

DUSA PHARMACEUTICALS INC

Form 10-Q

May 05, 2011

Table of Contents

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

(Mark One)

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

For the quarterly period ended: March 31, 2011

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

For the transition period from _____ to _____

Commission file number: 001-31533

DUSA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

01887
(Zip Code)

(978) 657-7500

(Registrant's Telephone Number, Including Area Code)
(Former Name, Former Address and Former Fiscal Year,
if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

(Do not check if a smaller reporting company)

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

As of May 4, 2011, the registrant had 24,433,969 shares of Common Stock, no par value per share, outstanding.

DUSA PHARMACEUTICALS, INC. TABLE OF CONTENTS TO FORM 10-Q

	Page Number
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements</u>	
- <u>Condensed Consolidated Balance Sheets at March 31, 2011 and December 31, 2010 (Unaudited)</u>	3
- <u>Condensed Consolidated Statements of Operations for the three-month periods ended March 31, 2011 and 2010 (Unaudited)</u>	4
- <u>Condensed Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2011 and 2010 (Unaudited)</u>	5
- <u>Notes to the Condensed Consolidated Financial Statements (Unaudited)</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	19
<u>Item 4. Controls and Procedures</u>	19
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	20
<u>Item 1A. Risk Factors</u>	20
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
<u>Item 3. Defaults Upon Senior Securities</u>	28
<u>Item 4. [Removed and Reserved.]</u>	28
<u>Item 5. Other Information</u>	28
<u>Item 6. Exhibits</u>	29
<u>SIGNATURES</u>	30
<u>Exhibit Index</u>	
<u>EX-31.A</u>	
<u>EX-31.B</u>	
<u>EX-32.A</u>	
<u>EX-32.B</u>	
<u>EX-99.1</u>	

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

	March 31, 2011	December 31, 2010
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 12,474,249	\$ 8,884,402
Marketable securities	8,593,100	10,762,559
Accounts receivable, net of allowance for doubtful accounts of \$75,000 and \$60,000 in 2011 and 2010, respectively	2,708,462	3,311,467
Inventory	2,528,236	2,165,220
Prepaid and other current assets	1,123,366	1,344,062
TOTAL CURRENT ASSETS	27,427,413	26,467,710
Restricted cash	175,028	174,753
Property, plant and equipment, net	1,552,104	1,582,777
Deferred charges and other assets	132,833	68,099
TOTAL ASSETS	\$ 29,287,378	\$ 28,293,339
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 1,007,696	\$ 162,742
Accrued compensation	401,242	2,243,997
Other accrued expenses	2,777,896	2,348,838
Deferred revenue	648,006	712,338
TOTAL CURRENT LIABILITIES	4,834,840	5,467,915
Deferred revenue	1,861,972	1,917,237
Warrant liability	3,392,486	1,203,553
Other liabilities	170,998	181,153
TOTAL LIABILITIES	10,260,296	8,769,858
COMMITMENTS AND CONTINGENCIES (NOTE 12)		
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: 24,413,969 and 24,239,365 shares of common shares, no par, at March 31, 2011 and December 31, 2010, respectively	151,638,956	151,703,468
Additional paid-in capital	9,596,083	9,399,434
Accumulated deficit	(142,261,500)	(141,656,600)

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Accumulated other comprehensive income	53,543	77,179
TOTAL SHAREHOLDERS EQUITY	19,027,082	19,523,481
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 29,287,378	\$ 28,293,339

See the accompanying Notes to the Condensed Consolidated Financial Statements.

3

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

	Three Months Ended March 31,	
	2011	2010
Product revenues	\$ 11,082,064	\$ 8,713,880
Cost of product revenues	1,760,370	1,818,185
GROSS MARGIN	9,321,694	6,895,695
Operating costs		
Research and development	1,323,644	1,109,667
Marketing and sales	3,973,224	3,613,799
General and administrative	2,457,247	2,463,164
TOTAL OPERATING COSTS	7,754,115	7,186,630
INCOME (LOSS) FROM OPERATIONS	1,567,579	(290,935)
Loss on change in fair value of warrants	(2,188,933)	(199,275)
Other income	16,454	65,727
NET LOSS	\$ (604,900)	\$ (424,483)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (0.02)	\$ (0.02)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED	24,283,398	24,122,459

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

	Three months ended March 31,	
	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (604,900)	\$ (424,483)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Accretion of premiums and discounts on marketable securities	(4,840)	2,712
Share-based compensation	196,649	211,777
Depreciation and amortization	106,284	102,986
Loss on change in fair value of warrants	2,188,933	199,275
Deferred revenues recognized	(119,597)	(159,032)
Changes in other assets and liabilities impacting cash flows from operations:		
Accounts receivable	603,005	570,089
Inventory	(363,016)	223,683
Prepaid and other assets	155,962	370,387
Accounts payable, accrued compensation and other accrued expenses	(568,743)	(95,462)
Other liabilities	(10,155)	(14,332)
NET CASH PROVIDED BY OPERATING ACTIVITIES	1,579,582	987,600
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of marketable securities	(1,499,337)	
Proceeds from maturities and sales of marketable securities	3,650,000	
Restricted cash	(275)	(91)
Purchases of property, plant and equipment	(75,611)	(28,554)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	2,074,777	(28,645)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options	126,508	
Settlements of restricted stock for tax withholding obligations	(191,020)	(30,368)
NET CASH USED IN FINANCING ACTIVITIES	(64,512)	(30,368)
NET INCREASE IN CASH AND CASH EQUIVALENTS	3,589,847	928,587
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	8,884,402	7,613,378
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 12,474,249	\$ 8,541,965

