our net operating loss carryforwards and other tax attributes that we may utilize to offset future taxable income, when earned, may be subject to certain limitations, based upon changes in the ownership of our common stock. In general, under IRC Section 382, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses and certain other tax assets to offset future taxable income. An ownership change occurs if the aggregate stock ownership of certain shareholders increases by more than 50 percentage points over such shareholders' lowest percentage ownership during the testing period, which is generally three years.

Based on an Internal Revenue Code, or IRC, Section 382 evaluation, we determined that we have experienced prior ownership changes, as defined under IRC Section 382, with the most recent change in ownership occurring in 2007. Our pre-change NOL carryforwards are subject to an annual limitation of approximately \$2.2 million per year. Further, additional rules provide for the enhancement of the aforementioned annual limitation for the first five years after the ownership change. A loss corporation may increase its IRC Section 382 limitation by the amount of the net unrealized built-in gain, or NUBIG, recognized within five years of the ownership change. Our calculated aggregate amount of NUBIG enhancement is approximately \$4.3 million (i.e., approximately \$868,000 per year for the first five years after the ownership change). This NUBIG enhancement will be utilized in conjunction with the approximately \$2.2 million of IRC Section 382 base annual limitation, resulting in approximately \$3.0 million per year for the first five years after the ownership change. Based on these additional factors, we estimate that we will be able to utilize approximately \$54.3 million of our current net operating losses, provided that sufficient income is generated and no further ownership changes were to occur. However, it is reasonably possible that a future ownership change, which could be the result of transactions involving our common stock that are outside of our control (such as sales by existing shareholders), could occur during 2011 or thereafter. Future ownership changes could further restrict our utilization of our net operating losses and tax credits, reducing or eliminating the benefit of such net operating losses and tax credits. If such future ownership changes were to occur, it is a possibility that the Company could be required to pay federal income taxes in the near-term.

***We Have Only A Limited Marketing And Sales Force Organization And As A Result, Our Revenues From Product Sales May Suffer.***

If we are unable to successfully market and sell sufficient quantities of our products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. We directly market our products in the United States. In Canada, we market Levulan<sup>®</sup> and the BLU-U<sup>®</sup> through a distributor. We have terminated our agreements with other foreign distributors. If our sales and marketing efforts fail, then sales of the Levulan<sup>®</sup>



Kerastick®, the BLU-U®, and other products will be adversely affected, which would adversely affect our results of operations and financial condition.

***The Commercial Success Of Any Product That We May Develop Will Depend Upon The Degree Of Market Acceptance Of Our Products Among Physicians, Patients, Health Care Payors, Private Health Insurers And The Medical Community.***

Our ability to commercialize any product that we may develop will be highly dependent upon the extent to which the product gains market acceptance among physicians, patients, health care payors, such as Medicare and Medicaid, private health insurers, including managed care organizations and group purchasing organizations, and the medical community. If a product does not achieve an adequate level of acceptance, we may not generate material product revenues. The degree of market acceptance of our currently marketed products will depend on a number of factors, including:

the effectiveness, or perceived effectiveness, of our product in comparison to competing products,

the existence of any significant side effects, as well as their severity in comparison to any competing products,

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potential advantages over alternative treatments,  
the ability to offer our product for sale at competitive prices,  
relative convenience and ease of administration,  
the strength of marketing and distribution support, and  
sufficient third-party coverage or reimbursement.

***Litigation Is Expensive And We May Not Be Able To Afford The Costs.***

The costs of litigation or any proceeding relating to our intellectual property or contractual rights could be substantial even if resolved in our favor. Some of our competitors have far greater resources than we do and may be better able to afford the costs of complex litigation. Also, in a lawsuit against a third party for infringement of our patents in the United States, that third party may challenge the validity of our patent(s). We cannot guarantee that a third party will not claim, with or without merit, that our patents are not valid or that we have infringed their patent(s) or misappropriated their proprietary material. We could get drawn into or decide to join, litigation as the holder of the patent. Defending these types of legal actions involve considerable expense and could negatively affect our financial results.

