

DUSA PHARMACEUTICALS INC

Form 10-Q

November 05, 2010

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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, 2010**

☐ **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 Website, 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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input type="checkbox"/>
(Do not check if a 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 4, 2010, the registrant had 24,228,215 shares of Common Stock, no par value per share, outstanding.



**DUSA PHARMACEUTICALS, INC.**  
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	September 30, 2010	December 31, 2009
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 6,184,261	\$ 7,613,378
Marketable securities, at fair value	10,796,735	9,055,959
Accounts receivable, net of allowance for doubtful accounts of \$63,000 and \$86,000 in 2010 and 2009, respectively	2,451,709	2,629,189
Inventory	2,269,605	2,170,275
Prepaid and other current assets	935,815	1,561,467
<b>TOTAL CURRENT ASSETS</b>	<b>22,638,125</b>	<b>23,030,268</b>
Restricted cash	174,587	174,255
Property, plant and equipment, net	1,494,630	1,660,755
Deferred charges and other assets	68,099	68,099
<b>TOTAL ASSETS</b>	<b>\$ 24,375,441</b>	<b>\$ 24,933,377</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 675,870	\$ 630,144
Accrued compensation	1,029,035	1,260,609
Other accrued expenses	2,128,985	2,456,612
Deferred revenues	475,034	902,597
<b>TOTAL CURRENT LIABILITIES</b>	<b>4,308,924</b>	<b>5,249,962</b>
Deferred revenues	2,255,650	2,906,020
Warrant liability	1,299,869	812,905
Other liabilities	80,015	123,016
<b>TOTAL LIABILITIES</b>	<b>7,944,458</b>	<b>9,091,903</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: 24,221,715 and 24,108,908 shares of common stock, no par, at September 30, 2010 and December 31, 2009, respectively	151,801,550	151,683,399
Additional paid-in capital	9,077,912	8,291,805
Accumulated deficit	(144,562,682)	(144,359,217)
Accumulated other comprehensive income	114,203	225,487

TOTAL SHAREHOLDERS' EQUITY	16,430,983	15,841,474
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 24,375,441	\$ 24,933,377

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

	Three-months ended September 30,		Nine-months ended September 30,	
	2010	2009	2010	2009
Product revenues	\$ 8,015,546	\$ 6,930,110	\$ 25,430,363	\$ 21,033,920
Cost of product revenues	1,627,782	1,594,692	5,228,075	4,973,782
<b>GROSS MARGIN</b>	<b>6,387,764</b>	<b>5,335,418</b>	<b>20,202,288</b>	<b>16,060,138</b>
Operating costs:				
Research and development	1,283,771	963,245	3,643,849	3,225,049
Marketing and sales	2,792,780	3,013,351	9,544,564	9,460,766
General and administrative	2,208,898	1,877,928	6,919,128	6,360,325
Settlements, net				75,000
<b>TOTAL OPERATING COSTS</b>	<b>6,285,449</b>	<b>5,854,524</b>	<b>20,107,541</b>	<b>19,121,140</b>
<b>INCOME (LOSS) FROM OPERATIONS</b>	<b>102,315</b>	<b>(519,106)</b>	<b>94,747</b>	<b>(3,061,002)</b>
Other income	61,183	79,815	188,752	223,801
(Loss) gain on change in fair value of warrants	(130,674)	24,051	(486,964)	(37,679)
<b>NET INCOME (LOSS)</b>	<b>\$ 32,824</b>	<b>\$ (415,240)</b>	<b>\$ (203,465)</b>	<b>\$ (2,874,880)</b>
<b>BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE</b>	<b>\$ 0.00</b>	<b>\$ (0.02)</b>	<b>\$ (0.01)</b>	<b>\$ (0.12)</b>
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING, BASIC</b>	<b>24,209,215</b>	<b>24,108,908</b>	<b>24,173,399</b>	<b>24,099,786</b>
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING, DILUTED</b>	<b>24,658,844</b>	<b>24,108,908</b>	<b>24,173,399</b>	<b>24,099,786</b>

See the accompanying Notes to the Condensed Consolidated Financial Statements.



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

	Nine-months ended September 30,	
	2010	2009
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (203,465)	\$ (2,874,880)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Accretion of premiums and discounts on marketable securities	5,236	43,407
Realized loss on sales of marketable securities		43,678
Share-based compensation	920,755	631,770
Depreciation and amortization	295,020	345,720
Loss on change in fair value of warrants	486,964	37,679
Deferred revenues recognized	(1,077,933)	(661,702)
Changes in other assets and liabilities impacting cash flows from operations:		
Accounts receivable	177,480	(151,411)
Inventory	(99,330)	476,658
Prepaid and other current assets	625,652	318,994
Accounts payable, accrued compensation and other accrued expenses	(513,474)	(1,626,748)
Other liabilities	(43,001)	(111,129)
<b>NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES</b>	<b>573,904</b>	<b>(3,527,964)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of marketable securities	(12,742,296)	(12,049,905)
Proceeds from maturities and sales of marketable securities	10,885,000	16,848,159
Restricted cash	(332)	(326)
Purchases of property, plant and equipment	(128,896)	(129,230)
<b>NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES</b>	<b>(1,986,524)</b>	<b>4,668,698</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from exercise of stock options	25,993	
Settlements of restricted stock for tax withholding obligations	(42,490)	(4,413)
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<b>(16,497)</b>	<b>(4,413)</b>
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(1,429,117)</b>	<b>1,136,321</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>7,613,378</b>	<b>3,880,673</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 6,184,261</b>	<b>\$ 5,016,994</b>

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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**DUSA PHARMACEUTICALS, INC.**

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

**1) BASIS OF PRESENTATION**

The Condensed Consolidated Balance Sheet as of September 30, 2010, the Condensed Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2010 and 2009, and the Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2010 and 2009 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, 2009 filed with the Securities and Exchange Commission. The balance sheet as of December 31, 2009 has been 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.

**2) NEW ACCOUNTING PRONOUNCEMENTS**

*Accounting Standards Recently Adopted*

In April 2010, the FASB issued ASU 2010-17, *Revenue Recognition - Milestone Method (Topic 605): Milestone Method of Revenue Recognition* ( ASU 2010-17 ). ASU 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and non-substantive milestones, and each milestone should be evaluated individually to determine if it is substantive. ASU 2010-17 became effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after September 15, 2010, with early adoption permitted. The Company adopted this guidance as of July 1, 2010. The adoption of ASU 2010-17 did not have a material impact on the Company.

*Accounting Standards To Be Adopted*

In October 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU No. 2009-13). ASU No. 2009-13, which amends existing revenue recognition accounting pronouncements, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. If the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after September 15, 2010, which for the Company means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 will require the Company to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. The potential impact of this standard is being evaluated.

### **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.

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Level 2: Observable market based inputs for similar assets 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.

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

		<b>Fair Value Measurements at September 30, 2010</b>		
	<b>Carrying Value</b>	<b>(Level 1)</b>	<b>(Level 2)</b>	<b>(Level 3)</b>
<b>Assets</b>				
Cash and cash equivalents	\$ 6,184,000	\$ 6,184,000	\$	\$
United States government-backed securities	10,010,000		10,010,000	
Corporate debt securities	787,000		787,000	
Total assets at fair value	16,981,000	6,184,000	10,797,000	
<b>Liabilities</b>				
Warrant liability	1,300,000			1,300,000
Total liabilities at fair value	\$ 1,300,000	\$	\$	\$ 1,300,000

		<b>Fair Value Measurements at December 31, 2009</b>		
	<b>Carrying Value</b>	<b>(Level 1)</b>	<b>(Level 2)</b>	<b>(Level 3)</b>
<b>Assets</b>				
Cash and cash equivalents	\$ 7,613,000	\$ 7,613,000	\$	\$
United States government-backed securities	8,150,000		8,150,000	
Corporate debt securities	906,000		906,000	
Total assets at fair value	16,669,000	7,613,000	9,056,000	
<b>Liabilities</b>				
Warrant liability	813,000			813,000
Total liabilities at fair value	\$ 813,000	\$	\$	\$ 813,000

The Company reviewed the level classifications of its investments at September 30, 2010 compared to December 31, 2009 and determined that there were no significant transfers between levels in the nine-month period ended September 30, 2010.

