DUSA PHARMACEUTICALS INC
Form 10-Q
May 12, 2009

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

(Mark One)

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

For the quarterly period ended: March 31, 2009

o **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 þ No o

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

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 o	Accelerated filer o	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of May 11, 2009, the registrant had 24,112,202 shares of Common Stock, no par value per share, outstanding.

DUSA PHARMACEUTICALS, INC.
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PART I.

ITEM 1. FINANCIAL STATEMENTS
DUSA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	March 31, 2009	December 31, 2008
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 3,670,824	$ 3,880,673
Marketable securities, at fair value	14,240,337	15,002,830
Accrued interest receivable	97,217	155,728
Accounts receivable, net of allowance for doubtful accounts of $111,000 and $98,000 in 2009 and 2008, respectively	2,124,394	2,367,803
Inventory	2,536,328	2,812,825
Prepaid and other current assets	1,285,129	1,718,073
TOTAL CURRENT ASSETS	23,954,229	25,937,932
Restricted cash	173,976	173,844
Property, plant and equipment, net	1,835,397	1,937,978
Deferred charges and other assets	149,856	160,700
TOTAL ASSETS	$ 26,113,458	$ 28,210,454
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 386,471	$ 305,734
Accrued compensation	554,262	1,515,912
Other accrued expenses	3,604,287	3,226,571
Deferred revenues	944,775	611,602
TOTAL CURRENT LIABILITIES	5,489,795	5,659,819
Deferred revenues	3,586,780	4,157,305
Warrant liability	571,370	436,458
Other liabilities	230,661	244,673
TOTAL LIABILITIES	9,878,606	10,498,255
COMMITMENTS AND CONTINGENCIES (NOTE 15)		
SHAREHOLDERS EQUITY		
Capital Stock Authorized:		
	151,663,943	151,663,943

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: 24,089,452 shares of common shares, no par, at March 31, 2009 and December 31, 2008		
Additional paid-in capital	7,714,027	7,514,900
Accumulated deficit	(143,457,856)	(141,850,925)
Accumulated other comprehensive income	314,738	384,281
TOTAL SHAREHOLDERS EQUITY	16,234,852	17,712,199
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 26,113,458	$ 28,210,454

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended March 31,	
	2009	2008
Product revenues	$ 7,138,269	$ 7,929,500
Cost of product revenues	1,938,226	1,700,317
GROSS MARGIN	5,200,043	6,229,183
Operating costs:		
Research and development	1,185,095	2,186,209
Marketing and sales	3,410,104	3,057,201
General and administrative	2,141,450	2,367,824
Net gain from settlement of litigation		(235,600)
TOTAL OPERATING COSTS	6,736,649	7,375,634
LOSS FROM OPERATIONS	(1,536,606)	(1,146,451)
Other income	64,587	206,852
Loss on change in fair value of warrants	(134,912)	(344,542)
NET LOSS	$ (1,606,931)	$ (1,284,141)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (0.07)	$ (0.05)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED	24,089,452	24,078,418

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Three months ended March 31,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(1,606,931)	$(1,284,141)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization (accretion) of premiums and discounts on marketable securities	2,189	(77,362)
Realized loss (gain) on sales of marketable securities	36,822	(2,364)
Share-based compensation	199,127	331,638
Depreciation and amortization	125,393	154,241
Loss on change in fair value of warrants	134,912	344,542
Deferred revenues recognized	(234,905)	(401,575)
Changes in other assets and liabilities impacting cash flows from operations:		
Accounts receivable	243,409	(499,961)
Inventory	276,497	(223,312)
Accrued interest receivable, prepaid and other current assets	491,455	(26,874)
Deferred charges and other assets	10,844	14,218
Accounts payable, accrued compensation and other accrued expenses	(503,197)	23,839
Deferred revenues	(2,447)	1,650,937
Other liabilities	(14,012)	1,649
NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES	(840,844)	5,475
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash paid for contingent consideration		(250,000)
Purchases of marketable securities	(5,994,220)	(7,936,363)
Proceeds from maturities and sales of marketable securities	6,648,159	7,973,061
Restricted cash	(132)	(1,077)
Purchases of property, plant and equipment	(22,812)	(122,945)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	630,995	(337,324)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Proceeds from exercise of options		4,000
NET CASH PROVIDED BY FINANCING ACTIVITIES		4,000
NET DECREASE IN CASH AND CASH EQUIVALENTS	(209,849)	(327,849)

CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,880,673	4,713,619
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 3,670,824	$ 4,385,770

See the accompanying Notes to the Condensed Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of March 31, 2009, and the Condensed Consolidated Statements of Operations and Cash Flows for the three months ended March 31, 2009 and 2008 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, 2008 filed with the Securities and Exchange Commission. The balance sheet as of December 31, 2008 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

In April 2009, the FASB issued the following new accounting standards:

FASB Staff Position FAS 157-4, *Determining Whether a Market Is Not Active and a Transaction Is Not Distressed*, or FSP FAS 157-4. FSP FAS 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS 157. FSP FAS 157-4 provides additional authoritative guidance in determining whether a market is active or inactive and whether a transaction is distressed, is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures.

FASB Staff Position FAS 115-2, FAS 124-2, and EITF 99-20-2, *Recognition and Presentation of Other-Than-Temporary Impairment,* provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. This FSP applies to debt securities.

FASB Staff Position FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, or FSP FAS 107-1 and APB 28-1, amends FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in all interim financial statements.

These standards are effective for the Company for the quarter ending June 30, 2009. The Company is evaluating the impact that these standards will have on its financial statements.

Recently adopted Accounting Pronouncements

In March 2008, the FASB issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities, as an amendment to SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities* (SFAS 161). SFAS 161 requires that objectives for using derivative instruments be disclosed in terms of underlying risk and accounting designation. The fair value of derivative instruments and their gains and losses will need to be presented in tabular format in order to present a more complete picture of the effects of using derivative instruments. SFAS 161 is effective for financial statements issued for periods beginning after November 15, 2008. The adoption of this pronouncement did not have a material impact on the Company s financial statements.

3) FAIR VALUE MEASUREMENTS

Effective January 1, 2008, the Company implemented FASB Statement No. 157, *Fair Value Measurements* (SFAS 157), for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. The adoption of SFAS 157 did not have an impact on the Company s financial results. As defined in SFAS 157, fair value is 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. Financial assets and liabilities carried at fair value are classified and disclosed in one of the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

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 includes financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, prepayment speeds, default rates, loss severity, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace. Financial instruments in this category include corporate debt and government-backed securities.
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. The following table presents information about the Company s assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2009, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	Level 2
Assets:	
United States government-backed securities	$ 12,762,000
Corporate debt securities	1,478,000
Total assets	$ 14,240,000

	Level 3
Liabilities:	
Warrant liability	$ 571,000
Total liabilities	$ 571,000

Changes in Level 3 Recurring Fair Value Measurements:
The table below includes a rollforward of the balance sheet amounts for the three-month period ended March 31, 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.

