DUSA PHARMACEUTICALS INC
Form 10-Q
November 06, 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: September 30, 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	22-3103129
(State of Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
25 Upton Drive, Wilmington, MA	01887
(Address of Principal Executive Offices)	(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 November 5, 2009, the registrant had 24,108,908 shares of Common Stock, no par value per share, outstanding.

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

	September 30, 2009	December 31, 2008
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 5,016,994	$ 3,880,673
Marketable securities, at fair value	10,012,948	15,002,830
Accounts receivable, net of allowance for doubtful accounts of $90,000 and $98,000 in 2009 and 2008, respectively	2,519,214	2,367,803
Inventory	2,336,167	2,812,825
Prepaid and other current assets	1,647,408	1,873,801
TOTAL CURRENT ASSETS	21,532,731	25,937,932
Restricted cash	174,170	173,844
Property, plant and equipment, net	1,721,488	1,937,978
Deferred charges and other assets	68,099	160,700
TOTAL ASSETS	$ 23,496,488	$ 28,210,454
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 188,417	$ 305,734
Accrued compensation	889,230	1,515,912
Other accrued expenses	2,343,822	3,226,571
Deferred revenues	1,045,505	611,602
TOTAL CURRENT LIABILITIES	4,466,974	5,659,819
Deferred revenues	3,061,700	4,157,305
Warrant liability	474,137	436,458
Other liabilities	133,544	244,673
TOTAL LIABILITIES	8,136,355	10,498,255
COMMITMENTS AND CONTINGENCIES (NOTE 16)		
SHAREHOLDERS EQUITY		
Capital Stock		
Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in Series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding: 24,108,908 and 24,089,452 shares of common stock, no par, at September 30, 2009 and December 31, 2008, respectively	151,683,399	151,663,943
Additional paid-in capital	8,122,801	7,514,900
Accumulated deficit	(144,725,805)	(141,850,925)
Accumulated other comprehensive income	279,738	384,281
TOTAL SHAREHOLDERS EQUITY	15,360,133	17,712,199

TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 23,496,488	$ 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 September 30,		Nine-months ended September 30,	
	2009	2008	2009	2008
Product revenues	$ 6,930,110	$ 5,726,071	$21,033,920	$21,767,810
Cost of product revenues	1,594,692	1,462,028	4,973,782	4,950,039
GROSS MARGIN	5,335,418	4,264,043	16,060,138	16,817,771
Operating costs:				
Research and development	963,245	1,487,816	3,225,049	5,049,327
Marketing and sales	3,013,351	2,967,431	9,460,766	9,520,865
General and administrative	1,877,928	1,911,028	6,360,325	6,603,989
Impairment charge related to contingent consideration		1,500,000		1,500,000
Settlements, net		650	75,000	(282,775)
TOTAL OPERATING COSTS	5,854,524	7,866,925	19,121,140	22,391,406
LOSS FROM OPERATIONS	(519,106)	(3,602,882)	(3,061,002)	(5,573,635)
Other income, net	79,815	114,260	223,801	538,212
Gain (loss) on change in fair value of warrants	24,051	651,767	(37,679)	775,636
NET LOSS	$ (415,240)	$ (2,836,855)	$ (2,874,880)	$ (4,259,787)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (0.02)	$ (0.12)	$ (0.12)	$ (0.18)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED	24,108,908	24,078,610	24,099,786	24,078,546

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

	Nine-months ended September 30,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (2,874,880)	$ (4,259,787)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion (amortization) of premiums and discounts on marketable securities	43,407	(95,139)
Realized loss on sales of marketable securities	43,678	42,989
Share-based compensation	631,770	1,042,811
Impairment charge related to contingent consideration		1,500,000
Depreciation and amortization	345,720	441,829
Loss (gain) on change in fair value of warrants	37,679	(775,636)
Deferred revenues recognized	(675,037)	(761,302)
Changes in other assets and liabilities impacting cash flows used in operations:		
Accounts receivable	(151,411)	1,093,357
Inventory	476,658	(327,363)
Prepaid and other current assets	226,393	(277,174)
Deferred charges and other assets	92,601	80,146
Accounts payable, accrued compensation and other accrued expenses	(1,626,748)	28,036
Deferred revenues	13,335	1,510,712
Other liabilities	(111,129)	(53,083)
NET CASH USED IN OPERATING ACTIVITIES	(3,527,964)	(809,604)
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash paid for contingent consideration		(1,750,000)
Purchases of marketable securities	(12,049,905)	(22,964,544)
Proceeds from maturities and sales of marketable securities	16,848,159	26,368,809
Restricted cash	(326)	(2,875)
Purchases of property, plant and equipment	(129,230)	(333,526)
NET CASH PROVIDED BY INVESTING ACTIVITIES	4,668,698	1,317,864
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options		4,000
Settlements of restricted stock for tax withholding obligations	(4,413)	
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES	(4,413)	4,000
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,136,321	512,260
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,880,673	4,713,619
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 5,016,994	$ 5,225,879

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

The Condensed Consolidated Balance Sheet as of September 30, 2009, the Condensed Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2009 and 2008, and the Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 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.

We evaluated all subsequent events that occurred after the balance sheet date through November 5, 2009, the day prior to the issuance of these financial statements.

2) NEW ACCOUNTING PRONOUNCEMENTS

Recently Adopted Accounting Standards

In April 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Codification (ASC) 320-10-65 (formerly FSP No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*), which establishes a new method of recognizing and reporting other-than-temporary impairments of debt securities and requires additional disclosures related to debt and equity securities. ASC 320-10-65 does not change existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. The adoption of this statement was not material to our financial position or results of operations.

In May 2009, the FASB issued ASC 855-10 (formerly SFAS No. 165, *Subsequent Events*), which provides guidance to establish general standards of accounting for, and disclosures of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855-10 is effective for interim or fiscal periods ending after June 15, 2009. We adopted this statement effective June 15, 2009.

In June 2009, the FASB issued ASC 105-10 (formerly SFAS 168), *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*. ASC 105-10 will become the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernment entities. It also modifies the GAAP hierarchy to include only two levels of GAAP; authoritative and non-authoritative. ASC 105-10 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. Therefore, the Company adopted ASC 105-10 for the reporting in our 2009 third quarter. The adoption did not have a significant impact on the reporting of our financial position, results of operations or cash flows.

Recently Issued Accounting Standards

In October 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements,* or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB Accounting Standards Codification, or ASC, Subtopic 605-25 (previously included within EITF 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). The consensus to EITF Issue No. 08-01, Revenue Arrangements with Multiple Deliverables, or EITF 08-01, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the

selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective

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prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company will have to evaluate the impact of this standard on future revenue arrangements that the Company may enter into.

3) FAIR VALUE MEASUREMENTS

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.

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 September 30, 2009, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

Assets:	
	Level 1
Cash equivalents	$ 3,634,000
	Level 2
United States government-backed securities	$ 9,104,000
Corporate debt securities	909,000
Total assets	$ 13,647,000
	Level 3
Liabilities:	
Warrant liability	474,000
Total liabilities	$ 474,000

Changes in Level 3 Recurring Fair Value Measurements:

The table below includes a rollforward of the balance sheet amounts for the nine-month period ended September 30, 2009 for the warrant liability, which is classified as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable parameters to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable components, observable components (that is, components that are actively quoted and can be validated

to external sources). Accordingly, the gains and losses in the table below include changes in fair value due in part to observable factors that are part of the methodology.

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

The recorded amounts of the Company s cash and cash equivalents, accrued interest receivable, accounts receivable and accounts payable at September 30, 2009 approximate fair value.