Additionally, if a third-party were to file a United States patent application, or be issued a patent claiming technology also claimed by us in a pending United States application(s), we may be required to participate in interference proceedings in the USPTO to determine the priority of the invention. A third-party could also request the declaration of a patent interference between one of our issued United States patents and one of its patent applications. Any interference proceedings likely would require participation by us and/or PARTEQ, which could involve substantial legal fees and result in a loss or lessening of our patent protection.

***Because Of The Nature Of Our Business, The Loss Of Key Members Of Our Management Team Could Delay Achievement Of Our Goals.***

We are a small company with only 94 employees, including 1 part-time employee, as of September 30, 2011. We are highly dependent on several key officer/employees with specialized scientific and technical skills without whom our business, financial condition and results of operations would suffer, especially in the photodynamic therapy portion of our business. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very few people with their expertise could be hired. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain other qualified personnel in our specialty drug and light device areas.

***Collaborations With Outside Scientists May Be Subject To Restriction And Change.***

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These scientists and advisors are not our employees and may have other commitments that limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

**Risks Related To Our Industry**

***Product Liability And Other Claims Against Us May Reduce Demand For Our Products Or Result In Damages.***

***We Are Subject To Risk From Potential Product Liability Lawsuits Which Could Negatively Affect Our Business.***

The development, manufacture and sale of medical products expose us to product liability claims related to the use or misuse of our products. Product liability claims can be expensive to defend and may result in significant judgments against us. A successful claim could materially harm our business, financial condition and results of operations. Additionally, we cannot guarantee that continued product liability insurance coverage will be available in the future at acceptable costs. If we believe the cost of coverage is too high, we may self-insure.

*Our Business Involves Environmental Risks And We May Incur Significant Costs Complying With Environmental Laws And Regulations.*

We have used various hazardous materials, such as mercury in fluorescent tubes in our research and development activities. We are subject to federal, state and local laws and regulations which govern the use, manufacture, storage, handling and disposal of hazardous materials and specific waste products. We believe that we are in compliance in all material respects with currently applicable environmental laws and regulations. However, we cannot guarantee that we will not incur significant costs to comply with environmental laws and regulations in the future. We also cannot guarantee that current or future environmental laws or regulations will not materially adversely affect our operations, business or financial condition. In addition, although we believe our safety procedures for handling and disposing of these materials comply

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with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages, and this liability could exceed our resources.

***We May Not Be Able To Compete Against Traditional Treatment Methods Or Keep Up With Rapid Changes In The Biotechnology And Pharmaceutical Industries That Could Make Some Or All Of Our Products Non-Competitive Or Obsolete.***

*Competing Products And Technologies Based On Traditional Treatment Methods May Make Our Products Or Potential Products Noncompetitive Or Obsolete.*

Well-known pharmaceutical, biotechnology and medical device companies are marketing well-established therapies for the treatment of AKs and acne. Doctors may prefer to use familiar methods, rather than trying our products. Reimbursement issues affect the economic competitiveness of our products as compared to other more traditional therapies.

Many companies are also seeking to develop new products and technologies, and receiving approval for treatment of AKs and acne. Our industry is subject to rapid, unpredictable and significant technological change. Competition is intense. Our competitors may succeed in developing products that are safer, more effective or more desirable than ours. Many of our competitors have substantially greater financial, technical and marketing resources than we have. In addition, several of these companies have significantly greater experience than we do in developing products, conducting preclinical and clinical testing and obtaining regulatory approvals to market products for health care. We cannot guarantee that new drugs or future developments in drug technologies will not have a material adverse effect on our business. Increased competition could result in:

price reductions,

lower levels of third-party reimbursements,

failure to achieve market acceptance, and

loss of market share,

any of which could adversely affect our business, results of operations and financial condition.

Further, we cannot give any assurance that developments by our competitors or future competitors will not render our technology obsolete or less advantageous.