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Three-month period ended March 31, 2009					
	Fair Value at	Total Unrealized	Purchases, Sales, Issuances, Settlements,	Transfers In and/or Out of	Fair Value at March 31,	Change in Unrealized Gains Related to Financial Instruments Held at March 31,

	January 1, 2009	(Gains)/Losses	net	Level 3	2009	2009
Warrant Liability	$ 436,000	$ 135,000	$	$	$ 571,000	$ 135,000

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4) WARRANTS

On October 29, 2007, the Company sold, through a private placement, 4,581,043 shares of its common stock and warrants to purchase 1,145,259 shares of common stock with an exercise price of $2.85. The warrants have a 5.5 year term and became exercisable on April 30, 2008. The warrants are recorded as a derivative liability at fair value. At March 31, 2009 and December 31, 2008, the aggregate fair value of these warrants was $571,000 and $436,000, respectively. Assumptions used for the Black-Scholes option-pricing models as of March 31, 2009 and December 31, 2008 are as follows:

	March 31, 2009	December 31, 2008
Expected volatility	78.9%	75.0%
Remaining contractual term (years)	4.08	4.33
Risk-free interest rate	1.67%	1.55%
Expected dividend yield	0%	0%
Common stock price	$1.23	$ 1.05

5) MARKETABLE SECURITIES

The Company s investment securities consist of securities of the U.S. government and its agencies, and investment grade corporate bonds. The Company has historically classified all investment securities as available-for-sale and recorded such investments at fair market value. Since the Company s investments are managed by a third-party investment advisor pursuant to a discretionary arrangement, for securities with unrealized losses at March 31, 2009 and 2008, which totaled $41,000 and $6,000, respectively, an other-than-temporary impairment was considered to have occurred and the cost basis of such securities were written down to their fair values with the amount of the write-down included in earnings as realized losses and which are included in other income in the accompanying Condensed Consolidated Statements of Operations. As of March 31, 2009, current yields range from 0.35% to 7.37% and maturity dates range from May 2009 to January 2013. The estimated fair value and cost of marketable securities at March 31, 2009 and December 31, 2008 are as follows:

	March 31, 2009		
	Amortized Cost	Gross Unrealized Gains	Fair Value
United States government-backed securities	$12,477,000	$285,000	$12,762,000
Corporate debt securities	1,448,000	30,000	1,478,000
Total marketable securities available-for-sale	$13,925,000	$315,000	$14,240,000

	December 31, 2008		
	Amortized Cost	Gross Unrealized Gains	Fair Value
United States government-backed securities	$11,956,000	$357,000	$12,313,000
Corporate debt securities	2,662,000	28,000	2,690,000

Total marketable securities available-for-sale	$14,618,000	$385,000	$15,003,000

The change in gross unrealized gains on such securities for the three month periods ended March 31, 2009 and 2008 were $(70,000) and $167,000, respectively, and have been recorded in accumulated other comprehensive income, which is reported as part of shareholders equity in the Condensed Consolidated Balance Sheets. Realized (losses)/gains on sales of marketable securities were $(37,000) and $2,000 for the three months ended March 31, 2009 and 2008, respectively.

6) CONCENTRATIONS

The Company invests cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. The Company manages the credit risk associated with its investments in marketable securities by investing in U.S. government securities and investment grade corporate bonds. The Company is also exposed to concentration of credit risk related to accounts receivable that are generated from its distributors and 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

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the three-months ended March 31, 2009 and 2008, and accounts receivable as of March 31, 2009 and December 31, 2008 are as follows:

	% of revenue three months ended		% of accounts receivable	
	March 31, 2009	March 31, 2008	March 31, 2009	December 31, 2008
Customer A	2%	2%	6%	11%
Customer B	1%	12%	1%	
Customer C	1%	8%		
Customer D		5%		
Customer E	2%	5%	2%	1%
Customer F	4%		11%	9%
Other Customers	90%	68%	80%	79%
Total	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.

7) INVENTORY

Inventory consisted of the following:

	March 31, 2009	December 31, 2008
Finished goods	$1,324,000	$1,348,000
BLU-U® evaluation units	83,000	166,000
Work in process	525,000	698,000
Raw materials	604,000	601,000
Total	$2,536,000	$2,813,000

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 of three years to cost of product revenues to approximate its net realizable value.

8) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	March 31, 2009	December 31, 2008
Research and development costs	$ 233,000	$ 190,000
Marketing and sales costs	376,000	191,000

Reserve for sales returns and allowances	430,000	500,000
Accrued FDA fees	589,000	589,000
Reserve for chargebacks and rebates	10,000	30,000
Other product related costs	938,000	824,000
Legal and other professional fees	637,000	467,000
Employee benefits	311,000	278,000
Other accrued expenses	80,000	158,000
Total	$3,604,000	$3,227,000

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9) SHARE-BASED COMPENSATION

Total share-based compensation expense, related to all of the Company s share-based awards, recognized for the three-month periods ended March 31, 2009 and 2008 included the following line items:

	Three-months ended March 31, 2009	Three-months ended March 31, 2008
Cost of product revenues	$ 20,000	$ 24,000
Research and development	50,000	121,000
Selling and marketing	(15,000)	(60,000)
General and administrative	144,000	247,000
Total	$199,000	$ 332,000

The weighted-average estimated fair value of employee stock options granted during the three-month period ended March 31, 2009 was $0.81 per share, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	Three months ended March 31, 2009
Volatility	73.4%
Risk-free interest rate	1.87%
Expected dividend yield	0%
Expected life-directors and officers	6.5 years
Expected life-non-officer employees	5.7 years

A summary of stock option activity for the three-month period ended March 31, 2009 follows:

		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, beginning of period	3,011,063	$ 9.89		$
Options granted	686,650	$ 1.23		
Options forfeited	(4,175)	$ 4.56		
Options expired	(104,563)	$ 9.12		
Options exercised		$		
Outstanding, end of period	3,588,975	$ 8.28	4.1	$ 6,992
Exercisable, end of period	2,461,125	$ 11.12	3.0	$

Options vested and expected to vest, end of period	3,403,966	$	8.65	4.0	$	5,541

During the first quarter of 2009 and the second quarter of 2008, respectively, the Company issued 280,000 and 102,000 unvested shares of common stock to its officers. The Company also issued 45,000 shares of unvested common stock to its Board of Directors during the first quarter of 2009. The unvested shares of common stock vest over 4 years at a rate of 25% per year. The fair value on the date of grant was $1.22 and $2.20 per share in 2009 and 2008, respectively. At March 31, 2009 the total amount of unrecognized compensation expense related to grants of options and unvested common stock was $1,355,000 and $511,000, respectively. The unrecognized compensation related to unvested common stock will be recognized over a weighted-average period of 3.7 years.

10) BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per common share is based upon the weighted average number of common shares outstanding during each period. Stock options, unvested common stock grants and warrants are not included in the computation of the weighted average number of common shares outstanding for dilutive net loss per common share during each of the periods presented in the Consolidated Statements of Operations, as the effect would be antidilutive. For the three-month period ended March 31, 2009, and 2008, stock options, unvested common stock grants, warrants and rights totaling approximately 5,400,000 and 4,214,000 shares, respectively, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive.

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11) SEGMENT REPORTING

The Company has two reportable operating segments: Photodynamic Therapy (PDT) Drug and Device Products and Non-Photodynamic Therapy (Non-PDT) Drug 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	
	2009	2008
REVENUES		
PDT drug and device product revenues	$6,719,000	$5,830,000
Non-PDT drug product revenues	419,000	2,100,000
Total revenues	7,138,000	7,930,000
COSTS OF PRODUCT REVENUES		
PDT drug and device cost of product revenues	1,715,000	1,274,000
Non-PDT drug cost of product revenues	223,000	427,000
Total costs of product revenues	1,938,000	1,701,000
GROSS MARGIN		
PDT drug and device product gross margins	5,004,000	4,556,000
Non-PDT drug product gross margins	196,000	1,673,000
Total gross margins	$5,200,000	$6,229,000

During the three-month periods ended March 31, 2009 and 2008, the Company derived revenues from the following geographies based on the location of the customer (as a percentage of product revenues):

	2009	2008
United States	95%	92%
Canada	2%	2%
Korea	2%	5%
Other	1%	1%
Total	100%	100%

12) COMPREHENSIVE LOSS

For the three-month periods ended March 31, 2009 and 2008, comprehensive loss consisted of the following:

	March 31, 2009	March 31, 2008
NET LOSS	$(1,607,000)	$(1,284,000)
Change in net unrealized gains on marketable securities available-for-sale	(70,000)	167,000
COMPREHENSIVE LOSS	$(1,677,000)	$(1,117,000)

13) STIEFEL AGREEMENT

In January 2006, as amended in September 2007, the Company licensed to Stiefel Laboratories, Inc. the exclusive Latin American rights to market Levulan® PDT for payments by Stiefel of up to $2,250,000. The Company also manufactures and supplies finished product for Stiefel, which the Company began shipping in September 2007. In consideration for the transaction Stiefel agreed to pay the Company as follows: (i) $375,000 upon launch of the product in either Mexico or Argentina; (ii) $375,000 upon receipt of acceptable pricing approval in Brazil; (iii) two installments of $375,000 each for cumulative end-user sales in Brazil totaling 150,000 units and 300,000 units, and (iv) two installments of $375,000 each for cumulative sales in countries excluding Brazil totaling 150,000 units and 300,000 units. Stiefel launched the product in October 2007 in Mexico and Argentina and in April 2008 in Brazil. The Company is deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the fourth quarter of 2015, which is the term of the Stiefel Agreement. Stiefel pays a fixed price per unit for the inventory as well as a royalty based on a percentage of the net sales price to end-users. During the three-month periods ended March 31, 2009 and 2008, the Company s sales of Levulan® Kerastick® to Stiefel were $0 and $202,000, respectively. At

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March 31, 2009 and December 31, 2008 the total revenues deferred associated with shipments to Stiefel were $351,000 and $389,000, 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 March 31, 2009 and December 31, 2008 associated with milestone payments received from Stiefel were $599,000 and $621,000, respectively.

The agreement with Stiefel also establishes minimum purchase quantities over the first five years following regulatory approval. The first contract year for all countries other than Brazil began in October 2007, and for Brazil began in April 2008. For the contract year ended in October 2008 Stiefel did not meet its minimum purchase obligations under the agreement. The agreement provides that within 60 days of the year end, Stiefel is required to pay the Company the difference between its actual purchases and the contractual minimums (a gross up payment). If Stiefel fails to make the gross up payment, the Company s remedies include, without limitation, appointing one or more distributors in the territory or terminating the agreement. Stiefel did not make the gross up payment within the contractual time period, and the parties are presently discussing actions to be taken, if any, due to the first year shortfall. Also, since Stiefel s sales to third parties during the contract year ended October 2008 were below its minimum purchase obligations, Stiefel has the unilateral right to cancel the contract. Stiefel has not exercised this right.

14) DAEWOONG AGREEMENT

In January 2007 the Company licensed to Daewoong the exclusive rights to market Levulan® 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 three-month periods ended March 31, 2009 and 2008, the Company s sales of Levulan® Kerastick® to Daewoong were $0 and $998,000, respectively. At March 31, 2009 and December 31, 2008 the total revenues deferred associated with shipments to Daewoong were $1,026,000 and $1,144,000, 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 March 31, 2009 and December 31, 2008 associated with milestone payments received from Daewoong were $1,592,000 and $1,643,000, respectively. The agreement with Daewoong also establishes minimum purchase quantities over the first five years following regulatory approval.

15) 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 ending 50 months from the date of close. The first cumulative sales milestone was achieved during 2008, and accordingly a cash payment in the amount of $1.5 million was paid to the former Sirius shareholders in that year. The payment made during 2008 was recorded initially as goodwill and then subsequently deemed impaired and expensed during the same period as described below.

If the remaining sales milestones are attained, they 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

Legal Matters

River s Edge Litigation Settlement

As part of the settlement of litigation between DUSA and River s Edge Pharmaceuticals, LLC in October 2007, the parties entered into a Settlement Agreement and Mutual Release (the Settlement Agreement) to dismiss the lawsuit brought by DUSA against River s Edge asserting a number of claims arising out of River s Edge s alleged infringement of the Company s Nicomide® patent, U.S. Patent No. 6,979,468, under which DUSA formerly marketed, distributed and sold Nicomide®. As part of the terms of this agreement, River s Edge agreed to pay to DUSA $25.00 for every bottle of River s Edge product above 5,000 bottles that was substituted for Nicomide® after September 30, 2007. The net gain from settlement of litigation for the three-month periods ended

March 31, 2009 and 2008 was $0 and $236,000, respectively, and is recorded in the accompanying Condensed Consolidated Statement of Operations as a separate component of operating expenses.

On August 12, 2008, the Company entered into a worldwide non-exclusive patent License Agreement to its patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to its Settlement Agreement with River s Edge. The amendment to the Settlement Agreement, which has been further amended as described in Note 16 *Subsequent Events*, 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 is being 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 Consolidated Statements of Operations.

WINSTON LABORATORIES ARBITRATION

In October 2008, the Company was notified that Winston Laboratories, Inc. had filed a demand for arbitration against the Company. The demand for arbitration arises out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement (together, the Agreement) and claims that DUSA breached the Agreement. Winston Laboratories is claiming damages in excess of $2,000,000. The Company plans to defend itself vigorously and has not recorded any liability pursuant to the claim at March 31, 2009.

The Company has not accrued any amounts for potential contingencies as of March 31, 2009.

16) SUBSEQUENT EVENTS

River s Edge Amendment to License Agreement

In April 2009, the Company and River s Edge entered into an Amendment to the License Agreement (the License Amendment) originally entered into in August 2008. The License Amendment grants 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 is required to make a minimum guaranteed payment to the Company of $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. The License Agreement, as amended, has a term of 30 months, subject to a further extension under certain circumstances to 48 months, and may be terminated early by River s Edge on 30 days prior written notice to the Company. Under the License Agreement, River s Edge has assumed all regulatory responsibilities for the Licensed Products. If River s Edge terminates the License Agreement prior to the payment of the $5,000,000, all of the rights and licenses granted by the Company to River s Edge will revert to the Company.

Third Amendment to Merger Agreement

In April 2009, the Company and the former shareholders of Sirius Laboratories, Inc., some of whom were acting through their shareholder representatives, 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 mentioned above, a release, and the Third Amendment to the Merger Agreement, dated as of December 30, 2005, by and among the DUSA Pharmaceuticals, Inc., Sirius Laboratories, Inc. 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 documents entered into in April 2009, the Company has 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 deletes 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 the new Milestone Termination Date, 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.

Nicomide Recall

In April 2009, the Company initiated a Class III recall on 3 lots of its product, Nicomide®, due to a failure of the annual stability lot. The Company believes that there is no health risk associated with this product. The recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Since the Company had stopped shipping Nicomide® at the end of June 2008, the Company believes there is minimal inventory at the wholesale level, and as a result this action is not expected to have a material impact to the Company s financial condition or results of its operations.

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

OVERVIEW

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

Historically, we devoted most of our resources to advancing the development and marketing of our Levulan® PDT/PD 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. When Levulan® is used and followed with exposure to light to detect medical conditions, it is known as Levulan® photodetection, or Levulan® PD. 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.

Sirius Laboratories, Inc., or Sirius, a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Nicomide®, its key product, is a vitamin-mineral product formerly prescribed by dermatologists. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide®, or License Agreement, with River s Edge Pharmaceuticals, LLC, or River s Edge, and an amendment to our Settlement Agreement with River s Edge regarding earlier litigation. See Note 15 of the Notes to the Condensed Consolidated Financial Statements. The amendment to the Settlement Agreement 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 changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we were paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales®. In April 2009, we and River s Edge entered into an Amendment to the License Agreement, or License Amendment. The License Amendment grants 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, we are required to transfer all of our rights, title and interest in and to 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 our receipt of $5,000,000. Of the $5,000,000, River s Edge is required to make a minimum guaranteed payment to us of $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. The License Agreement, as amended, has a term of 30 months, subject to a further extension under certain circumstances to 48 months, and may be terminated early by River s Edge on 30 days prior written notice. Under the License Agreement, River s Edge has assumed all regulatory responsibilities for the Licensed Products. If River s Edge terminates the License Agreement prior to the payment of the $5,000,000, all of the rights and licenses granted by us to River s Edge will revert to us.