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. Assumptions used for the Black-Scholes option-pricing models to determine the fair value of the warrant liability as of September 30, 2009 and December 31, 2008 are as follows:

	September 30, 2009	December 31, 2008
Expected volatility	84.4%	75.0%
Remaining contractual term (years)	3.58	4.33
Risk-free interest rate	1.67%	1.55%
Expected dividend yield	0%	0%
Common stock price	$ 1.09	$ 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 September 30, 2009 and 2008, which totaled $7,000 and $36,000, respectively, an other-than-temporary impairment was considered to have occurred and the cost basis of such securities was written down to their fair values with the amount of the write-down included in earnings as realized losses in the accompanying Condensed Consolidated Statements of Operations. As of September 30, 2009, current yields range from 0.76% to 6.01% and maturity dates range from November 2009 to January 2013. The estimated fair value and cost of marketable securities at September 30, 2009 and December 31, 2008 are as follows:

	September 30, 2009		
	Amortized Cost	Unrealized Gains	Fair Value
United States government-backed securities	$8,912,000	$192,000	$ 9,104,000

Corporate securities	821,000	88,000	909,000
Total marketable securities available-for-sale	$9,733,000	$280,000	$10,013,000

	December 31, 2008		
	Amortized Cost	Unrealized Gains	Fair Value
United States government-backed securities	$11,956,000	$357,000	$12,313,000
Corporate securities	2,662,000	28,000	2,690,000
Total marketable securities available-for-sale	$14,618,000	$385,000	$15,003,000

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The increase (decrease) in net unrealized gains on such securities for the three- and nine-month periods ended September 30, 2009 was ($34,000) and ($105,000), respectively, as compared to $58,000 and $45,000 for the three- and nine-month periods ended September 30, 2008, and has been recorded in accumulated other comprehensive income, which is reported as part of shareholders equity in the Condensed Consolidated Balance Sheets.

6) CONCENTRATIONS

The Company is exposed to concentrations of credit risk related to accounts receivable that are generated from its customers. From time to time, the Company is also exposed to concentrations of revenues with significant customers, including its international distribution partners and domestic wholesalers. To manage credit risk, the Company performs regular credit evaluations of its customers. As the Company believes appropriate, the Company provides allowances for bad debts. Concentrations in the Company s total revenues for the three- and nine-months ended September 30, 2009 and 2008, and accounts receivable as of September 30, 2009 and December 31, 2008 are as follows:

	% of Revenue		% of Revenue			
	Three months ended		Nine months ended		% of Accounts Receivable	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008	September 30, 2009	December 31, 2008
Customer A	2%	1%	3%	2%	7%	11%
Customer B	1%	1%	1%	9%	2%	
Customer C	1%		1%	8%		
Customer D				4%		
Customer E	3%	4%	3%	3%	3%	1%
Customer F	1%	8%	1%	2%	3%	9%
Other customers	92%	86%	91%	72%	85%	79%
Total	100%	100%	100%	100%	100%	100%

7) INVENTORY

Inventory consisted of the following:

	September 30, 2009	December 31, 2008
Finished goods	$1,298,000	$1,348,000
BLU-U® evaluation units	37,000	166,000
Work in process	433,000	698,000
Raw materials	568,000	601,000
Total	$2,336,000	$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:

	September 30, 2009	December 31, 2008
Research and development costs	$ 115,000	$ 190,000
Marketing and sales costs	228,000	191,000
Reserve for sales returns and allowances	300,000	500,000
Accrued FDA fees		589,000
Due to former Sirius shareholders	210,000	
Other product related costs	757,000	824,000
Legal and other professional fees	386,000	467,000
Employee benefits	284,000	278,000
Other expenses	64,000	188,000
Total	$2,344,000	$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- and nine-month periods ended September 30, 2009 and 2008 included the following line items:

	Three-months ended		Nine-months ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Cost of product revenues	$ 13,000	$ 18,000	$ 47,000	$ 59,000
Research and development	31,000	70,000	112,000	260,000
Marketing and sales	62,000	88,000	65,000	61,000
General and administrative	101,000	177,000	408,000	662,000
Share-based compensation expense	$207,000	$ 353,000	$632,000	$ 1,042,000

The weighted-average estimated fair values of employee stock options granted during the three- and nine-month periods ended September 30, 2009 were $0.80 and $0.81 per share, respectively, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	Three-months ended September 30, 2009	Nine-months ended September 30, 2009
Expected volatility	75.5%	73.6%
Risk-free interest rate	2.58%	2%
Expected dividend yield	0%	0%
Expected term-directors and officers (years)	6.5	6.5
Expected term-non-officer employees (years)	5.7	5.7

A summary of stock option activity is as follows:

		Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, beginning of period, July 1, 2009	3,593,275	$ 8.14		
Options granted	20,000	$ 1.22		
Options forfeited	(24,025)	$ 6.47		
Options expired		$		
Options exercised		$		
Outstanding, end of period	3,589,250	$ 8.11	3.72	$25
Exercisable, end of period	2,535,400	$10.67	2.75	

Options vested and expected to vest, end of period	3,445,703	$ 8.39	3.62	$ 21

At September 30, 2009 the total amount of unrecognized compensation expense related to grants of options was $1,038,000.

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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 September 30, 2009 the total amount of unrecognized compensation expense related to grants of unvested common stock was $442,000. The unrecognized compensation related to unvested common stock will be recognized over a weighted-average period of 3.2 years. The weighted average grant date fair value of the 22,750 shares that vested in 2009 and the 393,250 unvested shares of common stock at September 30, 2009 were $2.20 and $1.39, respectively.

10) BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per common share is based on the weighted-average number of shares outstanding during each period. For the three- and nine-month periods ended September 30, 2009, and 2008, stock options, unvested shares of common stock, warrants and rights totaling approximately 5,378,000 and 4,521,000 shares, respectively, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive.

11) SEGMENT REPORTING

The Company has two reportable operating segments: Photodynamic Therapy (PDT) Drug and Device Products and Non-Photodynamic Therapy (Non-PDT) Products. Operating segments are defined as components of the Company for which separate financial information is available to manage resources and evaluate performance regularly by the chief operating decision maker. The table below presents the revenues, costs of revenues and gross margins attributable to these reportable segments for the periods presented. The Company does not allocate research and development, selling and marketing and general and administrative expenses to its reportable segments, because these activities are managed at a corporate level.