Galderma, S.A., a large dermatology company, holds a non-exclusive license from us to Metvixia<sup>®</sup>, which was transferred to Galderma by Photocure ASA, our original licensee. This product received FDA approval for treatment of AKs in July 2004 and is directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product and its price is comparable to the price of Levulan<sup>®</sup>. While we are entitled to royalties on net sales of Metvixia<sup>®</sup>, Galderma has considerably more resources than we have, which could significantly hamper our ability to maintain or increase our market share. Metvixia's U.S. product revenues have not been significant to date. Also, Leo Pharma (PEP005), could negatively impact the market penetration of our PDT products.

***Our Competitors In The Biotechnology And Pharmaceutical Industries May Have Better Products, Manufacturing Capabilities Or Marketing Expertise.***

We are aware of several companies commercializing and/or conducting research with ALA or ALA-related compounds, including: Galderma, medac GmbH and photonamic GmbH & Co. KG (Germany); Biofrontera, PhotoTherapeutics, Inc. (U.K.), and Photocure ASA (Norway). We also anticipate that we will face increased competition as the scientific development of PDT advances and new companies enter our markets. Several companies are developing PDT agents other than Levulan<sup>®</sup>. These include: QLT Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); Leo Pharma A/S (Denmark), and Pharmacyclics, Inc. (U.S.). There are many pharmaceutical companies that compete with us in the field of dermatology, particularly in the acne market.

We expect that our principal methods of competition with other PDT products will be based upon such factors as:

the ease of administration of our method of PDT,

the degree of generalized skin sensitivity to light,

the number of required doses,

the selectivity of our drug for the target lesion or tissue of interest, and

the type and cost of our light systems.

Our primary competition in the acne market includes oral and topical antibiotics, other topical prescription and over-the-counter products, as well as various laser and non-laser light treatments. The market is highly competitive and other large and small companies have more

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experience than we do which could make it difficult for us to penetrate the market. The entry of new products from time to time would likely cause us to lose market share.

**Risks Related To Our Stock**

***Our Stock Price Is Highly Volatile And Sudden Changes In The Market Value Of Our Stock Occur Making An Investment Risky.***

The price of our common stock has been highly volatile, which may create an increase in the risk of capital losses for our shareholders. From January 1, 2010 to September 30, 2011, the closing price of our stock has ranged from a low of \$1.35 to a high of \$6.77. The significant general market volatility in similar stage pharmaceutical and biotechnology companies also made the market price of our stock volatile.

***Significant Fluctuations In Orders For Our Products, On A Monthly And Quarterly Basis, Are Commonly Based On External Factors And Sales Promotion Activities. These Fluctuations Could Increase The Volatility Of Our Stock Price.***

The price of our common stock may be affected by the amount of quarterly shipments of our products to end-users. Since our PDT products are still in relatively early stages of adoption, and sales volumes are still low, a number of factors could affect product sales levels and growth rates in any period. These could include the level of penetration in new markets outside of the United States, the timing of medical conferences, sales promotion activities, and large volume purchases by our higher usage customers. In addition, seasonal fluctuations in the number of patients seeking treatment at various times during the year could impact sales volumes. These factors could, in turn, affect the volatility of our stock price.

***Future Sales Of Securities May Cause Our Stock Price To Decline.***

As of September 30, 2011, there were outstanding options and warrants to purchase 3,960,000 shares of common stock, with exercise prices ranging from \$1.10 to \$15.90 per share for options, and \$2.85 per share for warrants. In addition, there were approximately 901,000 shares of unvested common stock. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. Also, if some or all of such shares are sold into the public market over a short period of time, the value of all publicly traded shares could decline, as the market may not be able to absorb those shares at then-current market prices. Additionally, such sales may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all. The holders may exercise their securities during a time when we would likely be able to raise capital from the public on terms more favorable than those provided in these securities.