We are developing Levulan® PDT and PD under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen s University, Kingston, Ontario, Canada. In January, 2009, we filed a request for reexamination with the USPTO of one of the Queen s patents that cover our approved indication for AK. 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®

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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.

As of March 31, 2009, we had an accumulated deficit of approximately $143,458,000. 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 a sustainable basis. If our domestic PDT revenue growth rates for the remainder of 2009 are comparable to prior year levels, we expect to become cash flow positive and profitable on a quarterly basis sometime late in 2009. We recorded significant impairment changes of goodwill during the fourth quarter of 2007 and the third quarter of 2008. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our PDT therapy by the medical and consumer constituencies, increased sales of our products and other factors contained in this report.

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, 2008. Since all of these accounting policies do not require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting policies with our Audit Committee. There have been no changes to our critical accounting policies in the three months ended March 31, 2009.

RESULTS OF OPERATIONS THREE MONTHS ENDING MARCH 31, 2009 VERSUS MARCH 31, 2008

REVENUES Total revenues for the three-month period ended March 31, 2009 were $7,138,000, as compared to $7,930,000 in 2008 and were comprised of the following:

	2009	2008	Increase/(Decrease)
PDT PRODUCT REVENUES			
LEVULAN® KERASTICK® PRODUCT REVENUES			
United States	$5,685,000	$4,774,000	$ 911,000
Canada	135,000	159,000	(24,000)
Korea	170,000	365,000	(195,000)
Rest of world	87,000	56,000	31,000
Subtotal Levulan® Kerastick® product revenues	6,077,000	5,354,000	723,000
BLU-U® PRODUCT REVENUES			
United States	642,000	476,000	166,000
Subtotal BLU-U® product revenues	642,000	476,000	166,000
TOTAL PDT PRODUCT REVENUES	6,719,000	5,830,000	889,000
TOTAL NON-PDT DRUG PRODUCT REVENUES	419,000	2,100,000	(1,681,000)
TOTAL PRODUCT REVENUES	$7,138,000	$7,930,000	$ (792,000)

For the three-month period ended March 31, 2009, total PDT Drug and Device Products revenues, comprised of revenues from our Kerastick® and BLU-U® products, were $6,719,000. This represents an increase of $889,000 or 15%, over the comparable 2008 total of $5,830,000. The increase in revenues was driven primarily by increased

Kerastick® and BLU-U® revenues in the United States.

For the three-month period ended March 31, 2009, Kerastick® revenues were $6,077,000, representing an increase of $723,000 or 13%, over the comparable 2008 total of $5,354,000. Kerastick® unit sales to end-users for the three-month period ended March 31, 2009 were 51,947, including 46,662 sold in the United States, 1,500 sold in Canada and 2,274 sold in Korea. Kerastick® units sold in the three-month period ended March 31, 2008 were 52,110, including 43,296 sold in the United States, 2,100 sold in Canada and 6,036 sold in Korea. Our average net selling price for the Kerastick® increased to $115.36 per unit for the three-month period ended March 31, 2009 from $101.33 per unit in 2008. Our average net selling price for the Kerastick® in the US increased from $110.26 per unit in 2008 to $121.83 per unit in 2009. The increase in 2009 Kerastick® revenues was driven mainly by an increase in both sales volumes and average net selling price in the United States, partially offset by a decrease in international Kerastick® revenues. The decrease in Korea is attributable to the purchase of launch quantities in the 2008 period.

For the three-month period ended March 31, 2009, BLU-U® revenues were $642,000, representing a $166,000 or a 35% increase, over the comparable 2008 total of $476,000. The increase in 2009 BLU-U® revenues was driven by increased overall sales volumes, offset in part by a decrease in our average selling price. In the three-month period ended March 31, 2009, there were 81 units sold, versus 56 units in 2008. All of the units sold in both years were sold in the United States. Our average net selling price for the BLU-U® decreased to $7,589 for the three-month period ended March 31, 2009 from $8,245 for 2008. 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 March 31, 2009, there were approximately 31 units in the field pursuant to this evaluation program, compared to 58 units in the field at December 31, 2008. 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 Drug Product Revenues reflect the revenues generated by the products acquired as part of our acquisition of Sirius. Total Non-PDT drug product revenues for the three-month period ended March 31, 2009 were $419,000, compared to $2,100,000 for the comparable 2008 period. The substantial majority of the Non-PDT product revenues were from Nicomide® related royalties and sales of ClindaReach®. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River s Edge. The amendment to the Settlement Agreement, which has been further amended as described further in Note 16 *Subsequent Events* to the Condensed Consolidated Financial Statements, allowed River s Edge to manufacture and market a 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, we were 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. The Settlement Agreement and the subsequent amendment are described in Notes 15 and 16 to the Condensed Consolidated Financial Statements.

The decrease in our total revenues for the three month period ended March 31, 2009 compared with the comparable period in 2008 results from decreases in Non-PDT revenues and international Kerastick® revenues, partially offset by increased PDT segment revenues in the United States. We must continue to increase sales from these levels in order for us to become profitable. PhotoCure 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 now commercially available. While we are entitled to royalties from PhotoCure on its net sales of Metvixia®, a large dermatology company has the marketing rights in the U.S., which may adversely affect our ability to maintain or increase our Levulan® market. Nonetheless, we remain confident that PDT revenues in the United States should continue to increase through increased consumption of our PDT products by our existing customers, as well as the addition of new customers. We expect to be able to grow our PDT segment revenues in the United States during 2009, due in part to the 6% increase in reimbursement of our PDT-related procedure fee, which became effective January 1, 2009, as well as our price increases, which were effective October 1, 2008 and January 1, 2009. We also believe that these two price increases may have impacted the purchasing patterns of our larger customers during this quarter. Although we expect growth in our PDT segment revenues, a portion of our customer base, i.e., those focusing on the cosmetic market, are more susceptible to the uncertain economic conditions facing our markets, and reduced sales to that customer base could be expected until the economy recovers. The vast majority of our international sales and medi-spa sales fall into this market. We expect our Non-PDT revenues for 2009 to be significantly reduced compared to 2008 since, although we are receiving royalties, we are no longer manufacturing and marketing Nicomide® as a prescription product and we licensed the AVAR product line.

COST OF PRODUCT REVENUES Cost of product revenues for the three-month period ended March 31, 2009 were $1,938,000 as compared to $1,701,000 in 2008. A summary of the components of cost of product revenues and royalties is provided below:

	2009	2008	Increase/ (Decrease)

Levulan® Kerastick® Cost of Product Revenues and Royalties			
Direct Levulan® Kerastick® Product costs	$ 564,000	$638,000	$ (74,000)
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	359,000	10,000	349,000
Royalty and supply fees	253,000	248,000	5,000
Subtotal Levulan® Kerastick® Cost of Product Revenues and Royalties	1,176,000	896,000	280,000
BLU-U® Cost of Product Revenues			
Direct BLU-U® Product Costs	291,000	201,000	90,000
Other BLU-U® Product Costs including internal costs assigned to support products; as well as, costs incurred to ship, install and service the BLU-U® in physicians offices	248,000	177,000	71,000
Subtotal BLU-U® Cost of Product Revenues	539,000	378,000	161,000

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	2009	2008	Increase/ (Decrease)
TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	1,715,000	1,274,000	441,000
Non-PDT Drug Cost of Product Revenues and Royalties	223,000	427,000	(204,000)
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	$ 1,938,000	$ 1,701,000	$ 237,000