	Three-month period ended		Nine-month period ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
REVENUES				
PDT drug and device product revenues	$6,700,000	$5,157,000	$19,836,000	$16,416,000
Non-PDT product revenues	230,000	569,000	1,198,000	5,352,000
Total revenues	6,930,000	5,726,000	21,034,000	21,768,000
COSTS OF REVENUES				
PDT drug and device cost of product revenues	1,226,000	1,146,000	4,227,000	3,589,000
Non-PDT cost of product revenues	369,000	316,000	747,000	1,361,000
Total costs of product revenues	1,595,000	1,462,000	4,974,000	4,950,000
GROSS MARGIN				
PDT drug and device product gross margin	5,474,000	4,011,000	15,609,000	12,827,000
Non-PDT product gross margin	(139,000)	253,000	451,000	3,991,000
Total gross margin	$5,335,000	$4,264,000	$16,060,000	$16,818,000

During the three- and nine-month periods ended September 30, 2009 and 2008, the Company derived revenues from the following geographies based on the location of the customer (as a percentage of product revenues):

	Three-months ended		Nine-months ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
United States	93%	93%	94%	93%
Canada	2%	1%	2%	2%
Korea	3%	4%	2%	3%
Other	2%	2%	2%	2%
Total	100%	100%	100%	100%

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12) COMPREHENSIVE LOSS

For the three- and nine-month periods ended September 30, 2009 and 2008, comprehensive loss consisted of the following:

	Three-months ended September 30,		Nine-months ended September 30,	
	2009	2008	2009	2008
NET LOSS	$(415,000)	$(2,837,000)	$(2,875,000)	$(4,259,000)
Change in net unrealized (losses) gains on marketable securities available-for-sale	(34,000)	58,000	(105,000)	45,000
COMPREHENSIVE LOSS	$(449,000)	$(2,779,000)	$(2,980,000)	$(4,214,000)

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 nine-month periods ended September 30, 2009 and 2008 the Company s sales of Levulan® Kerastick® to Stiefel were $18,000 and $303,000, respectively. At September 30, 2009 and December 31, 2008 the total revenues deferred associated with shipments to Stiefel were $313,000 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 September 30, 2009 and December 31, 2008 associated with milestone payments received from Stiefel were $556,000 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 years ended in October 2008 and 2009 and April 2009 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). To date, Stiefel has failed to make the gross-up payments, and accordingly, the Company is considering its remedies, which include, without limitation, appointing one or more other distributors in the territory or terminating the agreement. Also, since Stiefel s sales to third parties during the contract years ended October 2008 and 2009 and April 2009 were below its minimum purchase obligations, Stiefel has the unilateral right to terminate the contract. Stiefel has not exercised this right.

14) DAEWOONG AGREEMENT

In January 2007 the Company licensed to Daewoong Pharmaceutical Co., LTD. and its wholly-owned subsidiary DNC Daewoong Derma & Plastic Surgery Network Company, 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 nine-month periods ended September 30, 2009 and 2008, the Company s sales of Levulan® Kerastick® to Daewoong were $0 and $998,000, respectively. At September 30, 2009 and December 31, 2008 the total revenues deferred associated with shipments to Daewoong were $801,000 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 September 30, 2009 and December 31, 2008 associated with milestone payments received from Daewoong were $1,489,000 and $1,643,000, respectively. The agreement with Daewoong also establishes a cumulative minimum purchase quantity over the first five years following regulatory approval. If Daewoong fails to meet its minimum purchase quantities, the Company may, in addition to other remedies, at its sole discretion, appoint one or more other distributors in the covered territories, or terminate the agreement.

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15) SETTLEMENTS, NET

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 (loss) gain from settlement of the River s Edge litigation for the three- and nine-month periods ended September 30, 2008 was ($1,000) and $283,000, respectively, and is recorded in the accompanying Condensed Consolidated Statement of Operations in Settlements, net. There were no related gains or losses recorded in 2009.

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 in April 2009 as described in the following paragraph, had allowed River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changed certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, the Company was 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.

In April 2009, the Company and River s Edge entered into an Amendment to their License Agreement (the License Amendment). The License Amendment granted River s Edge an exclusive license to U.S. Patent, No. 6,979,468, and a license to use all know-how and the trademark associated with the Licensed Products worldwide. Under the License Amendment, DUSA is required to transfer all of its rights, title and interest in and to the DUSA s patent, know-how and trademark relating to the Licensed Products (but not the copyright registration relating to product labeling) to River s Edge upon the Company s receipt of $5,000,000. Of the $5,000,000, River s Edge 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 the License Agreement is terminated 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.

The Company is recording the revenue from the License Amendment on a cash basis. The Company received the first $200,000 installment payment under the License Amendment during the second quarter of 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations, but has not received any further payments. In the event that the Company terminates the License Agreement, which it has the right to do for non-payment, the Company will consider introducing a niacinamide product under the Dietary Supplement Health and Education Act, but in that case, the Company would expect volume and revenues to be lower than historical levels of Nicomide. As of November 6, 2009, payments due from River s Edge are six months, or $1.2 million, in arrears. The Company is evaluating its options for termination of the License Agreement, the potential to market a niacinamide product under the Dietary Supplement Health and Education Act, and the collection of the amounts due from River s Edge.

In 2009, another company has launched a substitutable niacinamide product. In July 2009, River s Edge filed a lawsuit against it alleging infringement of the Nicomide® patent. The validity of the patent is being tested again as a request for *ex parte* reexamination of this patent was filed by an unknown third party with the U.S. Patent and Trademark Office, or USPTO, on August 19, 2009. An order issued by the USPTO on October 16, 2009 accepted the reexamination. Also, other new products have been launched that are competing with Nicomide®.

Winston Laboratories Arbitration Settlement

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

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16) COMMITMENTS AND CONTINGENCIES

Business Acquisition

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

Third Amendment to Merger Agreement

In April 2009, the Company and the former shareholders of Sirius entered into a letter agreement providing for the consent of the former Sirius shareholders to the Amendment to the License Agreement with River s Edge mentioned above in Note 15 Settlements, Net, a release, and the Third Amendment to the Merger Agreement, dated as of December 30, 2005, by and among the DUSA Pharmaceuticals, Inc., Sirius and the shareholders of Sirius. Pursuant to the Merger Agreement prior to this amendment, the Company agreed to pay additional consideration after the closing of the merger to the former shareholders of Sirius based upon the attainment of pre-determined total cumulative sales milestones for the products acquired from Sirius over the period ending 50 months from the date of the March 2006 closing of the original Merger Agreement. Pursuant to the agreements entered into in April 2009, the Company 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 removes the Company s obligation to market the Sirius products according to certain previously required standards and allows the Company to manage all business activities relating to the products acquired from Sirius without further approval from the former Sirius shareholders.

In April 2009 the Company paid to the former Sirius shareholders, on a pro rata basis, $100,000. In addition, in the event that the $1,000,000 milestone payment that would become due to the former Sirius shareholders under the Merger Agreement if cumulative Net Sales of the Sirius products reach $35,000,000 is not, in fact, triggered by 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. The $100,000 payment to Sirius shareholders, along with the present value of the guaranteed $250,000 milestone payment, or $210,000, have been included in general and administrative expense for the nine-month period ended September 30, 2009 in the accompanying Condensed Consolidated Statement of Operations.

Other

The amount of the net operating loss carryforwards and other tax attributes that may be utilized to offset future taxable income, when earned, may be subject to certain limitations, based upon changes in the ownership of the Company s common stock under IRC Section 382 that may have occurred in the public market. The Company is in the process of analyzing whether such ownership changes may have occurred and will assess the effects of prior ownership changes, if any, on its ability to utilize its net operating loss carryforwards and other tax attributes.

The Company has not accrued amounts for any other potential contingencies as of September 30, 2009.

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 Levulan® Kerastick® 20% Topical Solution with PDT, the BLU-U® brand light source, and ClindaReach®.

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

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

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® was its key product, a vitamin-mineral product 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 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. 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 the License Agreement is terminated 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 recording the revenue under the License Amendment on a cash basis. We received the first $200,000 installment payment under the License Amendment during the second quarter of 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations, but have not received any further payments. In the event that we terminate the License Agreement, which we have the right to do for non-payment, we will consider introducing a niacinamide product under the Dietary Supplement Health and Education Act, but in that case, the Company would expect volume and revenues to be lower than historical levels of Nicomide. As of November 6, 2009, payments due from River s Edge are six months, or $1.2 million, in arrears. We are evaluating our options for termination of the License Agreement, the potential to market a niacinamide product under the Dietary Supplement Health and Education Act, and the collection of the amounts due from River s Edge.