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

The Condensed Consolidated Balance Sheet as of March 31, 2011, and the Condensed Consolidated Statements of Operations and Cash Flows for the three-month periods ended March 31, 2011 and 2010 of DUSA Pharmaceuticals, Inc. (the Company or DUSA) have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). These condensed consolidated financial statements are unaudited but include all normal recurring adjustments, which management of the Company believes to be necessary for fair presentation of the periods presented. The results of the Company s operations for any interim period are not necessarily indicative of the results of the Company s operations for any other interim period or for a full year.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements should be read in conjunction with the Consolidated Financial Statements and Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission. The balance sheet as of December 31, 2010 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

2) FINANCIAL INSTRUMENTS*Fair Value Measurements*

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

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

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

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

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

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

		Fair Value Measurements at March 31, 2011		
	Carrying Value	(Level 1)	(Level 2)	(Level 3)
Assets				
Cash and cash equivalents	\$ 12,474,000	\$ 12,474,000		
United States government-backed securities	7,824,000		\$ 7,824,000	
Corporate securities	769,000		769,000	
Total assets at fair value	21,067,000	12,474,000	8,593,000	
Liabilities				
Warrant liability	3,392,000			\$ 3,392,000
Total liabilities at fair value	\$ 3,392,000	\$	\$	\$ 3,392,000

Table of Contents

	Carrying Value	Fair Value Measurements at December 31, 2010		
		(Level 1)	(Level 2)	(Level 3)
Assets				
Cash and cash equivalents	\$ 8,884,000	\$ 8,884,000		
United States government-backed securities	9,985,000		\$ 9,985,000	
Corporate securities	778,000		778,000	
Total assets at fair value	19,647,000	8,884,000	10,763,000	
Liabilities				
Warrant liability	1,203,000			\$ 1,203,000
Total liabilities at fair value	\$ 1,203,000	\$	\$	\$ 1,203,000

The Company reviewed the level classifications of its investments at March 31, 2011 compared to December 31, 2010 and determined that there were no significant transfers between levels in the three months ended March 31, 2011.

The table below includes a roll forward of the balance sheet amounts for the three-month period ended March 31, 2011 for the warrant liability, which is classified as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable parameters to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable components, observable components (that is, components that are actively quoted and can be validated to external sources). Accordingly, the gains and losses in the table below include changes in fair value due in part to observable factors that are part of the methodology.

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
Three-Month Period Ended March 31, 2011**

	Fair Value at January 1, 2011	Total Unrealized Loss Recognized in Statement Of Operations	Purchases, Sales, Issuances, Settlements, net	Transfers In and/or Out of Level 3	Fair Value at March 31, 2011	Change in Unrealized Losses in 2011
Warrant Liability	\$ 1,203,000	\$ 2,189,000	\$	\$	\$ 3,392,000	\$ (2,189,000)

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
Three-Month Period Ended March 31, 2010**

	Fair Value at	Total Unrealized Loss Recognized in	Purchases, Sales, Issuances,	Transfers In and/or	Fair Value at	Change in
--	------------------	---	------------------------------------	---------------------------	------------------	-----------

	January 1, 2010	Statement Of Operations	Settlements, net	Out of Level 3	March 31, 2010	Unrealized Gains in 2010
Warrant Liability	\$ 813,000	\$ 199,000	\$	\$	\$ 1,012,000	\$ (199,000)

Marketable Securities

The Company's marketable securities consist of the following:

	March 31, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government-backed securities	\$ 7,804,000	\$ 29,000	\$ (9,000)	\$ 7,824,000
Corporate securities	735,000	34,000		769,000
Total marketable securities	\$ 8,539,000	\$ 63,000	\$ (9,000)	\$ 8,593,000

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

The Company amortizes or accretes the premiums and discounts paid for the securities into interest income over the period to maturity of the securities. The decrease in net unrealized gains on such securities for the three-month periods ended March 31, 2011 and 2010 was \$24,000 and \$34,000, respectively, which has been recorded in accumulated other comprehensive income and is reported as part of

Table of Contents

shareholders' equity in the Condensed Consolidated Balance Sheets. Realized losses on sales of marketable securities were \$0 for the three-month periods ended March 31, 2011 and 2010. As of March 31, 2011, current yields range from 0.15% to 6.18% and maturity dates range from April 2011 to December 2013.

Common Stock Warrants

Upon issuance of the warrants on October 29, 2007, the Company recorded the warrant liability at its initial fair value of \$1,950,000. Warrants that are classified as a liability are revalued at each reporting date until the warrants are exercised or expire with changes in the fair value reported in the Company's Condensed Consolidated Statements of Operations as gain or loss on fair value of warrants. Non-cash losses for the three-month periods ended March 31, 2011 and 2010, were \$2,189,000 and \$199,000, respectively. At March 31, 2011 and December 31, 2010, the aggregate fair value of these warrants was \$3,392,000 and \$1,204,000, respectively. Assumptions used for the Black-Scholes option-pricing models in determining the fair value as of March 31, 2011 and December 31, 2010 are as follows:

	March 31, 2011	December, 31 2010
Expected volatility	68.1%	81%
Remaining contractual term (years)	2.1	2.3
Risk-free interest rate	0.8%	0.7%
Expected dividend yield	0%	0%
Common stock price	\$5.20	\$ 2.45

3) CONCENTRATIONS

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

4) INVENTORY

Inventory consisted of the following:

	March 31, 2011	December 31, 2010
Finished goods	\$ 1,104,000	\$ 907,000
BLU-U® evaluation units	102,000	129,000
Work in process	281,000	371,000
Raw materials	1,041,000	758,000
Total	\$ 2,528,000	\$ 2,165,000