MARGINS Total product margins for the three-month period ended March 31, 2009 was $5,200,000 as compared to $6,229,000 for the comparable 2008 period, as shown below:

	2009		2008		Increase/ (Decrease)
Levulan® Kerastick® Gross Margin	$ 4,901,000	81%	$ 4,458,000	83%	$ 443,000
BLU-U® Gross Margin	103,000	16%	98,000	21%	5,000
Total PDT Drug and Device Gross Margin	$ 5,004,000	74%	$ 4,556,000	78%	$ 448,000
Total Non-PDT Drug Gross Margin	196,000	47%	$ 1,673,000	80%	(1,477,000)
TOTAL GROSS MARGIN	$ 5,200,000	73%	$ 6,229,000	79%	$ (1,029,000)

Kerastick® gross margins for the three-month period ended March 31, 2009 were 81% versus 83% for the comparable 2008 period. The decrease in the Kerastick® margin is mainly attributable to the absence of production volumes associated with initial stocking orders from our international partners, which occurred in the first quarter of 2008, partially offset by an increase in both sales volumes and the average selling price in the U.S. 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 can achieve improved gross margins on our Kerastick® during 2009 due to the anticipated increased volumes from continued growth in the U.S.

BLU-U® margins for the three month period ended March 31, 2009 were 16% versus 21% for the comparable 2008 period. The decrease in gross margin is a result of a decrease in the average selling price per unit; as well as, increased overall costs incurred to support the product line. Our short-term strategy is to at a minimum breakeven on device sales in an effort to drive Kerastick® sales volumes.

Non-PDT Drug Product Margins reflect the gross margin generated by the products acquired as part of our merger with Sirius. Total margin for the three-month period ended March 31, 2009 was 47% compared with 80% for the comparable period in 2008. Non-PDT Product margins in 2009 were negatively impacted by our discontinuance of sales of Nicomide® as a prescription product.

RESEARCH AND DEVELOPMENT COSTS Research and development costs for the three-month period ended March 31, 2009 were $1,185,000 as compared to $2,186,000 in the comparable 2008 period. The decrease in 2009 compared to 2008 was due primarily to the absence of spending related to our Phase IIb clinical trial on acne, which

concluded in October 2008, and a one-time $0.6 million Prescription Drug User Fee Act (PDUFA) charge, which occurred in the first quarter of 2008, related to our approved AK indication.
Based on the results of the Phase IIb clinical trial, which were previously announced, we will not pursue further clinical development of Levulan® PDT with BLU-U® for moderate to severe acne. However, we do expect to continue to support investigator initiated studies in moderate to severe acne with Levulan and various light sources. In May 2009 we filed a 510(k) application with the FDA for an expansion of our BLU-U® label to include severe acne. We previously had filed a patent application to cover an invention arising from the study.
We initiated a Phase II pilot clinical trial, which we expect will include up to 36 patients at multiple centers across the United States, for 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. An Orphan Drug Designation Application with respect to the prevention of cancer occurrence in these patients is pending with the FDA, and we expect a decision by FDA by the end of the second quarter of 2009. We expect enrollment of these patients to take approximately one year. We expect to receive preliminary results from the study in approximately 15 months and full results in approximately two years.
We expect that our overall research and development costs for 2009 will remain below 2008 levels since we will not have expenditures relating to the acne trial.
We have entered into a series of agreements for our research projects and clinical studies. As of March 31, 2009 future minimum payments to be made pursuant to these agreements, under certain terms and conditions, total approximately $788,000 for the remainder of 2009.
MARKETING AND SALES COSTS Marketing and sales costs for the three-month period ended March 31, 2009 were $3,410,000 as compared to $3,057,000 for the comparable 2008 period. 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 $2,309,000 for the three-month period ended March 31, 2009, compared to $2,057,000 in the comparable 2008 period. The increase in this category is

due to primarily to increased headcount. The remaining expenses consisted of tradeshows, miscellaneous marketing and outside consultants totaling $1,101,000 for the three-month period ended March 31, 2009, compared to $1,000,000 for the comparable 2008 period. The increase in this category is due primarily to an increase in tradeshow related expenditures. We expect marketing and sales costs for the full year 2009 to increase slightly over 2008 levels, but to decrease as a percentage of revenues.

GENERAL AND ADMINISTRATIVE COSTS General and administrative costs for the three-month period ended March 31, 2009 were $2,141,000 as compared to $2,368,000 for the comparable 2008 period. The decrease is mainly attributable to a decrease in compensation related costs, offset by an increase in legal expenses. General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period particularly in light of our litigation strategy to protect our intellectual property. We may incur significant legal fees in 2009 due to the arbitration process which has been commenced by Winston Laboratories. See Note 17 to the Condensed Consolidated Financial Statements.

NET GAIN FROM SETTLEMENT OF LITIGATION During the fourth quarter of 2007, we entered into a Settlement Agreement and Mutual Release with River s Edge Pharmaceuticals, LLC. Under the terms of the Settlement Agreement, River s Edge made a lump-sum settlement payment to us in the amount of $425,000 for damages and paid to DUSA $25.00 for every prescription of NIC 750 above 5,000 prescriptions that were substituted for Nicomide® from September 30, 2007 through June 30, 2008. During the three-month periods ended March 31, 2009 and 2008 the net gain from settlement of litigation was $0 and $236,000, respectively. These payments under the Settlement Agreement ceased due to an amendment effective as of July 3, 2008. See Note 15 to the Condensed Consolidated Financial Statements.

OTHER INCOME, NET Other income for the three-month period ended March 31, 2009, decreased to $65,000, as compared to $207,000 during the same period in 2008. This decrease reflects a decrease in our average investable cash balances during 2009 as compared to 2008 along with a general decrease in interest rates over the same timeframe.

LOSS ON CHANGE IN FAIR VALUE OF WARRANTS The warrants issued to investors in connection with the October 29, 2007 private placement were recorded initially at fair value and are marked to market each reporting period. The increase in the liability during the three month periods ended March 31, 2009 and 2008 was $135,000 and $345,000, respectively, which resulted in a non-cash loss in both periods. The increases in fair value were due primarily to increases in our stock price during both quarters.

NET LOSS We incurred a net loss of $1,607,000, or $0.07 per share, for the three-month period ended March 31, 2009, as compared to a net loss of $1,284,000, or $0.05 per share, for the comparable 2008 period. The increase in the net loss is attributable to the reasons discussed above.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2009, we had approximately $17,911,000 of total liquid assets, comprised of $3,671,000 of cash and cash equivalents and marketable securities available-for-sale totaling $14,240,000. We believe that our liquidity will be sufficient to meet our cash requirements for at least the next twelve months based on our projections of revenues and spending over that timeframe. We have invested our funds in liquid investments, so that we will have ready access to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis. As of March 31, 2009, these securities had a weighted average yield of 2.98% and maturity dates ranging from May 2009 to January 2013. Our net cash used in operations for the three-month period ended March 31, 2009 was $841,000, versus $5,000 provided by operations in the comparable prior year period. The year over year decrease in cash from operations is primarily attributable to an increase in our net loss as well as a decrease in payments received from our international distributor partners primarily from a one-time milestone payment and purchase of launch quantities and the absence of a bonus payout in 2008. As of March 31, 2009 working capital (total current assets minus total current liabilities) was $18,464,000, as compared to $20,278,000 as of December 31, 2008. Total current assets decreased by $1,984,000 during the three-month period ended March 31, 2009, due primarily to decreases in our marketable securities, accounts receivable, inventory and prepaid and other current asset balances. Total current liabilities decreased by $170,000 during the same period due primarily to a decrease in accrued compensation, partially offset by an increase in other accrued expenses and the current portion of deferred revenues associated with our international distributions agreements. In response to the instability in the global financial markets, we regularly review our

marketable securities holdings, and have reduced or avoided investing in securities deemed to have increased risk. We do not hold any asset-backed or auction rate securities.