We are marketing Levulan® PDT 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 responded to the first office action on October 27, 2009. We also own or license certain other patents relating to our BLU-U® device and methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA®, DUSA Pharmaceuticals, Inc.®, Levulan®, Kerastick®, BLU-U®, Nicomide®, Nicomide-T®, ClindaReach®, Meted®, and Psoriacap® are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Numerous other trademark applications are pending.

As of September 30, 2009, we had an accumulated deficit of approximately $144,726,000. 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.

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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 not all of these accounting policies require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting policies with our Audit Committee. With the exception of the updated accounting policies listed below, there have been no material changes to our critical accounting policies in the nine months ended September 30, 2009.

Fair Value Measurements of Marketable Securities

In determining the fair value of our marketable securities, we consider the level of market activity and the availability of prices for the specific securities that we hold. For our Level 2 financial instruments, comprising our corporate debt and United States government-backed securities, we use quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency in the determination of value. We also access publicly available market activity from third party databases and credit ratings of the issuers of the securities we hold to corroborate the data used in the fair value calculations obtained from our primary source. We also take into account credit rating changes, if any, of the securities or recent marketplace activity. We do not have any Level 1 or Level 3 marketable securities.

RESULTS OF OPERATIONS THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 VERSUS SEPTEMBER 30, 2008

REVENUES Total revenues for the three- and nine-month periods ended September 30, 2009 were $6,930,000 and $21,034,000, respectively, as compared to $5,726,000 and $21,768,000 in 2008, and were comprised of the following:

	Three months ended September 30,			Nine months ended September 30,		
	2009	2008	INCREASE/ (DECREASE)	2009	2008	INCREASE/ (DECREASE)
PDT product revenues						
Levulan® Kerastick® product revenues						
United States	$5,790,000	$4,374,000	$1,416,000	$17,096,000	$13,720,000	$ 3,376,000
Canada	162,000	72,000	90,000	404,000	449,000	(45,000)
Korea	201,000	186,000	15,000	498,000	710,000	(212,000)
Other	91,000	99,000	(8,000)	261,000	289,000	(28,000)
Subtotal Levulan® Kerastick® product revenues	6,244,000	4,731,000	1,513,000	18,259,000	15,168,000	3,091,000
BLU-U® product revenues						
United States	456,000	376,000	80,000	1,577,000	1,198,000	379,000
Korea		50,000	(50,000)		50,000	(50,000)
Subtotal BLU-U® product revenues	456,000	426,000	30,000	1,577,000	1,248,000	329,000
Total PDT product revenues	6,700,000	5,157,000	1,543,000	19,836,000	16,416,000	3,420,000
Total Non-PDT product revenues	230,000	569,000	(339,000)	1,198,000	5,352,000	(4,154,000)

Total product revenues	$6,930,000	$5,726,000	$1,204,000	$21,034,000	$21,768,000	$ (734,000)

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For the three- and nine-month periods ended September 30, 2009, total PDT Drug and Device Products revenues, comprised of revenues from our Kerastick® and BLU-U® products, were $6,700,000 and $19,836,000, respectively. This represents an increase of $1,543,000, or 30%, and $3,420,000, or 21%, over the comparable 2008 totals of $5,157,000 and $16,416,000, respectively. The incremental revenue was driven primarily by increased Kerastick® revenues and BLU-U® revenues in the United States.

For the three- and nine-month periods ended September 30, 2009, Kerastick® revenues were $6,244,000, and $18,259,000, respectively, representing a $1,513,000, or 32%, and $3,091,000, or 20%, increase over the comparable 2008 totals of $4,731,000 and $15,168,000, respectively. Kerastick® unit sales to end-users were 53,622 and 155,384, for the three- and nine-month periods ended September 30, 2009, respectively. Included in revenues for the nine months ended September 30, 2009, are 4,500 units sold in Canada and 6,606 sold in Korea. This represents an increase from 44,668 and 145,256 Levulan® Kerastick® units sold in the three- and nine-month periods ended September 30, 2008, respectively. Included in revenues for the nine months ended September 30, 2008, are 5,700 units sold in Canada and 10,692 sold in Korea. Our overall average net selling price for the Kerastick® increased to $115.87 per unit for the first nine months of 2009 from $102.79 per unit for the first nine months of 2008. Our average net selling price for the Kerastick® in the United States increased to $121.66 per unit in 2009 from $110.15 per unit in 2008. The increase in 2009 Kerastick® revenue was driven by increased sales volumes in the United States along with the increase in our overall average unit selling price.

For the three- and nine-month periods ended September 30, 2009, BLU-U® revenues were $456,000 and $1,577,000, respectively, representing a $30,000, or 7%, and $329,000, or 26%, increase over the comparable 2008 totals of $426,000 and $1,248,000, respectively. The increase in year-to-date 2009 BLU-U® revenues was driven by increased overall sales volumes, partially offset by a decrease in our average selling price. In the three- and nine-month periods ended September 30, 2009, there were 59 and 198 units sold, respectively, versus 57 and 154 units sold, respectively, in the comparable 2008 periods. All of the units sold in 2009 were sold in the United States. For the nine months ended September 30, 2008, 149 of the units were sold in the United States with 5 sold in Korea. For the first nine months of 2009, our average net selling price for the BLU-U® decreased to $7,591 from $7,820 in 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 September 30, 2009, there were approximately 9 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 Product revenues for the three- and nine-month periods ended September 30, 2009 were $230,000 and $1,198,000, respectively, compared to $569,000 and $5,352,000, respectively for the comparable 2008 periods. The substantial majority of the Non-PDT product revenues were from Nicomide® related royalties from River s Edge, as further described below, 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. 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.

The decrease in our total revenues for the nine month period ended September 30, 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. We cannot provide any assurance that we will be able to increase sales sufficiently to become profitable, and we cannot provide assurance that a material increase in sales will necessarily cause us to be 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. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. While we are entitled to royalties on net sales of Metvixia, Galderma has a large sales force and considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share. However, our PDT segment revenues in the United States have grown during 2009, due in part to the

6% increase in Medicare reimbursement of our PDT-related procedure fee, which became effective January 1, 2009, as well as our pricing strategies. Although we expect growth in our PDT segment revenues, we are susceptible to the uncertain economic conditions, particularly with our customer base in the U.S. that focuses on the cosmetic market and with the international markets. Reduced sales to the cosmetic customer base and softness in the international markets could be expected until the economy recovers. We expect our Non-PDT revenues for the full year 2009 to be significantly reduced compared to 2008 since we are no longer manufacturing and marketing Nicomide® and are experiencing difficulty collecting payments due under the License Agreement with River s Edge.