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

5) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	March 31, 2011	December 31, 2010
Research and development costs	\$ 240,000	\$ 231,000
Marketing and sales costs	238,000	195,000
Reserve for sales returns and allowances	158,000	125,000
Other product related costs	831,000	798,000
Legal and other professional fees	453,000	308,000
Due to former Sirius shareholders	237,000	232,000
Employee benefits	337,000	298,000
Other expenses	284,000	162,000
Total	\$ 2,778,000	\$ 2,349,000

Table of Contents**6) SHARE-BASED COMPENSATION**

Total share-based compensation expense, related to all of the Company's share-based awards, recognized for the three-month periods ended March 31, 2011 and 2010 is included in the following line items:

	Three months ended March 31, 2011	Three months ended March 31, 2010
Cost of product revenues	\$ 9,000	\$ 14,000
Research and development	27,000	35,000
Selling and marketing	54,000	28,000
General and administrative	107,000	135,000
Total	\$ 197,000	\$ 212,000

The weighted-average estimated fair value of stock options granted during the three-month periods ended March 31, 2011 and 2010 was \$2.77 and \$1.11 per share, respectively, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	Three months ended March 31, 2011	Three months ended March 31, 2010
Volatility	77.0%	75.4%
Risk-free interest rate	2.4%	2.7%
Expected dividend yield	0%	0%
Expected life-directors and officers	5.9 years	6.0 years
Expected life-non-officer employees	5.6 years	5.8 years

A summary of stock option activity for the three-month period ended March 31, 2011 follows:

		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, beginning of period	3,064,050	\$ 4.09		
Options granted	119,300	\$ 4.20		
Options forfeited	(6,425)	\$ 1.49		
Options expired	(62,500)	\$ 14.04		
Options exercised	(67,325)	\$ 1.88		
Outstanding, end of period	3,047,100	\$ 3.94	4.51	\$ 7,212,000

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Exercisable, end of period	2,016,377	\$ 5.00	3.99	\$ 3,776,000
Options vested and expected to vest, end of period	2,934,208	\$ 4.01	4.46	\$ 6,869,000

Unvested Shares of Common Stock

The Company has issued unvested shares of common stock, which vest over 4 years at a rate of 25% per year, as follows:

	Three months ended March 31, 2011	Three months ended March 31, 2010
Outstanding unvested shares of common stock, beginning of period	586,000	393,250
Shares granted	450,000	308,000
Shares vested	(154,000)	(81,250)
Outstanding, end of period	882,000	620,000
Weighted average grant date fair value of shares vested during period	\$ 1.43	\$ 1.22
Weighted average grant date fair value of shares granted during period	\$ 4.20	\$ 1.65
Weighted average grant date fair value of unvested shares, end of period	\$ 2.90	\$ 1.54
Weighted average remaining years to vest	3.17	3.25

At March 31, 2011 total unrecognized estimated compensation cost related to non-vested common shares was \$2,302,000, which is expected to be recognized over a weighted average period of 3.17 years. At March 31, 2011 total unrecognized estimated compensation cost related to stock options was \$1,066,000 which is expected to be recognized over a weighted average period of 2.53 years.

Table of Contents**7) BASIC AND DILUTED NET LOSS PER SHARE**

Basic net loss per common share is based upon the weighted average number of common shares outstanding during each period. Stock options, unvested common stock grants and warrants are not included in the computation of the weighted average number of common shares outstanding for dilutive net loss per common share during each of the periods presented in the Consolidated Statements of Operations, as the effect would be antidilutive. For the three-month periods ended March 31, 2011, and 2010, the following are not included in weighted average common shares outstanding because they are antidilutive:

	Three-month periods ended March 31,	
	2011	2010
Stock options	3,047,000	3,143,000
Warrants	1,145,000	1,395,000
Unvested shares of common stock	882,000	620,000
Total	5,074,000	5,158,000

8) SEGMENT REPORTING

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

	Three-month period ended March 31,	
	2011	2010
REVENUES		
PDT drug and device product revenues	\$ 10,982,000	\$ 8,296,000
Non-PDT drug product revenues	100,000	418,000
Total revenues	11,082,000	8,714,000
COSTS OF PRODUCT REVENUES		
PDT drug and device cost of product revenues	1,617,000	1,581,000
Non-PDT drug cost of product revenues	143,000	237,000
Total cost of product revenues	1,760,000	1,818,000
GROSS MARGINS		
PDT drug and device product gross margins	9,365,000	6,715,000
Non-PDT drug product gross margins	(43,000)	181,000
Total gross margins	\$ 9,322,000	\$ 6,896,000

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

During the three-month periods ended March 31, 2011 and 2010, the Company derived revenues from the following geographies based on the location of the customer (as a percentage of product revenues):

	2011	2010
United States	97%	97%
Canada	2%	1%
Korea	1%	1%
Other		1%
Total	100%	100%

9) COMPREHENSIVE LOSS

For the three-month periods ended March 31, 2011 and 2010, comprehensive loss consisted of the following:

	March 31, 2011	March 31, 2010
NET LOSS	\$ (605,000)	\$ (424,000)
Change in net unrealized gains on marketable securities available-for-sale	(24,000)	(34,000)
COMPREHENSIVE LOSS	\$ (629,000)	\$ (458,000)

Table of Contents**10) SIGNIFICANT PRODUCT AGREEMENTS***Stiefel Agreement*

In the third quarter of 2010, the Company gave notice to Stiefel Laboratories, Inc. terminating the parties Marketing, Distribution and Supply Agreement, dated January 12, 2006, as amended, as of September 26, 2007. The termination of this Agreement, which had appointed Stiefel as the Company's exclusive marketing and distribution partner for the Company's product, the Levula[®] Kerastick, in Latin America, resulted in the acceleration of the recognition of deferred revenues of \$555,000, comprised of deferred drug shipments of \$87,000 and the unamortized balance of milestone payments of \$468,000, and the acceleration of deferred cost of revenues of \$42,000.