The table below includes a rollforward of the balance sheet amounts for the nine-month periods ended September 30, 2010 and 2009 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). Accordingly, the gains and losses in the table below include changes in fair value due in part to observable factors that are part of the methodology.

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

	<b>Fair Value</b>	<b>Total</b>	<b>Purchases, Sales, Issuances, Settlements, net</b>	<b>Transfers In and/or Out of Level 3</b>	<b>Fair Value at September 30, 2010</b>	<b>Change in Unrealized Gains Related to Financial Instruments Held at September 30 2010</b>
	<b>at January 1, 2010</b>	<b>Unrealized Loss</b>				
Warrant Liability	\$813,000	\$487,000	\$	\$	\$1,300,000	\$(487,000)

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)**  
**Nine-month Period Ended September 30, 2009**

	<b>Fair Value</b>	<b>Total</b>	<b>Purchases, Sales, Issuances, Settlements, net</b>	<b>Transfers In and/or Out of Level 3</b>	<b>Fair Value at September 30, 2009</b>	<b>Change in Unrealized Gains Related to Financial Instruments Held at September 30, 2009</b>
	<b>at January 1, 2009</b>	<b>Unrealized Loss</b>				
Warrant Liability	\$436,000	\$38,000	\$	\$	\$474,000	\$(38,000)

*Marketable Securities*

The Company's marketable securities consist of the following:

	<b>Amortized Cost</b>	<b>September 30, 2010 Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
United States government-backed securities	\$ 9,955,000	\$ 55,000	\$	\$ 10,010,000
Corporate debt securities	728,000	59,000		787,000
Total marketable securities	\$ 10,683,000	\$ 114,000	\$	\$ 10,797,000

**December 31, 2009**  
**Gross                  Gross**

	<b>Amortized Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>
United States government-backed securities	\$ 8,005,000	\$ 145,000	\$	\$ 8,150,000
Corporate debt securities	826,000	80,000		906,000
Total marketable securities	\$ 8,831,000	\$ 225,000	\$	\$ 9,056,000

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, 2010 and 2009 was \$111,000 and \$105,000, 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 and \$44,000 for the nine-month periods ended September 30, 2010 and 2009, respectively. As of September 30, 2010, current yields range from 0.1% to 6.1% and maturity dates range from January 2011 to December 2013.

#### *Common Stock Warrants*

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 (losses) gains for the three and nine-month periods ended September 30, 2010 were \$(131,000) and \$(487,000), respectively, compared with \$24,000 and \$(38,000), respectively, for the comparable 2009 periods. At September 30,

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2010 and December 31, 2009, the aggregate fair value of these warrants was \$1,300,000 and \$813,000, respectively. Assumptions used for the Black-Scholes option-pricing models in determining the fair value as of September 30, 2010 and December 31, 2009 are as follows:

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
Expected volatility	83.6%	88.0%
Remaining contractual term (years)	2.6	3.3
Risk-free interest rate	0.53%	1.9%
Expected dividend yield	0%	0%
Common stock price	\$ 2.45	\$ 1.60

**4) CONCENTRATIONS**

The Company is exposed to concentrations of credit risk related to accounts receivable that are generated from its customers. From time to time, the Company is also exposed to concentrations of revenues with significant customers. To manage credit risk, the Company performs regular credit evaluations of its customers and provides allowances for potential credit losses, when applicable. Concentrations in the Company's total revenues for the three and nine months ended September 30, 2010 and 2009, and accounts receivable as of September 30, 2010 and December 31, 2009 are as follows:

	% of Revenue		% of Revenue		% of Accounts Receivable	
	Three months ended		Nine months ended		September December	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009	September 30, 2010	December 31, 2009
Customer A	3%	3%	3%	3%	5%	3%
Customer B	2%	3%	2%	3%	5%	5%
Customer C	2%	2%	2%	3%	3%	4%
Other customers	93%	92%	93%	91%	87%	88%
Total	100%	100%	100%	100%	100%	100%

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 30, 2010</b>	<b>December 31, 2009</b>
Finished goods	\$ 1,157,000	\$ 974,000
BLU-U® evaluation units	121,000	58,000
Work in process	345,000	398,000



Raw materials	647,000	740,000
Total	\$ 2,270,000	\$ 2,170,000

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 product revenues using an estimated life of three years to approximate its net realizable value.

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Other accrued expenses consisted of the following:

	September 30, 2010	December 31, 2009
Research and development costs	\$ 104,000	\$ 92,000
Marketing and sales costs	157,000	418,000
Reserve for sales returns and allowances	150,000	225,000
Other product related costs	775,000	849,000
Legal and other professional fees	403,000	334,000
Due to former Sirius shareholders	228,000	214,000
Employee benefits	284,000	271,000
Other accrued expenses	28,000	54,000
Total	\$2,129,000	\$2,457,000

**7) SHARE-BASED COMPENSATION***Modifications To Equity Awards For Former Members Of The Board Of Directors*

During the third quarter of 2010, the Company modified the terms of stock options and restricted stock awards to three former members of the Company's board of directors. The modifications included both extending the post-termination exercise period for stock options and accelerating the vesting of restricted stock awards. The modification to the restricted stock awards accelerated the vesting on all 11,250 shares of unvested restricted stock. As a result of these modifications, the Company recorded a non-cash charge to earnings of \$176,000 during the third quarter of 2010, which is included in general and administrative in the following table.

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, 2010 and 2009 included the following line items:

	Three-months ended		Nine-months ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Cost of product revenues	\$ 11,000	\$ 13,000	\$ 38,000	\$ 47,000
Research and development	29,000	31,000	94,000	112,000
Marketing and sales	37,000	62,000	83,000	65,000
General and administrative	356,000	101,000	706,000	408,000
Share-based compensation expense	\$433,000	\$ 207,000	\$921,000	\$ 632,000

*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, 2010 were \$1.58 and \$1.18 per share, respectively, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	Three months ended September 30, 2010	Nine months ended September 30, 2010
Expected volatility	75.80%	75.45%

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Risk-free interest rate	1.82%	2.60%
Expected dividend yield	0%	0%
Expected life-directors and officers (years)	6.03	6.03
Expected life-non-officer employees (years)	5.77	5.77

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A summary of stock option activity for the nine-month period ended September 30, 2010 is as follows:

		Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, beginning of period, January 1, 2010	2,664,000	\$ 6.71		\$
Options granted	731,100	\$ 1.75		
Options forfeited	(19,800)	\$ 2.17		
Options expired	(181,900)	\$ 25.84		
Options exercised	(20,650)	\$ 1.26		
Outstanding, end of period	3,172,750	\$ 4.54	4.66	\$ 1,600,037
Exercisable, end of period	1,872,238	\$ 6.56	3.94	\$ 457,539
Options vested and expected to vest, end of period	3,013,008	\$ 4.70	4.59	\$ 1,455,923

*Unvested Shares Of Common Stock*

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

	2010	2009
Outstanding, beginning of period, January 1, 2010	393,250	91,000
Shares granted	308,000	325,000
Shares vested	(115,250)	(22,750)
Outstanding, end of period, September 30, 2010	586,000	393,250
Weighted average grant date fair value of shares vested during period	\$ 1.41	\$ 2.20
Weighted average grant date fair value of shares granted during period	\$ 1.65	\$ 1.22
Weighted average grant date fair value of unvested shares, end of period	\$ 1.52	\$ 1.39
Weighted average remaining years to vest	2.90	3.30

At September 30, 2010 total unrecognized estimated compensation cost related to non-vested common shares was \$674,000, which is expected to be recognized over a weighted average period of 2.9 years. At September 30, 2010 total unrecognized estimated compensation cost related to stock options was \$1,015,000 which is expected to be recognized over a weighted average period of 2.75 years.