COST OF PRODUCT REVENUES Cost of product revenues for the three- and nine-month periods ended September 30, 2009 were $1,595,000 and $4,974,000 as compared to $1,462,000 and $4,950,000 in the comparable periods in 2008. A summary of the components of cost of product revenues and royalties is provided below:

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	THREE MONTHS ENDED SEPTEMBER 30,		
	2009	2008	INCREASE/ (DECREASE)
Levulan® Kerastick® cost of product revenues and royalties			
Direct Levulan® Kerastick® product costs	$ 583,000	$ 547,000	$ 36,000
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	50,000	2,000	48,000
Royalty and supply fees (1)	238,000	197,000	41,000
Subtotal Levulan® Kerastick® cost of product revenues and royalties	$ 871,000	$ 746,000	$ 125,000
BLU-U® cost of product revenues			
Direct BLU-U® product costs	$ 212,000	$ 205,000	$ 7,000
Other BLU-U® product costs including internal costs assigned to support products; as well as, costs incurred to ship and install the BLU-U® in physicians offices	143,000	195,000	(52,000)
Subtotal BLU-U® cost of product revenues	$ 355,000	$ 400,000	$ (45,000)
TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	$1,226,000	$1,146,000	$ 80,000
Non-PDT cost of product revenues and royalties	$ 369,000	$ 316,000	$ 53,000
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	$1,595,000	$1,462,000	$ 133,000

	NINE MONTHS ENDED SEPTEMBER 30,		
	2009	2008	INCREASE/ (DECREASE)
Levulan® Kerastick® cost of product revenues and royalties			
Direct Levulan® Kerastick® product costs	$1,686,000	$1,778,000	$ (92,000)
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	498,000	5,000	493,000
Royalty and supply fees (1)	726,000	668,000	58,000

Subtotal Levulan® Kerastick® cost of product revenues and royalties	$2,910,000	$2,451,000	$ 459,000
BLU-U® cost of product revenues			
Direct BLU-U® product costs	$ 712,000	$ 553,000	$ 159,000
Other BLU-U® product costs including internal costs assigned to support products; as well as, costs incurred to ship and install the BLU-U® in physicians offices	605,000	585,000	20,000
Subtotal BLU-U® cost of product revenues	$1,317,000	$1,138,000	$ 179,000
TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	$4,227,000	$3,589,000	$ 638,000
Non-PDT cost of product revenues and royalties	$ 747,000	$1,361,000	$(614,000)
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	$4,974,000	$4,950,000	$ 24,000

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

MARGINS Total product margins for the three- and nine-month periods ended September 30, 2009 were $5,335,000 and $16,060,000, respectively, as compared to $4,264,000 and $16,818,000 for the comparable 2008 periods, as shown below:

	THREE MONTHS ENDED SEPTEMBER 30,				
	2009		2008		INCREASE/ (DECREASE)
Levulan® Kerastick® gross margin	$ 5,373,000	86%	$ 3,986,000	84%	$ 1,387,000
BLU-U® gross margin	101,000	22%	25,000	6%	76,000
Total PDT drug & device gross margin	$ 5,474,000	82%	$ 4,011,000	78%	$ 1,463,000
Total Non-PDT gross margin	(139,000)	(60)%	253,000	44%	$ (392,000)
TOTAL GROSS MARGIN	$ 5,335,000	77%	$ 4,264,000	74%	$ 1,071,000

	NINE MONTHS ENDED SEPTEMBER 30,				
	2009		2008		INCREASE/ (DECREASE)
Levulan® Kerastick® gross margin	$ 15,349,000	84%	$ 12,717,000	84%	$ 2,632,000

BLU-U® gross margin	260,000	16%	110,000	9%	150,000
Total PDT drug & device gross margin	$ 15,609,000	79%	$ 12,827,000	78%	$ 2,782,000
Total Non-PDT gross margin	451,000	38%	3,991,000	75%	$ (3,540,000)
TOTAL GROSS MARGIN	$ 16,060,000	76%	$ 16,818,000	77%	$ (758,000)

Kerastick® gross margins for the three- and nine-month periods ended September 30, 2009 were 86% and 84% versus 84% for both periods in 2008. The margin improvement for the third quarter is attributable to increased U.S. sales volumes and an increased overall average selling price. Our long-term goal is to achieve higher gross margins on Kerastick® sales which will be significantly dependent on increased volume. We believe that we could achieve improved gross margins on our Kerastick® from further volume growth and price increases in the U.S.
BLU-U® margins for the three- and nine-month periods ended September 30, 2009 were 22% and 16%, respectively, versus 6% and 9% for the comparable 2008 periods. The increase in gross margin is a result of increased sales volumes, partially offset by a decrease in our average selling price. It is important for us to sell BLU-U® units in an effort to drive Kerastick® sales volumes and accordingly, we may

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sell BLU-U s at low profit margins. Non-PDT gross margins reflect the gross margin generated by the products acquired as part of our merger with Sirius. Total Non-PDT gross margins for the three- and nine-month periods ended September 30, 2009 were (60)% and 38%, respectively, compared to 44% and 75%, respectively, in the comparable prior year periods. Non-PDT Product margins in 2009 were negatively impacted by our discontinuance of sales of Nicomide®.

RESEARCH AND DEVELOPMENT COSTS Research and development costs for the three- and nine-month periods ended September 30, 2009 were $963,000 and $3,225,000 as compared to $1,488,000 and $5,049,000 in the comparable 2008 periods. 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 $600,000 Prescription Drug User Fee Act, or 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 received a response to our 510(k) application from the FDA in June 2009. The agency requested additional information in order to complete its review of our application, which included supplementary clinical data in support of our claims. Based on the FDA s requests and the anticipated costs of additional clinical trials, we have decided that we will not pursue the 510(k) application for an expansion of our BLU-U® claims at this time. 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 in the incidence of non-melanoma skin cancers in immunosuppressed solid organ transplant recipients, or SOTRs, who have demonstrated that they are at risk of developing multiple squamous cell carcinomas. 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. In May 2008, we filed an Orphan Drug Designation Application with the FDA for the prevention of cancer occurrence in these patients. We received correspondence from the FDA that our application was not granted on the basis that the agency believes that the prevalence of the target population with this disease state is greater than 200,000, which is the maximum number of patients allowed under the Orphan Drug legislation. We met with the FDA during the third quarter of 2009 to clarify and explain further our application and, based on that meeting, the agency has invited us to submit an amendment to our application for further evaluation. We are in the process of drafting the amendment and redefining our target population. We expect to submit the amendment in November 2009.

We have entered into a series of agreements for our research projects and clinical studies. As of September 30, 2009 future minimum payments to be made pursuant to these agreements, under certain terms and conditions, total approximately $1,001,000 for the remainder of 2009.

MARKETING AND SALES COSTS Marketing and sales costs for the three- and nine-month periods ended September 30, 2009 were $3,013,000 and $9,461,000, respectively, as compared to $2,967,000 and $9,521,000 for the comparable 2008 periods. These costs consisted primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling $2,205,000 and $6,762,000 for the three- and nine-month periods ended September 30, 2009, compared to $2,128,000 and $6,503,000 in the comparable periods in 2008. The increase in spending in the first nine months of 2009 is due to additional marketing and sales headcount. The remaining expenses consisted of tradeshows, miscellaneous marketing and outside consultants totaling $808,000 and $2,699,000 for the three- and nine-month periods ended September 30, 2009, compared to $839,000 and $3,018,000 for the comparable 2008 periods. The decrease in this category is due primarily to a decrease in tradeshow and other promotional spending in 2009. We expect marketing and sales costs for the full year 2009 to remain relatively constant with the 2008 levels.

GENERAL AND ADMINISTRATIVE COSTS General and administrative costs for the three- and nine-month periods ended September 30, 2009 were $1,878,000 and $6,360,000, respectively, as compared to $1,911,000 and

$6,604,000 for the comparable 2008 periods. The decrease in the first nine months is mainly attributable to a decrease in compensation-related costs, offset by the payment of $100,000 and accrual of $210,000 related to the Third Amendment to the Merger Agreement and related documents between us and the former Sirius shareholders entered into in April 2009. General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period.

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

During the fourth quarter of 2007 we entered into a Settlement Agreement and Mutual Release with River s Edge Pharmaceuticals, LLC (the Settlement Agreement). 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- and nine-month periods ended

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September 30, 2009 gains under the settlement agreement were $0 for both periods as compared to ($1,000) and $283,000 for the comparable 2008 periods. The payments under the Settlement Agreement ceased in 2008 due to an amendment which the parties entered into effective as of July 3, 2008. See Note 15 to the Condensed Consolidated Financial Statements.