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 three-month periods ended March 31, 2011 and 2010, the Company's shipments of Levula[®] Kerastick[®] to Daewoong were \$0. At March 31, 2011 and December 31, 2010 the total revenues deferred associated with shipments to Daewoong were \$423,000 and \$487,000, respectively, in accordance with the Company's policy of deferring revenues during a product's launch phase and recognizing revenues based on delivery to end-users. Deferred revenues at March 31, 2011 and December 31, 2010 associated with milestone payments received from Daewoong were \$1,180,000 and \$1,232,000, respectively. The agreement with Daewoong also establishes a cumulative minimum purchase quantity over the first five years following regulatory approval. If Daewoong fails to meet its minimum purchase quantities, the Company may, in addition to other remedies, at its sole discretion, appoint one or more other distributors in the covered territories, or terminate the agreement.

PhotoCure Agreement

On May 30, 2006, the Company entered into a patent license agreement under which the Company granted PhotoCure ASA a non-exclusive license under the patents the Company licenses from PARTEQ for ALA esters. In addition, the Company granted a non-exclusive license to PhotoCure for its existing formulations of Hexvix[®] and Metvix[®] (known in the U.S. as Metvixia[®]) for any patent the Company owns now or in the future. On October 1, 2009, Photocure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. While we are entitled to royalties on net sales of Metvixia, Galderma has considerably more resources than we have, which could significantly hamper our ability to maintain or increase our market share.

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

11) INCOME TAXES

Based on an Internal Revenue Code (IRC) Section 382 study performed, the Company determined that it has experienced prior ownership changes, as defined under IRC Section 382, with the most recent change in ownership occurring in 2007 (the 2007 Ownership Change). The Company's pre-change NOL carryforwards are subject to an annual limitation of approximately \$2.2 million per year. Further, additional rules provide for the enhancement of the aforementioned annual limitation for the first five years after the ownership change. A loss corporation may increase its IRC Section 382 limitation by the amount of the net unrealized built-in gain (NUBIG) recognized within five years

of the ownership change. The calculated aggregate amount of NUBIG enhancement for the Company is approximately \$4.3 million (i.e., approximately \$868,000 per year for the first five years after the ownership change). This NUBIG enhancement will be utilized in conjunction with the approximately \$2.2 million of IRC Section 382 base annual limitation, resulting in approximately \$3.0 million per year for the first five years after the ownership change. Based on these additional factors, the Company estimates that it will be able to utilize approximately \$54.3 million of its current net operating losses, provided that sufficient income is generated and no further ownership changes were to occur. However, it is reasonably possible that a future ownership change, which could be the result of transactions involving the Company's common stock that are outside of its control (such as sales by existing shareholders), could occur during 2011 or thereafter. Future ownership changes could further restrict the utilization of the Company's net operating losses and tax credits, reducing or eliminating the benefit of such net operating losses and tax credits. An ownership change occurs under IRC Section 382 if the aggregate stock ownership of certain shareholders increases by more than 50 percentage points over such shareholders' lowest percentage ownership during the testing period, which is generally three years.

Table of Contents**12) COMMITMENTS AND CONTINGENCIES****Business Acquisition**

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

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

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

Third Amendment to Merger Agreement

In April 2009, the Company and the former shareholders of Sirius entered into a letter agreement providing for the consent of the former Sirius shareholders to the Amendment to the License Agreement with River's Edge Pharmaceuticals, LLC, a release, and the Third Amendment to the Merger Agreement, dated as of December 30, 2005, by and among the DUSA Pharmaceuticals, Inc., Sirius and the shareholders of Sirius. Pursuant to the Merger Agreement prior to this amendment, the Company agreed to pay additional consideration after the closing of the merger to the former shareholders of Sirius based upon the attainment of pre-determined total cumulative sales milestones for the products acquired from Sirius over the period ending 50 months from the date of the March 2006 closing of the original Merger Agreement. Pursuant to the agreements entered into in April 2009, the Company agreed to extend the Milestone Termination Date from 50 months from the date of the closing of the original Merger Agreement until December 31, 2011 and to include in the definition of Net Sales in the Merger Agreement payments which the Company may receive from the divestiture of Sirius products. The Third Amendment to the Merger Agreement also removes the Company's obligation to market the Sirius products according to certain previously required standards and allows the Company to manage all business activities relating to the products acquired from Sirius without further approval from the former Sirius shareholders. In April 2009 the Company paid to the former Sirius shareholders, on a pro rata basis, \$100,000. In addition, in the event that the \$1,000,000 milestone payment that would become due to the former Sirius shareholders under the Merger Agreement if cumulative Net Sales of the Sirius products reach \$35,000,000 is not, in fact, triggered by December 31, 2011, then the Company has agreed to pay \$250,000 to the former Sirius shareholders on a pro rata basis on or before January 6, 2012. The present value of the guaranteed \$250,000 milestone payment, or \$237,000, is included in other accrued expenses in the accompanying Consolidated Balance Sheets.

The Company has not accrued amounts for any other potential contingencies as of March 31, 2011.

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

Lease Arrangements

The Company leases its facilities under operating leases. The Company's lease arrangements have terms which expire through 2014. Total rent expense under operating leases was approximately \$85,000 and \$97,000 for the three-month periods ended March 31, 2011 and 2010, respectively. Future minimum payments under lease arrangements at March 31, 2010 are as follows:

Years Ending December 31,	Operating Lease Obligations
---------------------------	-----------------------------

2011	\$ 286,000
2012	389,000
2013	396,000
2014	366,000
Total	\$ 1,437,000

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

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

We are a vertically integrated dermatology company that is developing and marketing Levulan[®] 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[®].

Table of Contents

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

The Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® were launched in the United States, or U.S., in September 2000 for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp. 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. Nicamide® was its key product, a vitamin-mineral product prescribed by dermatologists. We merged with Sirius in March 2006.