**8) BASIC AND DILUTED NET 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.

Three months ended

Nine months ended

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	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Weighted average common shares outstanding-basic	24,209,215	24,108,908	24,173,399	24,099,786
Stock options and unvested shares of common stock	449,629			
Weighted average common shares outstanding-diluted	24,658,844	24,108,908	24,173,399	24,099,786

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

	Three months ended		Nine months ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Stock options	2,934,000	3,590,000	3,173,000	3,590,000
Warrants	1,395,000	1,395,000	1,395,000	1,395,000
Unvested shares of common stock	375,000	393,000	586,000	393,000
Total	4,704,000	5,378,000	5,154,000	5,378,000

**9) SEGMENT REPORTING**

The Company has two reportable operating 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.

	Three-month period ended		Nine-month period ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
<b>REVENUES</b>				
PDT drug and device product revenues	\$7,837,000	\$6,700,000	\$24,544,000	\$19,836,000
Non-PDT product revenues	179,000	230,000	886,000	1,198,000
Total revenues	8,016,000	6,930,000	25,430,000	21,034,000
<b>COSTS OF REVENUES</b>				
PDT drug and device cost of product revenues	1,305,000	1,226,000	4,348,000	4,227,000
Non-PDT cost of product revenues	323,000	369,000	880,000	747,000
Total costs of product revenues	1,628,000	1,595,000	5,228,000	4,974,000
<b>GROSS MARGIN</b>				
PDT drug and device product revenues	6,532,000	5,474,000	20,196,000	15,609,000
Non-PDT product gross margin	(144,000)	(139,000)	6,000	451,000
Total gross margin	\$6,388,000	\$5,335,000	\$20,202,000	\$16,060,000

During the three and nine-month periods ended September 30, 2010 and 2009, the Company derived revenues from the following geographies based on the location of the customer (as a percentage of product revenues):

Three-months ended                      Nine-months ended

	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
United States	89%	94%	94%	95%
Canada	2%	2%	2%	2%
Korea	1%	3%	1%	2%
Latin America	8%	1%	3%	1%
Total	100%	100%	100%	100%

**Table of Contents****10) COMPREHENSIVE LOSS**

For the three and nine-month periods ended September 30, 2010 and 2009, comprehensive loss consisted of the following:

	Three-months ended September 30,		Nine-months ended September 30,	
	2010	2009	2010	2009
NET INCOME (LOSS)	\$ 33,000	\$(415,000)	\$(203,000)	\$(2,875,000)
Change in net unrealized (losses) gains on marketable securities available-for-sale	(36,000)	(34,000)	(111,000)	(105,000)
COMPREHENSIVE LOSS	\$ (3,000)	\$(449,000)	\$(314,000)	\$(2,980,000)

**11) SIGNIFICANT PRODUCT AGREEMENTS***Stiefel Agreement*

On September 30, 2010, the Company gave notice to Stiefel Laboratories, Inc. 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 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.

*Daewoong Agreement*

In January 2007 the Company licensed to Daewoong Pharmaceutical Co., LTD. and its wholly-owned subsidiary DNC Daewoong Derma & Plastic Surgery Network Company (Daewoong), the exclusive rights to market Levula®an PDT in Korea and other Asia Pacific countries for payments by Daewoong of up to \$3,500,000. The Company also manufactures and supplies finished product for Daewoong, which the Company began shipping in October 2007. In consideration for the transaction Daewoong agreed to pay the Company as follows: (i) \$1,000,000 upon contract signing; (ii) \$1,000,000 upon achieving regulatory approval in Korea; and (iii) two installments of \$750,000 each for cumulative end-user sales totaling 200,000 units and 500,000 units. Daewoong launched the product in November 2007 in Korea. The Company is deferring and recognizing the up-front and regulatory approval milestones as license revenues on a straight-line basis, beginning with product launch in the territory through the fourth quarter of 2016, which is the term of the Daewoong Agreement. Daewoong pays a fixed price per unit for the inventory and an Excess Purchase Price, as defined in the Agreement, if the Average Selling Price to end-users during any calendar quarter exceeds a certain threshold. During the nine-month periods ended September 30, 2010 and 2009, the Company's shipments of Levula® Kerastick® to Daewoong were \$0. At September 30, 2010 and December 31, 2009 the total revenues deferred associated with shipments to Daewoong were \$536,000 and \$704,000, respectively, in accordance with the Company's policy of deferring revenues during a product's launch phase and recognizing revenues based on end-user demand. Deferred revenues at September 30, 2010 and December 31, 2009 associated with milestone payments received from Daewoong were \$1,284,000 and \$1,438,000, respectively. The agreement with Daewoong also establishes a cumulative minimum purchase quantity over the first five years following regulatory approval. If Daewoong fails to meet its minimum purchase quantities, the Company may, in addition to other remedies, at its sole discretion, appoint one or more other distributors in the covered territories, or terminate the agreement.

*Photocure Agreement*

On May 30, 2006, the Company entered into a patent license agreement under which the Company granted Photocure ASA (Photocure), 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. On October 1, 2009, Photocure announced that it had sold Metvix/Metvixia to Galderma, S.A. (Galderma), a large dermatology company. On January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex, Inc.

( PhotoMedex ) for Galderma's PDT application for the treatment of actinic keratoses, or AKs, under which Galderma is providing marketing support and distribution and PhotoMedex's sales force is promoting Metvixia and Galderma's Aktilite lamp to healthcare professionals throughout the United States.

Photocure is obligated to pay the Company royalties on sales of its ester products to the extent they are covered by its 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.

**Table of Contents****12) INCOME TAXES**

Based on an Internal Revenue Code (IRC) Section 382 study through December 31, 2009, the Company determined that it has experienced prior ownership changes, as defined under IRC Section 382, with the most recent change in ownership occurring in 2007 (the 2007 Ownership Change). As a result of the 2007 Ownership Change, it is expected that the pre-change net operating loss (NOL) carryforwards available to the Company, provided no additional ownership changes have occurred during 2010, will be limited to approximately \$48.6 million. The Company's pre-change NOL carryforwards are subject to an annual limitation of approximately \$3.0 million for the first five years following the 2007 Ownership Change and \$2.2 million annually thereafter through December 31, 2027. Additionally, the Company has \$5.2 million of NOLs subsequent to the 2007 Ownership Change. However, it is reasonably possible that a future ownership change, which could be the result of transactions involving the Company's common stock that are outside of its control (such as sales by existing shareholders), could occur during 2010 or thereafter. Future ownership changes could further restrict the utilization of the Company's net operating losses and tax credits, reducing or eliminating the benefit of such net operating losses and tax credits. An ownership change occurs under IRC Section 382 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.

**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:

Cumulative Sales Milestone:	Additional Consideration:
\$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 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 \$228,000, 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, 2010.