Since our inception, we have generated significant losses while we have advanced our product candidates into preclinical and clinical trials, development and commercialization. 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 continued losses from operations.

We are actively seeking to further expand or enhance our business by using our resources to acquire by license, purchase or other arrangements, additional businesses, new technologies, or products in the field of dermatology. For 2009, we are focusing primarily on increasing the sales of the Levulan® Kerastick® and the BLU-U®, as well as the Non-Photodynamic Therapy Drug Products and advancing our Phase II study for use of Levulan® PDT in SOTR.

DUSA has no off-balance sheet financing arrangements.

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If our domestic PDT growth rate in 2008 continues into 2009, we expect to become cash flow positive and profitable on a quarterly basis sometime late in 2009. If we are unable to do so, we may have to reduce our headcount, reduce spending in other areas, or 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 DUSA shares, as DUSA 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

The first cumulative sales milestone at $25.0 million was achieved during the third quarter of 2008, and a cash payment in the amount of $1.5 million was paid to the former Sirius shareholders during that period. The payment was recorded initially as goodwill and then subsequently deemed impaired and expensed during the same period. In April 2009, we entered into the Third Amendment to the Merger Agreement as described in Note 16 to the Notes to the Condensed Consolidated Financial Statements. In April 2009 we paid the former Sirius shareholders $100,000 on a pro rata basis and may be required to pay the $250,000 in January 2012 under certain circumstances.

Contractual Obligations and Other Commercial Commitments

L. PERRIGO COMPANY

On October 25, 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 was assigned to us as part of the Sirius merger. We were responsible for all development costs and for obtaining all necessary regulatory approvals and launched the product, ClindaReach , in March 2008. Perrigo is entitled to royalties on net sales of the product, including certain minimum annual royalties, which commenced May 1, 2006, in the amount of $250,000. The initial term of the agreement expires in July, 2011 and may be renewed based on certain minimum purchase levels and other terms and conditions.

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 Altana and pursuant to the terms of the merger agreement with Sirius, DUSA paid $250,000 on a pro rata basis to the former Sirius shareholders. Similarly, with the decision by DUSA 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 DUSA s 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. In connection with the Third Amendment to the merger agreement entered into April

2009, we paid the former Sirius shareholders $100,000 and may be required to pay the $250,000 in January 2012 under certain circumstances.

PARTEQ AGREEMENT

We license certain patents underlying our Levulan® PDT/PD 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.

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Annual minimum royalties to PARTEQ must total at least CDN $100,000 (U.S. $80,000 as of March 31, 2009).

NATIONAL BIOLOGICAL CORPORATION AMENDED AND RESTATED PURCHASE AND SUPPLY AGREEMENT

On June 21, 2004, we signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation, or NBC, one of the manufacturers of our BLU-U® light source. This agreement provides for the elimination of certain exclusivity clauses, permits us to order on a purchase order basis without minimums, and includes other modifications of the original agreement providing both parties greater flexibility related to the development and manufacture of light sources and the associated technology within the field of PDT. On December 23, 2008, we signed the Second Amendment to the Amended and Restated Purchase and Supply Agreement, which extends the Agreement until June 30, 2009, and gives us an option to extend for an additional two years subject only to agreement on price terms to be negotiated in good faith. The parties are actively engaged in discussions to extend the term of the agreement.

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. The agreement expires on December 31, 2009 and we are in discussions with Sochinaz regarding terms for its renewal. While we can obtain alternative supply sources in certain circumstances, any new supplier would have to be inspected and qualified by the 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. In the fourth quarter of 2008, we vacated the Toronto, Ontario office and have listed the space with a real estate broker for potential sublease.

RESEARCH AGREEMENTS

We have entered into various agreements for research projects and clinical studies. As of March 31, 2009, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately $1,243,000. Included in this future minimum payment is a master service agreement, effective June 15, 2001, with Therapeutics, Inc., which is renewable on an annual basis, to engage Therapeutics to manage the clinical development of our products in the field of dermatology. The agreement was renewed on June 15, 2008 for a one year period. 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 March 31, 2009:

	Total	1 Yr or less	2-3 Years	4-5 Years	After 5
Operating lease obligations	$ 1,550,000	$ 453,000	$ 903,000	$ 194,000	$
Purchase obligations (1, 2)	3,694,000	3,203,000	491,000		
Minimum royalty obligations (3)	780,000	326,000	340,000	114,000	
Total obligations	$ 6,024,000	$ 3,982,000	$ 1,734,000	$ 308,000	$

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 $100,000 and $111,000 for the three-month periods ended March 31, 2009 and 2008, 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. However, we expect the overall net effect of inflation on our operations to be minimal.

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 risk.

As of March 31, 2009, the weighted average rate of return on our investments was 2.98%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of March 31, 2009, the fair market value of the portfolio would decline by $138,000. Declines in interest rates could, over time, reduce our interest income.

Derivative Financial Instruments

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

Currency Exchange Rates

The royalties we earn each quarter under our agreement with Stiefel Laboratories 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 March 31, 2009.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2009 that have materially affected, or are reasonably likely to materially affect, DUSA s 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 management s statements regarding our strategies and core objectives for 2009, our use of estimates and assumptions in the preparation of our financial statements and policies and impact on us of the adoption of certain accounting standards, management s beliefs regarding the unique nature of Levulan® and its use and potential use, expectations regarding the enrollment and timing of results of clinical trials, future development of Levulan® and our other products and other potential indications, statements regarding the sale of Nicomide® in the future, beliefs concerning manufacture of the BLU-U® , intention to pursue licensing, marketing, co-promotion, collaboration or acquisition opportunities, status of clinical programs for all other indications and beliefs regarding potential efficacy and marketing, our beliefs regarding the safety, simplicity, reliability and cost-effectiveness of certain light sources, expectations regarding additional market expansion, expectations regarding the marketing and

distribution of Levulan® Kerastick® by Daewoong Pharmaceutical Co., Ltd. and Stiefel Laboratories, Inc., beliefs regarding the clinical benefit of Levulan® PDT for acne and other indications, expectations regarding the confidentiality of our proprietary information, statements of our intentions to seek additional U.S. and foreign regulatory approvals, and to market

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and increase sales outside the U.S., beliefs regarding regulatory classifications, filings, timelines, off-label use and environmental compliance, beliefs concerning patent disputes and litigation, intentions to defend our patent estate, the impact of a third-party s regulatory compliance and fulfillment of contractual obligations, and our anticipation that third parties will launch products upon receipt of regulatory approval, beliefs concerning the impact of price increases, expectations of increases or decreases in cost of product sales, expected use of cash resources, requirements of cash resources for our future liquidity, beliefs regarding investments and economic conditions, 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 including from Metvixia, expectations for growth of PDT segment revenues and reduction of Non-PDT segment revenues, expectations regarding the adequacy and availability of insurance, expectations regarding general and administrative costs, expectations regarding legal expenses, sales and marketing costs and research and development costs, levels of interest income and our capital resource needs, intention to raise additional funds to meet capital requirements and the potential dilution and impact on our business, potential for additional inspection and testing of our manufacturing facilities or additional FDA actions, beliefs regarding the adequacy of our inventory of Kerastick® and BLU-U® units, our manufacturing capabilities and the impact of inventories on revenues, beliefs regarding interest rate risks to our investments and effects of inflation, beliefs regarding the impact of any current or future legal proceedings, dependence on key personnel, and beliefs concerning product liability insurance, the enforceability of our patents, the impact of generic products, our beliefs regarding our sales and marketing efforts, competition with other companies, the adoption of our products, and the outcome of such efforts, our beliefs regarding our sales and marketing efforts, our beliefs regarding the use of our products and technologies by third parties, our beliefs regarding our compliance with applicable laws, rules and regulations, our beliefs regarding available reimbursement for our products, our beliefs regarding the current and future clinical development and testing of our potential products and technologies and the costs thereof, the volatility of our stock price, the impact of our rights plan, and the possibility that the holders of options and warrants will purchase our common stock by exercising these securities. 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.