OTHER INCOME, NET Other income for the three- and nine-month periods ended September 30, 2009, decreased to $80,000 and $224,000, respectively, from $114,000 and $538,000 during the comparable 2008 periods. This decrease reflects an increase in our average investable cash balances during 2009 as compared to 2008 along with a general decrease in interest rates over the same timeframe.

GAIN (LOSS) ON CHANGE IN FAIR VALUE OF WARRANTS The warrants issued to investors in connection with the October 29, 2007 private placement were recorded initially at fair value and are marked to market each reporting period. The decrease (increase) in the liability during the three- and nine-month periods ended September 30, 2009 were $24,000 and ($38,000), respectively, from $652,000 and $776,000 during the comparable 2008 periods, which resulted in non-cash gains or losses in all periods. The decreases or increases in fair value of the warrants are due primarily to changes in our stock price and the length of time remaining prior to their expiration.

NET LOSS For the three- and nine-month periods ended September 30, 2009, we incurred net losses of $415,000, or $0.02 per share, and $2,875,000, or $0.12 per share, respectively, as compared to net losses of $2,837,000, or $0.12 per share, and $4,260,000, or $0.18 per share for the comparable 2008 periods. The decrease in the net loss is attributable to the reasons discussed above.

The amount of the net operating loss carryforwards and other tax attributes that we may utilize to offset future taxable income, when earned, may be subject to certain limitation, based upon changes in the ownership of our common stock under IRC Section 382 that may have occurred in the public market. We are in the process of analyzing whether such ownership changes may have occurred and will assess the effects of prior ownership changes, if any, on our ability to utilize our net operating loss carryforwards and other tax attributes.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2009, we had approximately $15,030,000 of total liquid assets, comprised of $5,017,000 of cash and cash equivalents and marketable securities available-for-sale totaling $10,013,000. We believe that our liquidity will be sufficient to meet our cash requirements for at least the next twelve months. As of September 30, 2009, our marketable securities had a weighted average yield to maturity of 3.26% and maturity dates ranging from November 2009 to January 2013. Our net cash used in operations for the nine-month period ended September 30, 2009 was $3,528,000 versus $810,000 the comparable prior year period. The year-over-year increase in cash used in operations is primarily attributable to a one-time payment of a significant PDUFA fee, the bonus accrued in 2008, which was paid to our employees in 2009, (i.e. there was no bonus paid in 2008 related to 2007), a payment of which was not made in the prior year, and a year-over-year decrease in payments received from our international distributor partners, offset in part by a decrease in our net loss. As of September 30, 2009 working capital (total current assets minus total current liabilities) was $17,066,000, as compared to $20,278,000 as of December 31, 2008. Total current assets decreased by $4,405,000 during the nine-month period ended September 30, 2009, due primarily to decreases in our marketable securities, inventory and prepaid expenses and other current assets, offset in part by increases in our cash and cash equivalents and accounts receivable. Total current liabilities decreased by $1,193,000 during the same period due primarily to a decrease in accounts payable, accrued compensation and other accrued expenses, offset in part by an increase in the current portion of deferred revenues. In response to the instability in the financial markets, we regularly review our marketable securities holdings, and have invested primarily in securities of the U.S. government and its agencies.

Since our inception, we have generated significant losses while we have conducted preclinical and clinical trials, engaged in research and development and dedicated resources to the commercialization of our products. We have also incurred significant losses from the impairment of assets acquired in the acquisition of Sirius. We have funded our operations primarily through public offerings, private placements of equity securities and payments received under our collaboration agreements. We expect to incur 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 may expand or enhance our business in the future by using our resources to acquire by license, purchase or other arrangements, additional businesses, new technologies, or products in the field of dermatology. In 2009, we have focused 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. If we continue to be unprofitable and do not become cash flow positive from operations within a reasonable time, we may reduce our headcount or reduce spending in other areas. We may also seek to raise funds through financing transactions. We cannot predict whether financing will be available at all or on reasonable terms.

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

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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, or Third Amendment, as described in Note 16 to the Notes to the Condensed Consolidated Financial Statements. As consideration for the Third Amendment and related documents, we paid the former Sirius shareholders $100,000 on a pro rata basis and have guaranteed a payment of $250,000 in January 2012 to the former Sirius shareholders if the $35,000,000 sales milestone is not triggered.

We have no off-balance sheet financing arrangements.

Contractual Obligations and Other Commercial Commitments

L. PERRIGO COMPANY

On October 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 the former Sirius 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) could have been due 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®, 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, Inc. and pursuant to the terms of the merger agreement with Sirius, we paid $250,000 on a pro rata basis to the former Sirius shareholders. Similarly, with our decision in early 2008 not to develop a third product from a list of product candidates acquired as part of the merger, we paid another $250,000 on a pro rata basis to the former Sirius shareholders. The payments for ClindaReach® and the other two product decisions satisfy our obligations for the $1,500,000 portion of the purchase price mentioned above. In the third quarter of 2008, the first of the pre-determined total cumulative sales milestones for Sirius products was achieved, and accordingly, we made a cash payment of $1,500,000 to the former Sirius shareholders in consideration of the milestone achievement. In connection with the Third Amendment, we paid the former Sirius shareholders $100,000 on a pro rata basis. 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 we have agreed to pay $250,000 to the former Sirius shareholders on a pro rata basis on or before January 6, 2012. The $100,000 payment to Sirius shareholders, along with the present value of the guaranteed $250,000 milestone payment, or $210,000, have been included in general and administrative expense for the nine-month period ended September 30, 2009 in the accompanying Condensed Consolidated Statement of Operations.

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 ($92,000 as of September 30, 2009).

NATIONAL BIOLOGICAL CORPORATION AMENDED AND RESTATED PURCHASE AND SUPPLY AGREEMENT

On June 29, 2009, we extended the term of the 2004 Amended and Restated Purchase and Supply Agreement with National Biological Corporation, or NBC, one of the manufacturers of our BLU-U® light source, until June 30, 2011. We have an option to further extend the term for an additional two (2) years if we purchase a certain number of units. The parties agreed upon a tiered price schedule based on the volume of purchases and updated certain quality control provisions. All other terms and conditions of the 2004 agreement remain in effect.

SOCHINAZ SA

Under an agreement dated December 24, 1993, Sochinaz SA manufactures and supplies our requirements of Levulan® from its FDA approved facility in Switzerland. Our agreement, which was due to expire on December 31, 2009, has been renewed until December 31, 2015 on substantially the same terms, albeit with a revised pricing schedule to cover the new term. While we can obtain alternative supply sources in certain circumstances, any new supplier would have to be 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 subleased the space through June 30, 2010.

RESEARCH AGREEMENTS

We have entered into various agreements for research projects and clinical studies. As of September 30, 2009, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately $1,001,000. Included in this future minimum payment is a master service agreement, effective September 15, 2001, with Therapeutics, Inc., which is renewable on an annual basis, to engage Therapeutics, Inc. to manage the clinical development of our products in the field of dermatology. The agreement was renewed on June 15, 2009 for a one year period. Therapeutics, Inc. is entitled to receive a bonus valued at $50,000, in cash or stock at our discretion, upon each anniversary of the effective date.