**Table of Contents***Lease Arrangements*

The Company leases its facilities under operating leases. The Company's lease arrangements have terms which expire through 2012. Total rent expense under operating leases was approximately \$290,000 and \$293,000 for the nine-month periods ended September 30, 2010 and 2009, respectively. Future minimum payments under lease arrangements at September 30, 2010 are as follows:

<b>Years Ending December 31,</b>	<b>Operating Lease Obligations</b>
2010	\$ 117,000
2011	464,000
2012	438,000
2013	
Thereafter	
<b>Total</b>	<b>\$ 1,019,000</b>

**Legal Matters***River's Edge Litigation Settlement*

On August 12, 2008, the Company entered into a worldwide non-exclusive patent License Agreement with respect to its patent covering Nicomide®, or License Agreement, with River's Edge Pharmaceuticals, LLC (River's Edge), and an amendment to its Settlement Agreement with River's Edge regarding earlier patent litigation. The amendment to the Settlement Agreement, which was further amended in April 2009 as described in the following paragraph, had allowed River's Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changed certain payment obligations of River's Edge for sales of its substitutable product. In consideration for granting the license, the Company was paid a share of the net revenues, as defined in the License Agreement, of River's Edge's licensed product sales under the License Agreement. Royalty revenues recorded pursuant to the License Agreement are recorded in Product Revenues in the accompanying Condensed Consolidated Statements of Operations.

In April 2009, the Company and River's Edge entered into an Amendment to their License Agreement (the License Amendment). The License Amendment granted River's Edge an exclusive license to U.S. Patent, No. 6,979,468, and a license to use all know-how and the trademark associated with the Licensed Products worldwide. Under the License Amendment, DUSA is required to transfer all of its rights, title and interest in and to the DUSA's patent, know-how and trademark relating to the Licensed Products (but not the copyright registration relating to product labeling) to River's Edge upon the Company's receipt of \$5,000,000. Of the \$5,000,000, River's Edge was required to pay to the Company \$2,600,000, in thirteen monthly installments of \$200,000, subject to reduction under certain conditions, and pay additional consideration of \$2,400,000 payable over time based on a share of River's Edge's net revenues as defined in the License Amendment. River's Edge has informed us that they have ceased selling the product and we do not expect to receive additional revenues from River's Edge under the License Agreement without litigation. The validity of the Nicomide® patent was tested again as a request for ex parte reexamination of this patent was filed by an unknown third party with the U.S. Patent and Trademark Office, or USPTO, on August 19, 2009. On July 20, 2010, the USPTO issued a Notice of Intent to Issue Ex Parte Reexamination Certificate confirming the validity of patent claims which cover Nicomide® and we expect the process to conclude shortly.

*Settlements, net Winston Laboratories Arbitration Settlement*

In October 2008, the Company was notified that Winston Laboratories, Inc. (Winston) had filed a demand for arbitration against the Company. The demand for arbitration arose out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement (together the Agreement), and claimed that the Company breached the Agreement. Winston claimed damages in excess of \$2.0 million. The matter was settled on April 28, 2009 for cash consideration of \$75,000, and a mutual release.

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

**OVERVIEW**

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".

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

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

The Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® 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 under a former dermatology collaboration. 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® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions. We merged with Sirius Laboratories, Inc., or Sirius, a dermatology specialty pharmaceuticals company, in March 2006. Nicomide® was its key product, a vitamin-mineral product prescribed by dermatologists, but we no longer market Nicomide®. We do market ClindaReach® which we acquired from Sirius for the treatment of acne. We are marketing Levulan® PDT under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, or PARTEQ, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to our BLU-U® device and methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA®, DUSA Pharmaceuticals, Inc.®, Levulan®, Kerastick®, BLU-U®, Nicomide®, Nicomide-T®, ClindaReach®, Meted®, and Psoriacap® are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Numerous other trademark applications are pending.

We are responsible for manufacturing our Levulan® Kerastick® and for the regulatory, sales, marketing, and customer service and other related activities for all of our products, including our Levulan® Kerastick®. We are dependent upon sole-source suppliers for a number of our products and component parts. There can be no assurance that these suppliers will be able to meet our 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 our operating results in any given period.

### **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, 2009. Since not all of these accounting policies 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. There have been no material changes to our critical accounting policies in the nine months ended September 30, 2010.

**Table of Contents****RESULTS OF OPERATIONS THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 VERSUS SEPTEMBER 30, 2009**

**REVENUES** Total revenues for the three- and nine-month periods ended September 30, 2010 were \$8,016,000 and \$25,430,000, respectively, as compared to \$6,930,000 and \$21,034,000 in 2009, and were comprised of the following:

	Three months ended September 30,		INCREASE/ (DECREASE)	Nine months ended September 30,		INCREASE/ (DECREASE)
	2010	2009		2010	2009	
PDT product revenues						
Levulan® Kerastick® product revenues						
United States	\$ 6,663,000	\$ 5,790,000	\$ 873,000	\$ 21,780,000	\$ 17,096,000	\$ 4,684,000
Canada	153,000	162,000	(9,000)	379,000	404,000	(25,000)
Korea	109,000	201,000	(92,000)	322,000	498,000	(176,000)
Latin America	602,000	78,000	524,000	778,000	226,000	552,000
Rest-of-world	15,000	13,000	2,000	57,000	35,000	22,000
Subtotal Levulan® Kerastick® product revenues	7,542,000	6,244,000	1,298,000	23,316,000	18,259,000	5,057,000
BLU-U® product revenues						
United States	295,000	456,000	(161,000)	1,223,000	1,577,000	(354,000)
Canada				5,000		5,000
Subtotal BLU-U® product revenues	295,000	456,000	(161,000)	1,228,000	1,577,000	(349,000)
Total PDT product revenues	7,837,000	6,700,000	1,137,000	24,544,000	19,836,000	4,708,000
Total Non-PDT product revenues	179,000	230,000	(51,000)	886,000	1,198,000	(312,000)
Total product revenues	\$ 8,016,000	\$ 6,930,000	\$ 1,086,000	\$ 25,430,000	\$ 21,034,000	\$ 4,396,000

For the three- and nine-month periods ended September 30, 2010, total PDT product revenues, comprised of revenues from our Kerastick® and BLU-U® products, were \$7,837,000 and \$24,544,000, respectively. This represents an increase of \$1,137,000, or 17%, and \$4,708,000, or 24%, over the comparable 2009 totals of \$6,700,000 and \$19,836,000, respectively. The incremental revenue was driven primarily by increased Kerastick® revenues in the United States, as well as the acceleration of the recognition of deferred revenues of \$555,000 related to the termination of our Latin American distribution agreement with Stiefel Laboratories.

For the three- and nine-month periods ended September 30, 2010, Kerastick® revenues were \$7,542,000, and \$23,316,000, respectively, representing a \$1,298,000, or 21%, and \$5,057,000, or 28%, increase over the comparable 2009 totals of \$6,244,000, and \$18,259,000, respectively. Kerastick® unit sales to end-users were 53,724 and 176,924, for the three- and nine-month periods ended September 30, 2010, respectively. Included in revenues for the nine months ended September 30, 2010, are 4,014 units sold in Canada and 3,228 sold in Korea. This represents an increase from 53,622 and 155,384 Levulan® Kerastick® units sold in the three and nine-month periods ended September 30, 2009, respectively. Included in revenues for the nine months ended September 30, 2009, are 4,500 units sold in Canada and 6,606 sold in Korea. Our overall average net selling price for the Kerastick® increased to \$126.64 per unit for the first nine months of 2010 from \$115.87 per unit for the first nine months of 2009. Our average net selling price for the Kerastick® in the United States increased to \$129.71 per unit in 2010 from \$121.66 per unit in 2009. The increase in 2010 Kerastick® revenue was driven by increased sales volumes in the United States, an increase in our overall average unit selling price, and the acceleration of the recognition of deferred revenues of \$555,000 related to the termination of our Latin American distribution agreement with Stiefel Laboratories

For the three- and nine-month periods ended September 30, 2010, BLU-U® revenues were \$295,000 and \$1,228,000, respectively, representing a \$161,000, or 35%, and \$349,000, or 22%, decrease over the comparable 2009 totals of \$456,000 and \$1,577,000, respectively. The decrease in year-to-date 2010 BLU-U® revenues was the result of decreased overall sales volumes and a decrease in our average selling price. In the three- and nine-month periods ended September 30, 2010, there were 39 and 179 units sold, respectively, versus 59 and 198 units sold, respectively, in the comparable 2009 periods. All of the units sold in



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2010 were sold in the United States, except for one that was sold in Canada. For the nine months ended September 30, 2009, all of the units were sold in the United States. For the first nine months of 2010, our average net selling price for the BLU-U® decreased to \$6,679 from \$7,591 in 2009. The average net selling price of the BLU-U® decreased, in part, due to lower pricing offered to customers in an effort to sell our existing inventory in advance of the introduction of an upgraded design unit, which became available in April. 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 a purchase decision is required. At September 30, 2010, there were approximately 26 units in the field pursuant to this evaluation program, compared to 12 units in the field at December 31, 2009. 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.