***Our Common Stock May Not Continue To Trade On The Nasdaq Global Market, Which Could Reduce The Value Of Your Investment And Make Your Shares More Difficult To Sell.***

In order for our common stock to trade on the Nasdaq Global Market, we must continue to meet the listing standards of that market. Among other things, those standards require that our common stock maintain a minimum closing bid price of at least \$1.00 per share. During 2009 and 2010, our common stock traded at prices near and below \$1.00. If we do not continue to meet Nasdaq's applicable minimum listing standards, Nasdaq could delist us from the Nasdaq Global Market. If our common stock is delisted from the Nasdaq Global Market, we could seek to have our common stock listed on the Nasdaq Capital Market or other Nasdaq markets. However, delisting of our common stock from the Nasdaq Global Market could hinder your ability to sell, or obtain an accurate quotation for the price of, your shares of our common stock. Delisting could also adversely affect the perception among investors of DUSA and its prospects, which could lead to further declines in the market price of our common stock. Delisting may also make it more difficult and expensive for us to raise capital. In addition, delisting might subject us to a Securities and Exchange Commission rule that could adversely affect the ability of broker-dealers to sell or make a market in our common stock, thus hindering your ability to sell your shares.

***Effecting A Change Of Control Of DUSA Would Be Difficult, Which May Discourage Offers For Shares Of Our Common Stock.***

Our certificate of incorporation authorizes the board of directors to issue up to 100,000,000 shares of stock, 40,000,000 of which are common stock. The board of directors has the authority to determine the price, rights, preferences and privileges, including voting rights, of the remaining 60,000,000 shares without any further vote or

action by the shareholders. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future.

On September 27, 2002, we adopted a shareholder rights plan at a special meeting of our board of directors. The rights plan could discourage, delay or prevent a person or group from acquiring 15% or more of our common stock, thereby limiting, perhaps, the ability of certain of our shareholders to benefit from such a transaction.

The rights plan provides for the distribution of one right as a dividend for each outstanding share of our common stock to holders of record as of October 10, 2002. Each right entitles the registered holder to purchase one one-thousandths of a share of preferred stock at an exercise price of \$37.00 per right. The rights will be exercisable subsequent to the date that a person or group either has acquired, obtained the right to acquire, or commences or discloses an intention to commence a tender offer to acquire, 15% or more of our outstanding common stock or if a person or group is declared an Adverse Person, as such term is defined in the rights plan. The rights may be redeemed by us at a redemption price of one one-hundredth of a cent per right until ten days following the date the person or group acquires, or discloses an intention to acquire, 15% or more, as the case may be, of DUSA, or until such later date as may be determined by our board of directors.

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Under the rights plan, if a person or group acquires the threshold amount of common stock, all holders of rights (other than the acquiring person or group) may, upon payment of the purchase price then in effect, purchase shares of common stock of DUSA having a value of twice the purchase price. In the event that we are involved in a merger or other similar transaction where we are not the surviving corporation, all holders of rights (other than the acquiring person or group) shall be entitled, upon payment of the purchase price then in effect, to purchase common stock of the surviving corporation having a value of twice the purchase price. The rights will expire on October 10, 2012, unless previously redeemed. Our board of directors has also adopted certain amendments to our certificate of incorporation consistent with the terms of the rights plan.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

**ITEM 4. [REMOVED AND RESERVED].**

**ITEM 5. OTHER INFORMATION.**

On November 10, 2011, DUSA Pharmaceuticals, Inc. issued a press release announcing summary financial results for the fiscal quarter ended September 30, 2011. The press release issued in connection with such announcement is attached hereto as Exhibit 99.1.

**ITEM 6. EXHIBITS**

EXHIBIT

| NO.    | DESCRIPTION OF EXHIBIT  |
|--------|---|
| 3(a.1) | Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference.   |
| 3(a.2) | Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, and is incorporated herein by reference. |
| 3(b)   | By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant's current report on Form 8-K, filed on November 2, 2008, and is incorporated herein by reference.   |
| 31(a)  | Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.  |
| 31(b)  | Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.  |
| 32(a)  | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.   |
| 32(b)  | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.   |
| 99.1   | Press Release dated November 10, 2011.  |



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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/ Robert F. Doman  
Robert Doman  
President and Chief Executive Officer  
(principal executive officer)

Dated: November 10, 2011

By: /s/ Richard C. Christopher  
Richard C. Christopher  
Vice President, Finance and  
Chief Financial Officer  
(principal financial officer)

Dated: November 10, 2011

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**EXHIBIT INDEX**

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