Our contractual obligations and other commercial commitments to make future payments under contracts, including lease agreements, research and development contracts, manufacturing contracts, or other related agreements are as follows at September 30, 2009:

	Total	1 Yr or less	2-3 Years	4-5 Years	After 5
Operating lease obligations	$1,334,000	$ 454,000	$ 880,000	$	$
Purchase obligations (1, 2)	2,237,000	1,984,000	253,000		
Minimum royalty obligations (3)	681,000	342,000	247,000	92,000	
Total obligations	$4,252,000	$2,780,000	$1,380,000	$92,000	$

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 operating leases was approximately $97,000 and $293,000 for the three- and nine-month periods ended September 30, 2009, respectively, compared to $112,000 and $333,000 for the comparable 2008

periods.

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INFLATION

Although inflation rates have been comparatively low in recent years, inflation is expected to apply upward pressure on our operating costs. We have included an inflation factor in our cost estimates.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 non-U.S. government 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.

As of September 30, 2009, the weighted average yield to maturity on our investments was 3.26%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of September 30, 2009, the fair market value of the portfolio would decline by $115,000. Declines in interest rates could, over time, reduce our interest income.

ITEM 4. CONTROLS AND PROCEDURES

We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2009.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Forward-Looking Statements Safe Harbor

This report, including the Management s Discussion and Analysis of Financial Condition and Results of Operations, contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 21E of the Securities Exchange Act of 1934 which represent our expectations or beliefs concerning future events, including, but not limited to management s statements regarding our focus 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 and investigator studies, future development of Levulan® and our other products and other potential indications, 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 and increased sales, 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 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 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, 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, beliefs regarding economic conditions, beliefs concerning increased margins, 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 the use of our products and technologies by third parties, our beliefs regarding our

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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, the possibility that the holders of options and warrants will purchase our common stock by exercising these securities, statements regarding milestone payments to former Sirius shareholders, statements regarding the possibility of other companies distributing our products, statements regarding the agreement with Sochinaz, statements regarding our royalty revenues, statements regarding the impact of our marketing and sales efforts on volume and revenues and financial conditions and statements regarding the termination of the agreement with River s Edge. 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, pricing and 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 and profitability, 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 us. The demand for arbitration arose out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement, which we refer to together as the Agreement, and claimed that we breached the Agreement. The matter was settled on April 28, 2009 for cash consideration of $75,000 and a mutual release.

ITEM 1A. RISK FACTORS

Investing in our common stock is very speculative and involves a high degree of risk. You should carefully consider and evaluate all of the information in, or incorporated by reference in, this report. The following are among the risks we face related to our business, assets and operations. They are not the only ones we face. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of our common stock and you might lose all or part of our investment. This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. We use words such as anticipate , believe , expect , future and intend and similar expressions to identify forward-looki statements. Our actual business, financial condition and results of operations could differ materially from those anticipated in these forward-looking statements for many reasons, including the factors described below and elsewhere in this report. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this report.

Risks Related To DUSA

We 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, We May Need More Capital.

We have approximately $15,030,000 in cash, cash equivalents and marketable securities as of September 30, 2009. Our cash, cash equivalents and marketable securities should be sufficient for current operations for at least the next 12 months. If we are unable to become profitable in the near term, 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.

If A Competitive Product Is Successful Our Market Share Could Decrease and Our Ability Become Profitable Could Be Delayed

On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby we granted a non-exclusive license to PhotoCure under the patents we license from PARTEQ, for esters of ALA. Furthermore, we

granted a non-exclusive license to PhotoCure for its existing formulations of its Hexvix® and Metvix® (known in the United States as Metvixia®) products for any DUSA patents that

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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. Metvixia® is now commercially available and its price is comparable to the price of Levulan®. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. We are entitled to royalties on net sales of Metvixia, however, since it is marketed in the U.S. by Galderma S.A., which has a large sales force and considerably more resources than we have, our ability to maintain or increase our market could be significantly hampered.

Our Ability To Become Profitable May Be Delayed Since We No Longer Sell Nicomide® As A Prescription Product.

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 April 2009, we and River s Edge entered into an Amendment to the License Agreement (the 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 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. We received the first $200,000 installment payment under the License Amendment during the second quarter of 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations but have not received any further payments. We have the right to terminate the License Agreement for non-payment and we are evaluating our options to do so, as well as to market a niacinamide product under the Dietary Supplement Health and Education Act, but in that case, we would expect volume and revenues to be lower than historical levels.

Another company has launched a substitutable niacinamide product. In July 2009, River s Edge filed a lawsuit against it alleging infringement of the Nicomide® patent, and the validity of the patent is being tested again as a request for exparte reexamination of this patent was filed by a third party with the U.S. Patent and Trademark Office, or USPTO, on August 19, 2009. An order issued by the USPTO on October 16, 2009 accepts the request for reexamination. It is too early in the litigation and the reexamination process to assess the possible outcomes. Also, new products have been launched that are competing with Nicomide®.

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

In January 2009, we filed a request for reexamination with the United States Patent and Trademark Office, or 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 and we have responded to the first office action. 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 earlier than otherwise anticipated and we could lose market share. This would adversely affect our financial condition and results of operations and possibly prevent us from becoming profitable.

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

If we do not generate sufficient revenues from our approved products, we may be forced to delay or abandon our development program for 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 and results of operations. Without sufficient product sales, we would need alternative sources of funding. There is no guarantee that adequate funding sources could be found to continue the development of our technology.

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

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

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

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

control of marketing activities, including advertising and labeling, and

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

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

send warning letters,

impose fines and other civil penalties on us,

seize our products,

suspend our regulatory approvals,

cease the manufacture of our products,

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

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

require us to recall products,

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

impose restrictions on our operations, and/or

criminally prosecute us.

We and our manufacturers must continue to comply with current Good Manufacturing Practice regulations, or cGMP, and Quality System 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.

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The Current Global Credit And Financial Market Conditions May Affect Our Business.

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

Due to the tightening of global credit, there may be disruption or delay in the performance by our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including the active ingredient in Levulan® and key portion of the BLU-U®, portions of our product manufacturing, royalty revenues, clinical development of future 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. See Risk Factor *Our Ability To Become Profitable May Be Delayed Since We No Longer Sell Nicomide® As A Prescription Product.*

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 is generated by patients that pay for their procedures out-of-pocket. We believe that the recession may be causing some of 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.

Also, if any of our large customers were to suffer economic hardship and fail to pay us for their purchases of our products, our ability to reach profitability could be delayed, and our financial position, results of operations and cash flows could be negatively affected.

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 $2,875,000 for the nine-month period ended September 30, 2009. As of September 30, 2009, our accumulated deficit was approximately $145,000,000. 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 at all.

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

We will 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. Depending on the extent of available funding, we may delay, reduce in scope or eliminate our solid organ transplant recipient, or 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 could include restrictive covenants that would adversely affect the operation of our business. Failure to raise capital if needed could materially adversely affect our business, our financial condition, results of operations and cash flows.

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

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

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

- methods of using ALA and its unique physical forms in combination with light,
- compositions and apparatus for those methods, and
- unique physical forms of ALA.

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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, started 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. The USPTO accepted our request for reexamination during the first quarter of 2009 and we have responded to the first office action. If the USPTO determines that the patent is invalid, generic competitors could enter the market earlier than otherwise anticipated.

We have limited ALA patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic methods of treatment patents and applications have counterparts in only six foreign countries, and certain countries under the European Patent Convention. Even where we have patent protection, there is no guarantee that we will be able to enforce our patents. Additionally, enforcement of a given patent may not be practicable or an economically viable alternative.