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, 2010 were \$179,000 and \$886,000, respectively, compared to \$230,000 and \$1,198,000, respectively for the comparable 2009 periods. In 2010, the substantial majority of the Non-PDT product revenues were from sales of ClindaReach® and royalties received from River's Edge from sales of the AVAR® product line. Royalties from our license of the AVAR® product line with River's Edge will cease during the fourth quarter of 2010. In 2009, the substantial majority of Non-PDT product revenues were from Nicomide® related royalties, which included a \$200,000 installment payment received from River's Edge on the Nicomide® License Amendment. In light of the recent action by the United States Patent and Trademark Office issuing a Notice of Intent to Issue a Reexamination Certificate which affirms the validity of patent claims which cover Nicomide, we are evaluating our options relative to the Nicomide asset. We do not expect to derive significant revenues or cash flows, if at all, from this asset given its regulatory status. For more information on the Nicomide® License Amendment with River's Edge, see *Legal Matters* Note 13 to the Notes to the Condensed Consolidated Financial Statements.

The increase in our total product revenues for the three and nine-month periods ended September 30, 2010 compared with the comparable periods in 2009 results primarily from increased Kerastick® revenues in the United States and the acceleration of the recognition of deferred revenues related to the termination of our Latin American distribution agreement with Stiefel, partially offset by decreases in Kerastick® revenues in other international locations, BLU-U® revenues and other revenues. We must continue to increase sales from these levels in order for us to become profitable on a continuing basis. We cannot provide any assurance that we will be able to increase sales sufficiently to achieve profitability, and we cannot provide assurance that an increase in sales will necessarily cause us to be profitable on a continuing basis. Photocure received FDA approval to market Metvixia® for treatment of AKs in July 2004, and this PDT product, which is directly competitive with our Levulan® Kerastick® product, is commercially available. On October 1, 2009, Photocure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. On January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex, Inc., or PhotoMedex, for Metvixia under which Galderma is providing marketing support and distribution. PhotoMedex's sales force is promoting Metvixia and Galderma's Aktelite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia, Galderma and PhotoMedex together have considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share. Also, Leo Pharma, a Danish corporation that acquired Peplin in 2009, has announced that in 2012 it will be launching PEP005 for the treatment of AKs, which could impact our market share. Although we expect 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. Softness in the international markets could be expected until the economy recovers. We expect our Non-PDT product revenues for the full year 2010 to be reduced from full year 2009 levels since we do not expect to collect any more payments under the License Agreement with River's Edge without litigation, and the AVAR® royalty period ends during the fourth quarter of 2010. Also see the section entitled *Risk Factors* Any Failure to Comply with Government Regulations in the United States and Elsewhere Will Limit Our Ability to Market Our Products And Become Profitable.



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***COST OF PRODUCT REVENUES*** Cost of product revenues for the three- and nine-month periods ended September 30, 2010 were \$1,628,000 and \$5,228,000 as compared to \$1,595,000 and \$4,974,000 in the comparable periods in 2009. A summary of the components of cost of product revenues and royalties is provided below:

	THREE MONTHS ENDED SEPTEMBER 30,		
	2010	2009	INCREASE/ (DECREASE)
Levulan® Kerastick® cost of product revenues and royalties			
Direct Levulan® Kerastick® product costs	\$ 623,000	\$ 583,000	\$ 40,000
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	90,000	50,000	40,000
Royalty and supply fees (1)	275,000	238,000	37,000
Subtotal Levulan® Kerastick® cost of product revenues and royalties	\$ 988,000	\$ 871,000	\$ 117,000
BLU-U® cost of product revenues			
Direct BLU-U® product costs	\$ 151,000	\$ 212,000	\$ (61,000)
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	166,000	143,000	23,000
Subtotal BLU-U® cost of product revenues	\$ 317,000	\$ 355,000	\$ (38,000)
TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	\$1,305,000	\$1,226,000	\$ 79,000
Non-PDT drug cost of product revenues and royalties	\$ 323,000	\$ 369,000	\$ (46,000)
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$1,628,000	\$1,595,000	\$ 33,000

	NINE MONTHS ENDED SEPTEMBER 30,		
	2010	2009	INCREASE/ (DECREASE)
Levulan® Kerastick® cost of product revenues and royalties			
Direct Levulan® Kerastick® product costs	\$1,953,000	\$1,686,000	\$ 267,000
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	222,000	498,000	(276,000)
Royalty and supply fees (1)	891,000	726,000	165,000
Subtotal Levulan® Kerastick® cost of product revenues and royalties	\$3,066,000	\$2,910,000	\$ 156,000

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BLU-U® cost of product revenues			
Direct BLU-U® product costs	\$ 663,000	\$ 712,000	\$ (49,000)
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	619,000	605,000	14,000
Subtotal BLU-U® cost of product revenues	\$1,282,000	\$1,317,000	\$ (35,000)
TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	\$4,348,000	\$4,227,000	\$ 121,000
Non-PDT drug cost of product revenues and royalties	\$ 880,000	\$ 747,000	\$ 133,000
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$5,228,000	\$4,974,000	\$ 254,000

- 1) Royalty and supply fees reflect amounts paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, and ongoing royalties paid to Draxis Health, Inc., on sales of the Levulan® Kerastick® in Canada.

**MARGINS** Total product margins for the three- and nine-month periods ended September 30, 2010 were \$6,388,000 and \$20,202,000, respectively, as compared to \$5,335,000 and \$16,060,000 for the comparable 2009 periods, as shown below:

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	THREE MONTHS ENDED SEPTEMBER 30,				INCREASE/ (DECREASE)
	2010		2009		
Levulan® Kerastick® gross margin	\$6,554,000	87%	\$5,373,000	86%	\$1,181,000
BLU-U® gross margin	(22,000)	(7)%	101,000	22%	(123,000)
Total PDT drug & device gross margin	\$6,532,000	83%	\$5,474,000	82%	\$1,058,000
Total Non-PDT drug gross margin	(144,000)	(81)%	(139,000)	(60)%	\$ (5,000)
<b>TOTAL GROSS MARGIN</b>	<b>\$6,388,000</b>	<b>80%</b>	<b>\$5,335,000</b>	<b>77%</b>	<b>\$1,053,000</b>

	NINE MONTHS ENDED SEPTEMBER 30,				INCREASE/ (DECREASE)
	2010		2009		
Levulan® Kerastick® gross margin	\$20,250,000	87%	\$15,349,000	84%	\$4,901,000
BLU-U® gross margin	(54,000)	(4)%	260,000	16%	(314,000)
Total PDT drug & device gross margin	\$20,196,000	82%	\$15,609,000	79%	\$4,587,000
Total Non-PDT drug gross margin	6,000	1%	451,000	38%	\$ (445,000)
<b>TOTAL GROSS MARGIN</b>	<b>\$20,202,000</b>	<b>79%</b>	<b>\$16,060,000</b>	<b>76%</b>	<b>\$4,142,000</b>

Kerastick® gross margins for the three and nine-month periods ended September 30, 2010 were 87% versus 86% and 84%, respectively, for the comparable periods in 2009. The margin improvement 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 Latin American distribution agreement with Stiefel Laboratories. 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® sales which will be significantly dependent on increased volume. We believe that we could achieve improved gross margins on our Kerastick® from further volume growth and price increases in the U.S.