In October 2008, we were notified that Winston Laboratories, Inc. had filed a demand for arbitration against the Company. The demand for arbitration arises out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement, which we refer to together as the Agreement, and claims that DUSA breached the Agreement. Winston Laboratories is claiming damages in excess of $2.0 million. The Company plans to defend itself vigorously and has not recorded any liability pursuant to the claim at March 31, 2009.

ITEM 1A. RISK FACTORS

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

This report contains forward-looking statements 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 s expressions to identify forward-looking statements. Our actual results 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.

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Risks Related To DUSA

We Are Not Currently Profitable 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 As Expected, We May Need More Capital.

We have approximately $17,911,000 in cash, cash equivalents and marketable securities as of March 31, 2009. Our cash should be sufficient for current operations for at least the next 12 months. While our goal is to become cash flow positive and profitable on a quarterly basis sometime late in 2009, if we are unable to do so, we may have to reduce our headcount, curtail certain variable expenses, or raise funds through financing transactions. We cannot predict whether financing will be available at all or on reasonable terms.

Our Ability To Become Profitable Has Been Delayed Since We No Longer Sell and Distribute Nicomide® As A Prescription Product.

In March 2006, we acquired Nicomide® in connection with our merger with Sirius Laboratories, Inc. Following investigation by the FDA of Actavis Totowa, LLC, the former manufacturer of Nicomide®, in April 2008, Actavis ceased manufacturing several prescription vitamins, including Nicomide®. The FDA considers prescription dietary supplements to be unapproved new drugs. In response to our discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River s Edge which we entered into in October 2007 to settle certain patent litigation. The amendment to the Settlement Agreement allows 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 changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we were 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. In April 2009, we and River s Edge entered into an Amendment to the License Agreement (the License Amendment) originally entered into in August 2008. The License Amendment grants 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, we are required to transfer all of our rights, title and interest in and to our patent, know-how and trademark relating to the Licensed Products (but not the copyright registration relating to product labeling) to River s Edge upon our receipt of $5,000,000. Of the $5,000,000, River s Edge is required to make a minimum guaranteed payment to us of $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. The License Agreement, as amended, has a term of 30 months, subject to a further extension under certain circumstances to 48 months, and may be terminated early by River s Edge on 30 days prior written notice to us. Under the License Agreement, River s Edge has assumed all regulatory responsibilities for the Licensed Products. If River s Edge terminates the License Agreement prior to the payment of the $5,000,000, all of the rights and licenses granted by us to River s Edge will revert to us. Once we receive $5,000,000 under the terms of the License Agreement, we will no longer receive any revenues from sales of this product. If River s Edge terminates the License Agreement before we receive $5,000,000, we may consider selling the product in accordance with the Dietary Supplement Health and Education Act, but in that case, we would expect volume and revenues to be lower than historical levels.

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 we do not generate sufficient revenues from our approved products, we may be forced to delay or abandon our development program for solid organ transplant recipients or other 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. 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. We might be required to commit substantially greater capital than we have

available to research and development and we may not have sufficient funds to complete this program.

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, and
- control of marketing activities, including advertising and labeling.

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, as received by the manufacturer of our BLU-U®,
- impose fines and other civil penalties on us,
- seize our products,
- suspend our regulatory approvals,
- cease the manufacture of our products, as Actavis Totowa did with Nicomide®,
- refuse to approve pending applications or supplements to approved applications filed by us,
- refuse to permit exports of our products from the United States,
- require us to recall products,
- require us to notify physicians of labeling changes and/or product related problems,
- impose restrictions on our operations, and/or
- criminally prosecute us.

We and our manufacturers must continue to comply with cGMP and Quality System Regulation, or QSR, and equivalent foreign regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. In complying with cGMP 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 ingredients in Levulan® and the BLU-U® or our own Kerastick® facility, will continue to meet all applicable FDA regulations. If we, or any of our manufacturers, including without limitation, the manufacturer of the BLU-U®, who has received warning letters from the FDA, 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. As part of our FDA approval for the Levulan® Kerastick® for AK, we were required to conduct two Phase IV follow-up studies. We successfully completed the first study; and submitted our final report on the second study to the FDA in January 2004. The FDA has requested additional information, which was provided to them in June 2008. We are awaiting their response. 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.

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 be unable to 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 recent 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, clinical development of future

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collaboration products, 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 Affects Our Market, Our Cash Burn Will Increase And Our Ability To Achieve Profitability Will Be Delayed.

We are aware that a portion of our revenues are generated by patients that pay for their procedures out-of-pocket. We believe that the recession may be causing these patients to postpone or cancel their procedures, reducing our volume, and if this continues we will be required to use more of our cash. This could cause a delay in our ability to achieve profitability on a sustainable basis.

We Have Significant Losses And Anticipate Continued Losses.

We have a history of operating losses. We expect to have continued losses until sales of our products increase substantially. We incurred net losses of $6,250,000, $14,714,000 and $31,350,000 for the years ended December 31, 2008, 2007 and 2006, respectively, and $1,607,000 for the three-month period ended March 31, 2009. As of March 31, 2009, our accumulated deficit was approximately $143,458,000. 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 a sustainable basis.

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.

While we completed a private placement raising net proceeds of approximately $10.3 million in October 2007, 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 cannot predict whether any additional financing will be available at all or on acceptable terms. Depending on the extent of available funding, we may delay, reduce in scope or eliminate our SOTR research and development program. 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 include restrictive covenants that restrict our ability to operate our business. Failure to raise capital if needed could materially adversely impact our business, our financial condition, results of operations and cash flows.

If We Are Not Successful With The Reexamination Of Our Patent, We Could Lose Market Share.

In January 2009, we filed a request for reexamination with the United States Patent and Trademark Office (USPTO) of one of the patents licensed from Queens University covering certain methods of using our product, Levulan®, for our FDA-approved indication. The USPTO accepted our request for reexamination during the first quarter of 2009. While we believe that the reexamination will strengthen the patent, there is no guarantee that the process will be successful since the USPTO reviews the entire prosecution history of a patent during a reexamination and could determine that some or all of the patent claims are invalid. Typically, a reexamination takes approximately 18 months to complete. The patent is due to expire in 2013. If the USPTO finds that the patent is invalid, generic competitors could enter the market and we could lose market share. This would adversely affect our financial condition and results of operations and make it more difficult for us to become profitable.

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,

compositions and apparatus for those methods, and

unique physical forms of ALA.

We also own patents covering our BLU-U® and our Kerastick®. However, other third-parties may have blue light devices or drug delivery devices that do not infringe our patents.

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, start to expire in July 2009. The patents covering our AK product do not start to expire until 2013. In January 2009, we filed an application with the USPTO for reexamination of one of our patents. If the USPTO determines that the patent is invalid, generic competitors could enter the market.