We are marketing Levulan® PDT under an exclusive worldwide license of patents, many of which have expired, and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to our BLU-U® 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®, Nicamide®, Nicamide-T®, ClindaReach®, Meted®, and Psoriacap® are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Numerous other trademark applications are pending.

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

CRITICAL ACCOUNTING POLICIES

Our accounting policies are disclosed in Note 2 to the Notes to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2010. Since all of these accounting policies do not require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting policies with our Audit Committee. There have been no changes to our critical accounting policies in the three months ended March 31, 2011.

RESULTS OF OPERATIONS THREE MONTHS ENDING MARCH 31, 2011 VERSUS MARCH 31, 2010

Revenues Total revenues for the three-month period ended March 31, 2011 were \$11,082,000, as compared to \$8,714,000 in 2010 and were comprised of the following:

	2011	2010	Increase/(Decrease)
PDT DRUG AND DEVICE PRODUCT REVENUES			
LEVULAN® KERASTICK® PRODUCT REVENUES			
United States	\$ 10,187,000	\$ 7,549,000	\$2,638,000
Canada	183,000	57,000	126,000
Korea	116,000	109,000	7,000
Rest of world	7,000	87,000	(80,000)
Subtotal Levulan® Kerastick® product revenues	10,493,000	7,802,000	2,691,000
BLU-U® PRODUCT REVENUES			
United States	489,000	489,000	
Canada		5,000	(5,000)
Subtotal BLU-U® product revenues	489,000	494,000	(5,000)
	10,982,000	8,296,000	2,686,000

TOTAL PDT DRUG AND DEVICE PRODUCT
REVENUES

TOTAL NON-PDT DRUG PRODUCT REVENUES	100,000	418,000	(318,000)
TOTAL PRODUCT REVENUES	\$ 11,082,000	\$ 8,714,000	\$2,368,000

For the three-month period ended March 31, 2011, total PDT drug and device products revenues, comprised of revenues from our Kerastick® and BLU-U® products, were \$10,982,000. This represents an increase of \$2,686,000 or 32%, over the comparable 2010 total of \$8,296,000. The increase in revenues was driven by increased Kerastick® revenues in the United States.

For the three-month period ended March 31, 2011, Kerastick® revenues were \$10,493,000, representing an increase of \$2,691,000 or 35%, over the comparable 2010 total of \$7,802,000. Kerastick® unit sales to end-users for the three-month period ended March 31, 2011 were 75,213, including 72,036 sold in the United States, 1,938 sold in Canada and 1,239 sold in Korea. This represents an increase from 61,422 Kerastick® units sold in the three-month period ended March 31, 2010, including 59,214 sold in the United States, 600 sold in Canada, 1,116 sold in Korea and 492 sold in rest of world. Our average net selling price for the Kerastick® increased to \$138.73 per unit for the three-month period ended March 31, 2011 from \$125.15 per unit in 2010. Our average net selling price for the Kerastick® includes sales made directly to our end-user customers, as well as sales made to our international distributors. The increase in 2011 Kerastick® revenues was driven mainly by an increase in sales volumes in the United States as well as an increase in our overall average unit selling price.

Table of Contents

For the three-month period ended March 31, 2011, BLU-U[®] revenues were \$489,000, a decrease of \$5,000, or 1%, compared to the 2010 total of \$494,000. In the United States BLU-U[®] revenues were flat with an increase in our overall average selling price being offset by a decrease in our sales volumes. In the three-month period ended March 31, 2011, there were 64 units sold, as compared to a total of 77 units sold in 2010. Our average net selling price for the BLU-U[®] increased to \$7,434 for the three-month period ended March 31, 2011 from \$6,198 for 2010. The increase in our average selling price over the prior year is a result of incentive discounting in the prior year in advance of the introduction of our new upgraded unit. Our BLU-U[®] evaluation program allows customers to take delivery for a limited number of BLU-U[®] units for a period of up to four months for private practitioners and up to one year for hospital clinics, before we require a purchase decision. At March 31, 2011, there were approximately 21 units in the field pursuant to this evaluation program, compared to 28 units in the field at December 31, 2010. The units are classified as inventory in the financial statements and are being amortized during the evaluation period to cost of goods sold using an estimated life for the equipment of three years.

We have to continue to demonstrate the clinical value of our unique therapy, and the related product benefits as compared to other well-established conventional therapies, in order for the medical community to accept our products on a large scale. We are aware that physicians are using Levulan[®] with the BLU-U[®] using short incubation times, and with light devices manufactured by other companies, and for uses other than our FDA-approved use. While we are not permitted to market our products for so-called off-label uses, we believe that these activities are positively affecting the sales of our products. At present, we are continuing to evaluate the initiation of a DUSA-sponsored clinical trial designed to study the broad area application and/or short drug incubation, or BASDI, method of using the Levulan[®] Kerastick[®]. The protocol objectives would be to compare the safety and efficacy of various incubation times (1, 2 or 3 hours) of Levulan[®] plus BLU-U[®] PDT versus vehicle plus BLU-U[®] for the treatment of multiple actinic keratoses of the face or scalp. The timing of initiation of this study has been delayed as we refine the protocol in consultation with outside experts. We expect to complete our evaluation and determine next steps in the coming months.

Non-PDT drug product revenues reflect the revenues generated by the products acquired as part of our acquisition of Sirius. Total Non-PDT drug product revenues for the three-month period ended March 31, 2011 were \$100,000, compared to \$418,000 for the comparable 2010 period. In 2011, the substantial majority of the Non-PDT Drug Product revenues were from sales of ClindaReach[®]. In 2010, the substantial majority of the Non-PDT product revenues were from sales of ClindaReach[®] and royalties received from River's Edge from sales of the AVAR[®] product line. Royalties from our license of the AVAR[®] product line with River's Edge ceased during the fourth quarter of 2010.