BLU-U® margins for the three and nine-month periods ended September 30, 2010 were (7)% and (4)%, respectively, versus 22% and 16% for the comparable 2009 periods. The decrease in gross margin is a result of decreased sales volumes and a decrease in our average selling price. It is important for us to sell BLU-U® units in an effort to drive Kerastick® sales volumes and accordingly, we may sell BLU-U® 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, 2010 were

(81)% and 1%, respectively, compared to (60)% and 38%, 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® 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, 2010 were \$1,284,000 and \$3,644,000 as compared to \$963,000 and \$3,225,000 in the comparable 2009 periods. The increase in 2010 compared to 2009 was due primarily to increased spending on development projects and investigator studies. During the third quarter of 2010, we announced that we would be closing out our solid organ transplant recipient, or SOTR, clinical trial program in response to the FDA's denial of our application for Orphan Drug Designation for the use of Levulan® PDT for the prevention of squamous cell carcinomas, or SCC, in patients who have a proven history of multiple localized cutaneous SCCs, such as SOTRs. Even with the elimination of the SOTR study, we expect that our overall research and development costs for 2010 will be increased from 2009 levels.

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**MARKETING AND SALES COSTS** Marketing and sales costs for the three and nine-month periods ended September 30, 2010 were \$2,793,000 and \$9,545,000, respectively, as compared to \$3,013,000 and \$9,461,000 for the comparable 2009 periods. These costs consisted primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling \$2,260,000 and \$7,044,000 for the three and nine-month periods ended September 30, 2010, compared to \$2,206,000 and \$6,762,000 in the comparable periods in 2009. The increase in spending in the first nine months of 2010 is due to additional marketing and sales headcount. The remaining expenses consisted of tradeshow, miscellaneous marketing and outside consultants totaling \$533,000 and \$2,501,000 for the three and nine-month periods ended September 30, 2010, compared to \$807,000 and \$2,699,000 for the comparable 2009 periods. The decrease in this category is due primarily to a decrease in tradeshow and other promotional activities. We expect marketing and sales costs for the full year 2010 to increase over 2009 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, 2010 were \$2,209,000 and \$6,919,000, respectively, as compared to \$1,878,000 and \$6,360,000 for the comparable 2009 periods. The increase on a year-to-date basis is attributable to an increase in compensation related expense, primarily from a non-cash charge resulting from the modification of stock options for former members of the board of directors, as well as an increase 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 2010, we expect general and administrative costs to increase compared with 2009, but to decrease as a percentage of revenues.

**SETTLEMENTS, NET** During the second quarter of 2009 we settled the arbitration initiated by Winston Laboratories, Inc., or Winston, for a payment of \$75,000, and a mutual release and other customary terms. The arbitration which began in October 2008, alleged that we breached the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement.

**OTHER INCOME, NET** Other income for the three and nine-month periods ended September 30, 2010, decreased to \$61,000 and \$189,000, respectively, from \$80,000 and \$224,000 during the comparable 2009 periods. This decrease reflects a general decrease in interest rates over that timeframe.

**(LOSS) GAIN 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 (loss) gain during the three and nine-month periods ended September 30, 2010 were \$(131,000) and \$(487,000), respectively, from \$24,000 and \$(38,000) during the comparable 2009 periods. The non-cash (losses) gains on the warrants were due primarily to changes in our stock price.

**NET INCOME (LOSS)** For the three and nine-month periods ended September 30, 2010, our net income (loss) was \$33,000, or \$0.00 per share, for both basic and diluted earnings per share, and \$(203,000), or \$(0.01) per share, respectively, as compared to \$(415,000), or \$(0.02) per share, and \$(2,875,000), or \$(0.12) per share for the comparable 2009 periods. The increase in our net income or decrease in our net loss is attributable to the reasons discussed above.

On September 30, 2010, we gave notice to Stiefel Laboratories, Inc. terminating our 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 our exclusive marketing and distribution partner for our product, the Levulan® 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 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.

## **LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2010, we had approximately \$16,981,000 of total liquid assets, comprised of \$6,184,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$10,797,000. We believe that our liquidity will be sufficient to meet our cash requirements for at least the next twelve months. As of September 30, 2010, our marketable securities had a weighted average yield to maturity of 1.46% and maturity dates ranging from January 2011 to December 2013. Our net cash provided by operations for the nine-month period ended September 30,

2010 was \$574,000 versus net cash used in operations of \$(3,528,000) in the comparable prior year period. The year-over-year increase in cash from operations is primarily attributable to a decrease in our net loss, an increase in the non-cash charge related to the valuation of our warrants, and year-over-year improvements in changes to working capital. As of September 30, 2010 working capital (total current assets minus total current liabilities) was \$18,329,000, as compared to \$17,780,000 as of December 31, 2009. Total current assets decreased by \$392,000 during the nine-month period ended September 30, 2010, due primarily to decreases in cash and cash equivalents, accounts receivable and prepaid and other current asset balances, partially offset by increases in marketable securities and inventory. Total current liabilities decreased by \$941,000 during the same period due primarily to a decreases in accrued compensation, other accrued expenses and the current portion of deferred revenues, partially offset by an increase in accounts payable. In response to



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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. 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 2009 and 2010, we have focused primarily on selling our current products, which includes the Levulan® Kerastick® and the BLU-U®, as well as our Non-PDT products.

If we are unable to achieve profitability or maintain 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*****L. Perrigo 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 ANDA owned by Perrigo. The agreement, which covers our ClindaReach product, was assigned to us as part of the Sirius merger, and has been assigned by Perrigo to its affiliate, Perrigo Pharmaceuticals Company. The parties are negotiating an extension of the initial term of the agreement through December 31, 2011, subject to certain rights to early termination and expect that it will be signed shortly. Perrigo is entitled to royalties on net sales of the product, including certain minimum royalties. For calendar year 2011, we expect the minimum annual royalty to remain at \$250,000, subject to pro ration 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®, one of the new Sirius products, 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

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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® 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.

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. 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.

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 \$228,000, is included in other accrued expenses in the accompanying Condensed Consolidated Balance Sheet as of September 30, 2010.

### ***PARTEQ Agreement***

We license certain patents underlying our Levulan® 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, 2009, 2008 and 2007, actual royalties based on product sales were approximately \$1,019,000, \$873,000, and \$620,000, respectively. Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$97,000 as of September 30, 2010).

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

On June 29, 2009, we extended the term of the 2004 Amended and Restated Purchase and Supply Agreement with National Biological Corporation, or NBC, one of the manufacturers of our BLU-U® light source, until September 30, 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.

### ***Sochinaz SA***

Under an agreement dated December 24, 1993, Sochinaz SA manufactures and supplies our requirements of Levulan® 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 lease commitments for office space in Wilmington, Massachusetts, and Toronto, Ontario. The minimum lease payments disclosed below include the non-cancelable terms of the leases. We have vacated the

Toronto, Ontario office and have subleased the space through December 31, 2010 when the lease will terminate.