We have limited ALA patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic method 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 DUSA, 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, the licensor of our ALA patents, 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® products even though they are marketed for different uses.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River s Edge and an amendment to our Settlement Agreement with River s Edge. The amendment to the Settlement Agreement allows 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 changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we were 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. In April 2009, we and River s Edge entered into an Amendment to the License Agreement (the License Amendment) originally entered into in August 2008. The License Amendment grants 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 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 our receipt of $5,000,000. Of the $5,000,000, River s Edge is required to make a minimum guaranteed payment to us of $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. The License Agreement, as amended, has a term of 30 months, subject to a further extension under certain circumstances to 48 months, and may be terminated early by River s Edge on 30 days prior written notice to us. Under the License Agreement, River s Edge has assumed all regulatory responsibilities for the Licensed Products. If River s Edge terminates the License Agreement prior to the payment of the $5,000,000, all of the rights and licenses granted by us to River s Edge will revert to us

Another company has launched a substitutable niacinamide product. Under the Amendment to the License Agreement, River s Edge has the right but not the obligation to bring litigation against this third-party and the validity of the Nicomide® patent could be tested again. Also, new products have been launched that are competing with Nicomide®. These events could negatively impact our royalty revenues and delay our ability to be profitable.

Furthermore, PhotoCure 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 now commercially available. While we are entitled to royalties from PhotoCure on its net sales of Metvixia®, a large dermatology company has the marketing rights in the U.S., which may adversely affect our ability to maintain or increase our Levulan® market.

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 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 patent 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. 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.

In October 2008, Winston Laboratories, Inc. filed a notice of demand for arbitration with us alleging that we breached the agreements relating to Psoriatec®. We intend to vigorously defend ourselves, and this proceeding will likely involve considerable legal expenses which could negatively affect our financial results.

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®, And Meted®, Any Supply Or Manufacturing Problems Could Negatively Impact Our Sales As Occurred With Nicomide®.

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, 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 are quality or supply problems with any components or materials needed to manufacturer our products, we may not be able to quickly remedy the problem(s). Any of these problems could cause our sales to suffer.

The third-party contracts relating to the manufacturer of the BLU-U® and the active ingredient in the Levulan® are scheduled to expire in June and December of this year, respectively. If we cannot renew these agreements on terms which are acceptable to us, we would need to find new sources of supply. If we have any delay or problems with a new manufacturer, our revenues and results of operations could suffer.

We Have Only Limited Experience Marketing And Selling Pharmaceutical Products 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 are in negotiations with Stiefel because they did not purchase the required minimum number of Kerastick® units under our agreement. They have the right to

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terminate the contract. If our sales and marketing efforts fail, then sales of the Levulan® Kerastick®, the BLU-U®, and other products will be adversely affected and our goal to be profitable by late 2009 could be jeopardized.

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 and our SOTR product candidate, if approved for commercial sale, 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.

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, 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 Commercially Successful Products.

To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products. Except for Levulan® PDT for AKs, the BLU-U® for acne, the ClindaReach® pledget and several other products we acquired in our merger with Sirius, all of our other potential Levulan® and other potential product candidates are at an 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,

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- 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 the best of our knowledge, the FDA has approved only three 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 as happened with our acne trials.

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 or photodetection, known as PD, is safe and effective for any new use we are studying as we experienced with our recent acne 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.

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 87 employees, including 2 part-time employees, as of March 31, 2009. 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 in excess of our insurance coverage 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 the cost is too high, we may have to 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 assets. 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 or more effective than ours. Many of our competitors have substantially greater financial, technical and marketing resources than we have. In addition, several of these companies have significantly greater experience than we do in developing products, conducting preclinical and clinical testing and obtaining regulatory approvals to market products for health care.

We cannot guarantee that new drugs or future developments in drug technologies will not have a material adverse effect on our business. Increased competition could result in:

- price reductions,
- lower levels of third-party reimbursements,
- failure to achieve market acceptance, and
- loss of market share, any of which could adversely affect our business. Further, we cannot give any assurance that developments by our competitors or future competitors will not render our technology obsolete.

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® and Metvix® (known in the United States as Metvixia®) products for any DUSA patents that may issue or be licensed by us in the future.

PhotoCure received FDA approval to market Metvixia for treatment of AKs in July 2004 and it is directly competitive with our Levulan® Kerastick® product. We understand that Metvixia is now commercially available and that its price is comparable to the price of Levulan®. While we are entitled to royalties from PhotoCure on

its net sales of Metvixia, this product, which is marketed in the U.S. by a large dermatology company could adversely affect our ability to maintain or increase our market.

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: medac GmbH and photonamic GmbH & Co. KG (Germany); Biofrontera, PhotoTherapeutics, Inc. (U.K.) and PhotoCure ASA (Norway) which entered into a marketing agreement with Galderma S.A. for countries outside of Nordic countries for certain dermatology indications. We also anticipate that we will face increased competition as the scientific development of PDT and PD advances and new companies enter our markets. Several companies are developing PDT agents other than Levulan®. 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 and rosacea markets.

Axcan Pharma Inc. has received FDA approval for the use of its product, PHOTOFRIN®, for PDT in the treatment of high grade dysplasia associated with Barrett s Esophagus. Axcan is the first company to market a PDT therapy for this indication for which we designed our proprietary sheath device and have conducted pilot clinical trials.

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.

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. Recently, our common stock has traded at prices near and below $1.00. On October 16, 2008, and several times since then, Nasdaq suspended the enforcement of rules requiring a minimum $1.00 closing bid price. The suspension will remain in effect through July 19, 2009. 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 would 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 Results Of Operations And General Market Conditions For Specialty Pharmaceutical And Biotechnology Stocks Could Result In Sudden Changes In The Market Value Of Our Stock.

The price of our common stock has been highly volatile. These fluctuations create a greater risk of capital losses for our shareholders as compared to less volatile stocks. From January 1, 2008 to May 11, 2009, the price of our stock has ranged from a low of $0.87 to a high of $2.58. Factors that contributed to the volatility of our stock during this period included:

- quarterly levels of product sales;

- clinical trial results;
- general market conditions;
- patent litigation;
- increased marketing activities or press releases; and
- changes in third-party payor reimbursement for our therapy.

The significant general market volatility in similar stage pharmaceutical and biotechnology companies made the market price of our common stock even more 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.

If Outstanding Options, Warrants And Rights Are Converted, The Value Of The Shares Of Common Stock Outstanding Just Prior To The Conversion Will Be Diluted.

As of May 11, 2009, there were outstanding options and warrants to purchase 4,984,000 shares of common stock, with exercise prices ranging from $1.08 to $31.00 per share, and from $2.85 to $6.00 per share, respectively. In addition, there are 393,250 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. The holders are likely to 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 DUSA s 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 our shareholders to benefit from such a transaction.

The rights plan provides for the distribution of one right as a dividend for each outstanding share of our common stock to holders of record as of October 10, 2002. Each right entitles the registered holder to purchase one one-thousandths of a share of preferred stock at an exercise price of $37.00 per right. The rights will be exercisable subsequent to the date that a person or group either has acquired, obtained the right to acquire, or commences or discloses an intention to commence a tender offer to acquire, 15% or more of our outstanding common stock or if a person or group is declared an Adverse Person , as such term is defined in the rights plan. The rights may be redeemed by DUSA 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 the 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 DUSA is 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 DUSA s 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. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

EXHIBIT NO.	DESCRIPTION OF EXHIBIT
2(a.3)	Third Amendment to Merger Agreement between Registrant and Sirius Laboratories, Inc. dated April 21, 2009;
3(a.1)	Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant s Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference.
3(a.2)	Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, and is incorporated herein by reference.
3(b)	By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant s current report on Form 8-K, filed on November 2, 2008, and is incorporated herein by reference.
10(a)	Letter Agreement between Registrant and the representatives of Sirius Laboratories, Inc. dated April 3, 2009;
10(b)	Letter Agreement between Registrant and the representatives of Sirius Laboratories, Inc. dated April 21, 2009;
10(c)	Amendment to License Agreement between Registrant and River s Edge Pharmaceuticals, LLC dated April 21, 2009;
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 May 12, 2009.

SIGNATURES

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

DUSA Pharmaceuticals, Inc.

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

Dated: May 12, 2009

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

Dated: May 12, 2009

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