The increase in our total product revenues for the three-month period ended March 31, 2011 compared to the comparable 2010 period results primarily from increased Kerastick[®] revenues in the United States, partially offset by a decrease in Non-PDT revenues. During 2011, our PDT segment revenues in the United States grew as a result of increased demand for our product, as well as our pricing strategies. With respect to Kerastick[®] prices, we announced a price increase in the fourth quarter of 2010, which became effective January 1, 2011. We intend to announce a price increase each year in the fourth quarter, which will become effective on January 1 of the following year. This strategy is likely to have a positive impact on sales in the fourth quarter of each year.

Although we expect continued growth in our PDT segment revenues, we are susceptible to the uncertain economic conditions, particularly with our customer base in the U.S. and internationally where our product lacks reimbursement, and to increased competition particularly from Metvixia. Photocure received FDA approval to market Metvixia[®] for treatment of AKs in July 2004, and this product is directly competitive with our Levulan[®] Kerastick[®] product. 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 considerably more resources than we have, which could significantly hamper our ability to maintain or increase our market share. Metvixia is commercially available in the U.S., however, product revenues have not been significant to date. In addition, Leo Pharma, a Danish corporation that acquired Peplin in 2009, has announced that in 2012 it will be launching PEP005 for the treatment of AKs. We have also become aware that Photocure has announced plans to launch an ALA ester-based product, Allumera[™], as a cosmetic, during the second quarter of 2011, which could cause disruption in the marketplace. These products could negatively impact the market penetration of our PDT products. Also, softness

in the international markets should be expected to continue. Based on product quantities and projected monthly sales at our distributor in Korea, we expect during 2011 some of that product will become short-dated and no longer saleable. Accordingly, during 2011 we expect to recognize the related revenues and costs of revenues, which are included in deferred revenues and other current assets, respectively, in the accompanying condensed consolidated balance sheets.

Our ability to be profitable on a quarterly basis may also be affected by fluctuations in the demand for our products caused by both seasonal changes, such as when patient visits slow during summer months, and the timing of pricing changes, which may impact the purchasing patterns of our customers. In addition, we expect our Non-PDT product revenues for the full year 2011 to be reduced from 2010 levels since the AVAR[®] royalty period ended during the fourth quarter of 2010. We are considering other strategic alternatives relative to the Non-PDT asset portfolio.

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

Table of Contents

Cost Of Product Revenues and Royalties Cost of product revenues and royalties for the three-month period ended March 31, 2011 were \$1,760,000 as compared to \$1,818,000 in 2010. A summary of the components of cost of product revenues and royalties is provided below:

	2011	2010	Increase/ Decrease
Levulan® Kerastick® Cost of Product Revenues and Royalties			
Direct Levulan® Kerastick® Product costs	\$ 768,000	\$ 665,000	\$ 103,000
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	14,000	114,000	(100,000)
Royalty and supply fees (1)	411,000	306,000	105,000
Subtotal Levulan® Kerastick® Cost of Product Revenues and Royalties	1,193,000	1,085,000	108,000
BLU-U® Cost of Product Revenues			
Direct BLU-U® Product Costs	257,000	277,000	(20,000)
Other BLU-U® Product Costs including internal costs assigned to support products; as well as, costs incurred to ship, install and service the BLU-U® in physicians' offices	167,000	219,000	(52,000)
Subtotal BLU-U® Cost of Product Revenues	424,000	496,000	(72,000)
TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	1,617,000	1,581,000	36,000
Non-PDT Drug Cost of Product Revenues and Royalties	143,000	237,000	(94,000)
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$ 1,760,000	\$ 1,818,000	\$ (58,000)

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

Margins Total product margins for the three-month period ended March 31, 2011 was \$9,322,000, or 84%, as compared to \$6,896,000, or 79%, for the comparable 2010 period, as shown below:

	2011		2010		Increase/ (Decrease)
Levulan® Kerastick® gross margin	\$ 9,300,000	89%	\$ 6,717,000	86%	\$ 2,583,000
BLU-U® gross margin	65,000	13%	(2,000)		67,000
Total PDT drug and device gross margin	\$ 9,365,000	85%	\$ 6,715,000	81%	\$ 2,650,000
Total Non-PDT gross margin	(43,000)	(43)%	\$ 181,000	43%	(224,000)
TOTAL GROSS MARGIN	\$ 9,322,000	84%	\$ 6,896,000	79%	\$ 2,426,000

Kerastick® gross margins for the three-month period ended March 31, 2011 were 89% compared to 86% for the comparable 2010 period. The margin improvement for 2011 is attributable to increased U.S. sales volumes and an increase in our 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 can achieve improved gross margins on our Kerastick® from further volume growth and price increases in the U.S.

BLU-U[®] margins for the three-month period ended March 31, 2011 were 13% compared to 0% for the comparable 2010 period. The increase in gross margin is a result of an increase in our average selling price. It is important for us to sell BLU-U[®] units in an effort to increase Kerastick[®] sales volumes, and accordingly, we may sell BLU-U[®] units at low profit margins.

Non-PDT drug product margins reflect the gross margin generated by the products acquired as part of our merger with Sirius. Total Non-PDT drug product gross margins for the three-month period ended March 31, 2011 were (43)% compared to 43% for the comparable period in 2010. Non-PDT cost of goods sold for the first quarter of 2010 includes a charge of \$48,000, net of insurance recoveries of \$273,000, related to a shipment of ClindaReach that was lost while in-transit to us during the quarter.