**Table of Contents*****Research Agreements***

We have entered into various agreements for research projects and clinical studies. As of September 30, 2010, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$635,000. Included in this future payment is a master service agreement, effective September 15, 2001, with Therapeutics, Inc. for management services in connection with the clinical development of our products in the field of dermatology. The agreement was renewed on September 15, 2010 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, 2010:

	Total	1 Yr or less	2-3 Years	4-5 Years	After 5
Operating lease obligations	\$ 1,019,000	\$ 464,000	\$ 555,000	\$	\$
Purchase obligations (1, 2)	2,008,000	1,752,000	256,000		
Minimum royalty obligations (3)	541,000	347,000	194,000		
Total obligations	\$ 3,568,000	\$ 2,563,000	\$ 1,005,000	\$	\$

- 1) Research and development projects include various commitments including obligations for our study on the treatment of actinic keratoses and reduction of non-melanoma skin cancers in immunosuppressed solid organ transplant recipients, or SOTR, who have demonstrated that they are at risk of developing multiple squamous cell carcinomas.
- 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 \$290,000 and \$293,000 for the nine-month periods ended September 30, 2010 and 2009, respectively.

**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.

**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 market value, which approximates cost. In response to the instability in the global financial markets, we have regularly reviewed our marketable securities holdings, and have reduced or avoided investing in securities deemed to have increased credit risk.

As of September 30, 2010, the weighted average rate of return on our investments was 1.46%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of September 30, 2010, the fair value of the portfolio would decline by \$124,000. 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 our stock price as of the

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end of each reporting period, the historical volatility of our stock price, and risk-free interest rates commensurate with the remaining contractual term of the warrants. Changes in our stock price or in interest rates would result in a change in the value of the warrants.

### **Currency Exchange Rates**

The royalties we earn each quarter under our agreement with Stiefel Laboratories, if any, are based on a percentage of the net sales to end-users. These royalties are calculated in local currencies and converted to and paid in United States dollars each reporting period.

Under our agreement with Daewoong, revenues we earn under the excess purchase price provision of the agreement, if any, are calculated based on end-user pricing in local currencies and converted to United States dollars before a determination is made whether any payments are due us. These payments, if any, are made in United States dollars each reporting period.

Other exchange rates that we are subject to, such as the Canadian dollar, are not material to our operations.

### **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, 2010.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **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 beliefs regarding the ability for suppliers to meet our future requirements or provide us with favorable terms, expectations regarding contract negotiations with Perrigo, beliefs regarding potential reduction of headcount, beliefs regarding an interruption in the supply of products or parts or any significant price increase by sole source suppliers, expectations regarding the enrollment of patients into and timing of results of clinical trials, beliefs regarding sales on non-reimbursed procedures and softness in the international markets, expectations concerning manufacture of the BLU-U® in our facility, intention to pursue licensing, marketing, co-promotion, other arrangements, additional business or new technologies, beliefs regarding the status of clinical programs and beliefs regarding potential efficacy, expectations regarding collection of payments from the License Agreement with River's Edge, beliefs regarding the transfer to a new laboratory for analytical testing of our Levulan® Kerastick® product and potential impact on revenues, beliefs concerning achievement of higher margins on Kerastick sales and BLU-U® sales at low margins, beliefs regarding the impact on our market share of the promotion of Metvixia, expectations to reduce spending if we are unable to achieve profitability, expectations regarding the confidentiality of our proprietary information, expectations to raise funds through financing transactions and whether such financing will be available or at reasonable terms, beliefs regarding regulatory and environmental compliance and impact of failures in compliance, beliefs concerning patent disputes, expectations regarding the reexamination process of our patents, beliefs regarding the impact of litigation and ability to afford the costs, ability and intentions to defend and enforce our patents, the impact of a third-party's regulatory compliance status and fulfillment of contractual obligations, expectations of increases or decreases in the prices we charge for our products, our beliefs regarding the size of the market for our products and our product candidate, expected use and sufficiency of cash resources, beliefs regarding requirements of cash resources for our future liquidity, and research and development programs, beliefs regarding investments and economic conditions including the impact of our customer's failure to meet our payment or supply terms, expectations regarding outstanding options and warrants and our dividend policy, anticipation of increases or decreases in personnel, beliefs regarding the effect of reimbursement policies on revenues and acceptance of our therapies, expectations for future strategic opportunities and research and development programs and expenses, expectations for

continuing operating losses and competition, expectations regarding the adequacy and availability of insurance, expectations regarding general and administrative costs, expectations regarding sales and marketing costs and research and development costs, levels of interest income and our capital resource needs, the potential for additional inspection and testing of our manufacturing facilities or additional FDA actions, beliefs regarding interest rate risks to our investments and effects of inflation, beliefs regarding the impact of any current or future legal proceedings, beliefs regarding dependence on key personnel, beliefs concerning product liability insurance, beliefs regarding the enforceability of our patents, beliefs regarding the entry into the market and impact of generic products on revenues, financial condition, results of operations and profitability, beliefs regarding our sales and marketing efforts, beliefs regarding competition with other companies and effect of increased reimbursement, beliefs regarding the adoption of our products, expectations regarding additional milestone payments with respect to the Sirius merger, beliefs regarding the use of our products



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and technologies by third parties, beliefs regarding our compliance with applicable laws, rules and regulations, beliefs regarding available reimbursement for our products, beliefs regarding the current and future clinical development and testing of our potential products and technologies and the costs thereof, beliefs regarding the volatility of our stock price, beliefs regarding the impact of our rights plan, beliefs regarding the impact of future sales of securities, beliefs regarding the valuation of warrants, expectations related to the change in revenues of our PDT and Non-PDT products, expectations regarding the payment of remaining milestones to former Sirius shareholders, beliefs regarding market share and market penetration, beliefs regarding obtaining and sustaining profitability, expectations regarding the change in growth in our PDT Drug and Device Products segment, expectations regarding our manufacturing facility, beliefs regarding our SOTR research and development program, beliefs regarding Nasdaq listing, beliefs regarding Section 382 on our current and future NOLs, beliefs regarding unknown problems with the product, a manufacturer or its facility in the future, beliefs regarding financial position, results of operations and cash flows if needed capital is not raised, beliefs regarding our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income, beliefs regarding a future ownership change, beliefs regarding the outcome if some or all of our shares are sold into the public market over a short period of time, beliefs regarding our ability to sell equity securities or equity-related securities in the future, beliefs regarding our expectation and ability to obtain funds through other public or private financings, including equity financing, and/or through collaborative arrangements and its effect on our existing shareholders, beliefs regarding the impact that any manufacturing or supply problems could have on our sales and on our financial condition, beliefs regarding the scope of our patents, beliefs regarding competition from other ALA products, beliefs concerning safety procedures for hazardous materials, our compliance and risks of liability, expectations regarding the manufacture of our products, beliefs regarding collaborations with outside scientists, expectations regarding revenues from Nicomide®, and expectations regarding royalty payments.

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.

## **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 our investment. 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**

***We May Not Be Profitable On An Annual Basis And May Not Be Profitable In The Future Unless We Can Successfully Market And Sell Significantly Higher Quantities Of Our Products.***

***If We Do Not Become Profitable, We May Need More Capital.***

We have approximately \$16,981,000 in cash, cash equivalents and marketable securities as of September 30, 2010. Our cash, cash equivalents and marketable securities should be sufficient for current operations for at least the next 12 months. If we are unable to become profitable on an ongoing basis in the near term, we may have to reduce our headcount, curtail certain variable

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expenses, or raise funds through financing transactions. We cannot predict whether financing will be available at all or on reasonable terms.