Some of the indications for which we may develop PDT therapies may not be covered by the claims in any of our existing patents. Even with the issuance of additional patents to us, other parties are free to develop other uses of ALA, including medical uses, and to market ALA for such uses, assuming that they have obtained appropriate regulatory marketing approvals. ALA in the chemical form has been commercially supplied for decades, and is not itself subject to patent protection. There are reports of third-parties conducting clinical studies with ALA in countries outside the United States where PARTEQ, 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 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. We received the first $200,000 installment payment under the License Amendment during the six-month period ended September 30, 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations but have not received any further payments. We have the right to terminate the License Agreement for non-payment and we are evaluating our options to do so, as well as to market a niacinamide product under the Dietary Supplement Health and Education Act, but in that case, we would expect volume and revenues to be lower than historical levels.

Another company has launched a substitutable niacinamide product. In July 2009, River s Edge filed a lawsuit against them alleging infringement of the Nicomide® patent. The validity of the Nicomide® patent is being tested again as a request for exparte reexamination of this patent was filed by an unknown third party with the U.S. Patent and Trademark Office, or USPTO, on August 19, 2009. An order issued by the USPTO on October 16, 2009 accepted the request for reexamination. It is too early in the litigation and the reexamination process to assess the possible outcomes. Also, new products have been launched that are competing with Nicomide®. These events could negatively impact our 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. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company which has the marketing rights in the U.S. While we are entitled to royalties on net sales of Metvixia®, Galderma S.A. 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.

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

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

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

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 is 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 and could increase costs.

We Have Only Limited Experience Marketing And Selling Pharmaceutical Products Outside of the United States And As A Result, Our Revenues From Product Sales May Suffer.

If we are unable to successfully market and sell sufficient quantities of our products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. We are responsible for marketing our products in the United States and the rest of the world, except Canada, Latin America and parts of Asia, where we have distributors. We are in negotiations with Stiefel, our distributor in Latin America, because they did not purchase the required minimum number of Kerastick® units under our agreement. Both parties have the right to terminate the contract. In July 2009, GlaxoSmithKline, or GSK, completed its acquisition of Stiefel, and we do not know whether

GSK wants Stiefel to continue to distribute the Levulan® Kerastick®. If our sales and marketing efforts fail, then sales of the Levulan® Kerastick®, the BLU-U®, and other products will be adversely affected, which would adversely affect our financial condition.

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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, reduce the amounts of coverage or stop covering our products which are covered, our sales could be dramatically reduced.

We Have Only Three Therapies That Have Received Regulatory Approval Or Clearance, And We Cannot Predict Whether We Will Ever Develop Or Commercialize Any Other Levulan® Products.

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

Except for Levulan® PDT for AKs, the BLU-U® for acne, the ClindaReach® pledget and several other products we acquired in our merger with Sirius, all of our 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,

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.

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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.

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 may study. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy.

We have been informed by FDA that the agency does not believe that our application for Orphan Drug designation of use of Levulan® in immunosuppressed solid organ transplant recipients should be granted. We met with the FDA during the third quarter of 2009 to clarify and explain further our application and, based on that meeting, the agency has invited us to submit an amendment to our application for further evaluation. We are in the process of drafting the amendment and redefining our target population. We expect to submit the amendment in November, 2009. If we cannot obtain this designation, we may not continue to develop this indication. We have requested a meeting with the FDA to provide further clarification on the application and the related target population.

We have been informed by FDA that our 510(k) application for clearance of our BLU-U® to treat severe acne requires additional clinical data. Based on this information and the anticipated costs of additional clinical trials, we have decided that we will not pursue the 510(k) application for an expansion of our BLU-U® claims at this time.

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 September 30, 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 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.

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

We have used various hazardous materials, such as mercury in fluorescent tubes in our research and development activities. We are subject to federal, state and local laws and regulations which govern the use, manufacture, storage, handling and disposal of hazardous materials and specific waste products. We believe that we are in compliance in all material respects with currently applicable environmental laws and regulations. However, we cannot guarantee that we will not incur significant costs to comply with environmental laws and regulations in the future. We also cannot guarantee that current or future environmental laws or regulations will not materially adversely affect our operations, business or financial condition. In addition, although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages, and this liability could exceed our resources.

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

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

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

Many companies are also seeking to develop new products and technologies, and receiving approval for treatment of AKs and acne. Our industry is subject to rapid, unpredictable and significant technological change. Competition is intense. Our competitors may succeed in developing products that are safer, more effective or more desirable than ours. Many of our competitors have substantially greater financial, technical and marketing resources than we have. In addition, several of these companies have significantly greater experience than we do in developing products, conducting preclinical and clinical testing and obtaining regulatory approvals to market products for health care.

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. Metvixia® is now commercially available and its price is comparable to the price of Levulan®. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. We are entitled to royalties on net sales of Metvixia; however since it is marketed in the U.S. by Galderma, S.A., which has a large sales force and considerably more resources than we have, our ability to maintain or increase our market, could be significantly hampered.

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). 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.

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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. During 2009, our common stock has traded at prices near and below $1.00. If we do not continue to meet Nasdaq s applicable minimum listing standards, Nasdaq could delist us from the Nasdaq Global Market. If our common stock is delisted from the Nasdaq Global Market, we could seek to have our common stock listed on the Nasdaq Capital Market or other Nasdaq markets. However, delisting of our common stock from the Nasdaq Global Market could hinder your ability to sell, or obtain an accurate quotation for the price of, your shares of our common stock. Delisting could also adversely affect the perception among investors of DUSA and its prospects, which could lead to further declines in the market price of our common stock. Delisting 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, which creates an enhanced risk of capital losses for our shareholders. From January 1, 2008 to November 5, 2009, the price of our stock has ranged from a low of $0.87 to a high of $2.58. Factors that we believe may have contributed to the volatility of our stock during this period included:

clinical trial results,

health regulatory action,

patent litigation,

press releases, and

low volume and liquidity.

The significant general market volatility in similar stage pharmaceutical and biotechnology companies also made the market price of our stock volatile.

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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 Exercised, The Value Of The Shares Of Common Stock Outstanding Just Prior To The Conversion Will Be Diluted.

As of November 6, 2009, there were outstanding options and warrants to purchase 4,985,000 shares of common stock, with exercise prices ranging from $1.08 to $31.00 per share for options, and exercise prices ranging from $2.85 to $6.00 per share for warrants. In addition, there are 393,000 shares of unvested common stock. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. The holders may exercise their securities during a time when we would likely be able to raise capital from the public on terms more favorable than those provided in these securities.

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

Our certificate of incorporation authorizes the board of directors to issue up to 100,000,000 shares of stock, 40,000,000 of which are common stock. The board of directors has the authority to determine the price, rights, preferences and privileges, including voting rights, of the remaining 60,000,000 shares without any further vote or action by the shareholders. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future.

On September 27, 2002, we adopted a shareholder rights plan at a special meeting of 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 certain of our shareholders to benefit from such a transaction.

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

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ITEM 6. EXHIBITS.

EXHIBIT NO.	DESCRIPTION OF EXHIBIT
3(a.1)	Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant s Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference.
3(a.2)	Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, and is incorporated herein by reference
10	Fifth Amendment to Supply Agreement with Sochinaz S.A. dated September 10, 2009
3(b)	By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant s current report on Form 8-K, filed on November 2, 2008, and is incorporated herein by reference.
31(a)	Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
31(b)	Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
32(a)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32(b)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1	Press Release dated November 6, 2009

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SIGNATURES

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

DUSA Pharmaceuticals, Inc.

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

Dated November 6, 2009

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

Dated November 6, 2009

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