Research and Development Costs Research and development costs for the three-month period ended March 31, 2011 were \$1,324,000 as compared to \$1,110,000 in the comparable 2010 period. The increase in 2011 compared to 2010 was due primarily to increased spending related to the addition of medical science liaisons.

At present, we are continuing to evaluate the initiation of a DUSA-sponsored clinical trial designed to study the broad area application and/or short drug incubation, or BASDI, method of using the Levulan[®] Kerastick[®]. The protocol objectives would be to compare the safety and efficacy of various incubation times (1, 2 or 3 hours) of Levulan[®] plus BLU-U[®] PDT versus vehicle plus BLU-U[®] for the treatment of multiple actinic keratoses of the face or scalp. The timing of initiation of this study has been delayed as we refine the protocol in consultation with outside experts. We expect to complete our evaluation and determine next steps in the coming months.

Marketing and Sales Costs Marketing and sales costs for the three-month period ended March 31, 2011 were \$3,973,000 as compared to \$3,614,000 for the comparable 2010 period. These costs consisted primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling \$2,590,000 for the three-month period ended March 31, 2011, compared to \$2,457,000 in the comparable 2010 period. The increase in spending in 2011 in this category is due to increased headcount. The remaining expenses consisted of tradeshows, miscellaneous marketing and outside consultants totaling \$1,383,000 for the three-month period ended March 31, 2011, compared to \$1,157,000 for the comparable 2010 period. The increase in this category is due primarily to an increase in expenditures related to sales training and promotional materials. We expect marketing and sales costs for the full year 2011 to increase over 2010 levels, but to decrease as a percentage of revenues.

Table of Contents

General and Administrative Costs General and administrative costs were \$2,457,000 for the three-month period ended March 31, 2011 as compared to \$2,463,000 for the comparable prior year period. For the three-month period ended March 31, 2011, an increase in compensation related charges was offset by a decrease in professional services fees. General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period. For the full year 2011, we expect general and administrative costs to increase compared with 2010, but to decrease as a percentage of revenues.

Loss on Change in Fair Value of Warrants The warrants issued to investors in connection with the October 29, 2007 private placement were recorded initially at fair value and are marked to market each reporting period. The increase in the liability during the three-month periods ended March 31, 2011 and 2010 was \$2,189,000 and \$199,000, respectively, which resulted in non-cash losses in both periods. The changes in the fair value of the warrants are primarily due to changes in our stock price, our stock's historical volatility and the length of time remaining prior to expiration.

Other Income, Net Other income for the three-month period ended March 31, 2011 decreased compared to the comparable prior year period. Other income decreased to \$16,000 from \$66,000 during the same period in 2010. The decrease is generally due to decreased returns on our investments.

Income Taxes There is no provision for income taxes due to the full valuation allowance. As of December 31, 2010, we had net operating loss carryforwards remaining of approximately \$91,504,000 and tax credit carryforwards of approximately \$1,759,000 for Federal tax purposes. These amounts expire at various times through 2030. We have provided a full valuation allowance against the net deferred tax assets at March 31, 2011 and December 31, 2010.

Based on an Internal Revenue Code (IRC) Section 382 study performed, we determined that we have experienced prior ownership changes, as defined under IRC Section 382, with the most recent change in ownership occurring in 2007 (the 2007 Ownership Change). Our pre-change NOL carryforwards are subject to an annual limitation of approximately \$2.2 million per year. Further, additional rules provide for the enhancement of the aforementioned annual limitation for the first five years after the ownership change. A loss corporation may increase its IRC Section 382 limitation by the amount of the net unrealized built-in gain, or NUBIG, recognized within five years of the ownership change. Our calculated aggregate amount of NUBIG enhancement is approximately \$4.3 million (i.e., approximately \$868,000 per year for the first five years after the ownership change). This NUBIG enhancement will be utilized in conjunction with the approximately \$2.2 million of IRC Section 382 base annual limitation, resulting in approximately \$3.0 million per year for the first five years after the ownership change. Based on these additional factors, we estimate that we will be able to utilize approximately \$54.3 million of our current net operating losses, provided that sufficient income is generated and no further ownership changes were to occur. However, it is reasonably possible that a future ownership change, which could be the result of transactions involving our common stock that are outside of our control (such as sales by existing shareholders), could occur during 2011 or thereafter. Future ownership changes could further restrict our utilization of our net operating losses and tax credits, reducing or eliminating the benefit of such net operating losses and tax credits. An ownership change occurs under IRC Section 382 if the aggregate stock ownership of certain shareholders increases by more than 50 percentage points over such shareholders' lowest percentage ownership during the testing period, which is generally three years.

Net Loss We reported a net loss of \$605,000, or \$0.02 per share, for the three-month period ended March 31, 2011, as compared to a net loss of \$424,000, or \$0.02 per share, for the comparable 2010 period. The increase in net loss is attributable to the reasons discussed above.

LIQUIDITY AND CAPITAL RESOURCES**Liquidity and Capital Resources**

At March 31, 2011, we had approximately \$21,067,000 of total liquid assets, comprised of \$12,474,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$8,593,000. We believe that our liquidity will be sufficient to meet our cash requirements for at least the next twelve months. As of March 31, 2011, our marketable securities had a weighted average yield to maturity of 1.14% and maturity dates ranging from April 2011 to December 2013. Our net cash generated by operations in 2011 was \$1,580,000 versus \$988,000 in 2010. The year-over-year increase in cash generated by operations is primarily attributable to a small increase in our net loss, offset by a significant increase in non-cash charges, including a loss of \$2,189,000 on the change in the fair value of

our warrants. Our net cash provided by (used in) investing activities was \$2,075,000 in 2011 versus \$(29,000) in 2010. Net cash provided by (used in) investing activities is primarily the result of our net purchases and maturities of marketable securities. Our net cash used in financing activities for 2011 and 2010 was \$65,000 and \$30,000, respectively; and is comprised of proceeds from stock option exercises, offset by settlements of restricted stock for tax withholding obligations. As of March 31, 2011 working capital (total current assets minus total current liabilities) was \$22,593,000, as compared to \$21,000,000 as of December 31, 2010. Total current assets increased by \$960,000 during 2011, due primarily to increases in our cash and cash equivalents and inventory, offset in part by a decrease in our marketable securities, accounts receivable and prepaid and other current assets. Total current liabilities decreased by \$633,000 during 2011 due primarily to decreases in accrued compensation and the current portion of deferred revenues, offset in part by increases in accounts payable and other accrued expenses. In response to the instability in the financial markets, we regularly review our marketable securities holdings, and have invested primarily in securities of the U.S. government and its agencies.