*If A Competitive Product Is Successful Our Revenues Could Decline, And Our Ability To Become Profitable Could Be Delayed.*

On May 30, 2006, we entered into a patent license agreement with Photocure ASA whereby we granted a non-exclusive license to Photocure under the patents we license from PARTEQ, for esters of ALA. Furthermore, we granted a non-exclusive license to Photocure for its existing formulations of its Hexvix<sup>®</sup> and Metvix<sup>®</sup> (known in the United States as Metvixia<sup>®</sup>) products for any of our patents that may issue or be licensed by us in the future.

Photocure received FDA approval to market Metvixia<sup>®</sup> for treatment of AKs in July 2004, and this product, which is directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product, is commercially available. On October 1, 2009, Photocure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company, and on January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex for Metvixia under which Galderma is providing marketing support and distribution. PhotoMedex sales force is promoting Metvixia and Galderma's Aktelite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia, Galderma and PhotoMedex together have 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 be profitable on an ongoing basis. In addition, Leo Pharma, a Danish corporation that acquired Peplin in 2009, has announced that in 2012 it will be launching PEP005 for the treatment of AKs. This product could negatively impact the market penetration of our PDT products.

***Any Failure To Comply With Ongoing Governmental Regulations In The United States And Elsewhere Will Limit Our Ability To Market Our Products And Become Profitable.***

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 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.

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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.

During April 2010, we were advised that a receiver had been appointed for the laboratory that we were using to perform analytical release testing and stability testing of our Levulan® Kerastick® product due to non-payment of its bank loan. As a result, that laboratory was no longer able to perform these services on an on-going basis. We are working with this laboratory for the transfer of all samples, raw material and relevant technology. We engaged the services of a new laboratory and have successfully transferred the technology and analytical methods so that the new laboratory can perform all of the services we need. On May 5, 2010 following discussions with the FDA, we filed a 30-day Changes Being Effected (CBE-30) supplement to validate the use of the new laboratory. FDA had no comment on the supplement during the 30 day period so we began shipping product as permitted under FDA regulations. The FDA could still have comments on the CBE-30 and we would have to respond. Any significant interruption in our ability to ship product caused by FDA could have a negative effect on our revenues.

***If Product Sales Do Not Continue to Increase, We May Not Be Able To Advance Development Of Our 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.

***The Current 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 current 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® and key portion of the BLU-U®, portions of our product manufacturing, royalty revenues, 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 Achieve Profitability On An Annual Basis Could Be Delayed.***

If any of our large customers were to fail to pay us or fail to pay us on a timely basis for their purchases of our products, our ability to maintain profitability on a sustainable on-going basis could be delayed, and our financial position, results of operations and cash flows could be negatively affected.

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

We have had a history of operating losses. We may continue to incur losses on an annual basis unless sales of our products increase from present levels. We incurred net losses of \$2,508,000, \$6,250,000 and \$14,714,000 for the years ended December 31, 2009, 2008 and 2007, respectively, and a loss of \$203,000 for the nine-month period ended September 30, 2010. As of September 30, 2010, our accumulated deficit was approximately \$145,000,000. 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 collaborators may exceed revenues in the future, which may result in future losses from operations. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable on an annual basis, and to sustain profitability if it is achieved.

### ***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 IRC Section 382 study completed in early 2010, we have determined that an ownership change occurred in 2007, and as a result, approximately \$48.6 million of our net operating loss carryforwards are expected to be available to us. Our net operating loss carryforwards are subject to an annual limitation of approximately \$3.0 million for the first five years following the ownership change and \$2.2 million annually thereafter through December 31, 2027. We further believe that 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. Future ownership changes could further restrict the utilization of our net operating losses and tax credits, reducing or eliminating the benefit of such net operating losses and tax credits.

### ***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 business, our financial condition, results of operations and cash flows.

### ***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® 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® and BLU-U®, 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.



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The 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. With the newly allowed claims which issued on May 25, 2010, we have claims that cover our AK product until 2019. The reexamination by the USPTO of one of the patents we license from PARTEQ, the licensor of our ALA patents, that cover our approved product until 2013, has successfully concluded with affirmation of our original claims and the addition of eight new claims.

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 six 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® product even though they are marketed for different uses.

Photocure ASA received FDA approval to market Metvixia® for treatment of AKs in July 2004, and this product, which is directly competitive with our Levulan® Kerastick® product, is commercially available. On October 1, 2009, Photocure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. On January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex for Metvixia under which Galderma is providing marketing support and distribution. PhotoMedex's sales force is promoting Metvixia and Galderma's Aklilite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia, Galderma and PhotoMedex together have considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share.

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.

### ***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.

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***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 approval by the FDA to manufacture the BLU-U® and the Levulan® Kerastick® in our Wilmington, Massachusetts facility, at this time, with respect to the BLU-U®, we expect to utilize our own facility only as a back-up to our current third party manufacturer 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.

***We Have Only Limited Experience Marketing And Selling Pharmaceutical Products Outside Of The United States 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 are responsible for marketing our products in the United States and the rest of the world, except Canada, Latin America and parts of Asia, where we have distributors. We terminated our agreement with Stiefel, our former distributor in Latin America, on September 30, 2010. If our sales and marketing efforts fail, then sales of the Levulan® 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, and we may not become profitable. 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,

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.

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***If We Cannot 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® Kerastick® 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, reduce the amounts of coverage or stop covering our products which are covered, our sales could be dramatically reduced.

***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® Products.***

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

Except for Levulan® PDT for AKs, the BLU-U® for acne, the ClindaReach® 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 and 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® 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® 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 additional animal studies and/or human clinical trials before granting approval. Our Levulan® 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®. 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® 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.



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### ***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 89 employees, including 2 part-time employees, as of September 30, 2010. 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. Although our advisors and collaborators generally agree not to do competing work, 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 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.



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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.

On May 30, 2006, we entered into a patent license agreement with Photocure ASA whereby we granted a non-exclusive license to Photocure under the patents we license from PARTEQ, for esters of ALA. Furthermore, we granted a non-exclusive license to Photocure for its existing formulations of its Hexvix<sup>®</sup> and Metvix<sup>®</sup> (known in the United States as Metvixia<sup>®</sup>) products for any of our patents that may issue or be licensed by us in the future. Photocure received FDA approval to market Metvixia<sup>®</sup> for treatment of AKs in July 2004, and this product, which is directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product, is commercially available and its price is comparable to the price of Levulan<sup>®</sup>. On October 1, 2009, Photocure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. On January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex for Metvixia under which Galderma is providing marketing support and distribution. PhotoMedex sales force is promoting Metvixia and Galderma's Aktelite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia, Galderma and PhotoMedex together have considerably more resources than we have, which could significantly hamper our ability to maintain or increase our market share. *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/PhotoMedex, 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.); 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 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.

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**Risks Related To Our Stock**

***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, 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.

***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, 2008 to September 30, 2010, the price of our stock has ranged from a low of \$0.87 to a high of \$2.75. 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 Common 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 of 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, 2010, there were outstanding options and warrants to purchase 4,568,000 shares of common stock, with exercise prices ranging from \$1.08 to \$27.31 per share for options, and exercise prices ranging from \$2.85 to \$6.00 per share for warrants. In addition, there were 586,000 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.

***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

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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.

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 5, 2010, DUSA Pharmaceuticals, Inc. issued a press release announcing summary financial results for the fiscal quarter ended September 30, 2010. The press release issued in connection with such announcement is attached hereto as Exhibit 99.1.

**ITEM 6. EXHIBITS.**

**EXHIBIT**

<b>NO.</b>	<b>DESCRIPTION OF EXHIBIT</b>
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, 2009, 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 5, 2010.

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

Dated November 5, 2010

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

Dated November 5, 2010

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