Although we achieved profitability for the full year 2010, we generated losses for the three-month periods ended March 31, 2011 and 2010 and have generated significant cumulative losses through March 31, 2011 while we 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 during 2011. Our costs, including research and

Table of Contents

development costs for our product candidates and sales, marketing and promotion expenses for any of our existing or future products to be marketed by us or our distributors may exceed revenues in the future, which may result in 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 2010 and the three-month period ended March 31, 2011, we focused primarily on increasing the sales of the Levulan[®] Kerastick[®] and the BLU-U[®]. If we cannot continue to maintain positive cash flow from operations, we may reduce our headcount or reduce spending in other areas. We may also seek to raise funds through financing transactions. We cannot predict whether financing will be available at all or on reasonable terms.

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

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

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

Merger With Sirius Laboratories, Inc.

In March 2006, we closed our merger to acquire all of the common stock of Sirius Laboratories Inc. in exchange for cash and common stock worth up to \$30,000,000. Of the up to \$30,000,000, up to \$5,000,000, (\$1,500,000 of which would be paid in cash, and \$3,500,000 of which would be paid in cash or common stock) may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. With the launch of ClindaReach[®], one of the new Sirius products, we were obligated to make a cash payment of \$500,000 to the former shareholders of Sirius. Also, as a consequence of the decision not to launch the product under development with another third party and pursuant to the terms of the merger agreement with Sirius, we paid \$250,000 on a pro rata basis to the former Sirius shareholders. Similarly, with our decision in

early 2008 not to develop a third product from a list of product candidates acquired as part of the merger, another \$250,000 was paid on a pro rata basis to the former Sirius shareholders. The payments for ClindaReach® and the other two product decisions satisfy our obligations for the \$1,500,000 portion of the purchase price mentioned above. In the third quarter of 2008, the first of the pre-determined total cumulative sales milestones for Sirius products was achieved, and accordingly, we made a cash payment of \$1,500,000 to the former Sirius shareholders in consideration of the milestone achievement.

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

In April 2009 we paid to the former Sirius shareholders, on a pro rata basis, \$100,000. In addition, in the event that the \$1,000,000 milestone payment that would become due to the former Sirius shareholders under the merger agreement if cumulative net sales of the Sirius products reach \$35,000,000 is not, in fact, triggered by December 31, 2011, then we have agreed to pay \$250,000 to the former Sirius shareholders on a pro rata basis on or before January 6, 2012. The present value of the guaranteed \$250,000 milestone payment, or \$237,000, is included in other accrued expenses in the accompanying Condensed Consolidated Balance Sheet as of March 31, 2011.

Table of Contents**PARTEQ Agreement**

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

For the years ended December 31, 2010, 2009 and 2008, actual royalties based on product sales were approximately \$1,331,000, \$1,019,000, and \$873,000, respectively. Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$103,000 as of March 31, 2011).

National Biological Corporation Amended And Restated Purchase And Supply Agreement

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

Sochinaz SA

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

Lease Agreements

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

Research Agreements

We have entered into various agreements for research projects and clinical studies. As of March 31, 2011, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$1,784,000. Included in this future payment is a master service agreement, effective June 15, 2001, with Therapeutics, Inc. for management services in connection with the clinical development of our products in the field of dermatology. The agreement was renewed on June 15, 2010 for a one year period and is renewable annually. Therapeutics is entitled to receive a bonus valued at \$50,000, in cash or stock at our discretion, upon each anniversary of the effective date.

Our contractual obligations and other commercial commitments to make future payments under contracts, including lease agreements, research and development contracts, manufacturing contracts, or other related agreements are as follows at March 31, 2011:

	Total	1 Yr or less	2-3 Years	4-5 Years	After 5 Years
Operating lease obligations	\$ 1,437,000	\$ 383,000	\$ 788,000	\$ 266,000	\$
Purchase obligations (1, 2)	3,230,000	3,230,000			
Minimum royalty obligations (3)	508,000	353,000	155,000		
Total obligations	\$ 5,175,000	\$ 3,966,000	\$ 943,000	\$ 266,000	\$

- 1) Research and development projects include various commitments including obligations for our study on a broad area application, short drug incubation method of using the Levulan[®] Kerastick[®]
- 2) In addition to the obligations disclosed above, we have contracted with Therapeutics, Inc., a clinical research organization, to manage the clinical development of our products in the field of dermatology. This organization has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from \$250,000 to \$1,250,000, depending on the regulatory phase of development of products under Therapeutics management.
- 3) Minimum royalty obligations relate to our agreements with PARTEQ and Perrigo described above. Rent expense incurred under these operating leases was approximately \$85,000 and \$97,000 for the three-month periods ended March 31, 2011 and 2010, respectively.

Table of Contents

INFLATION

Although inflation rates have been comparatively low in recent years, inflation is expected to apply upward pressure on our operating costs. We have included an inflation factor in our cost estimates. However, we expect the overall net effect of inflation on our operations to be minimal.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rates

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

As of March 31, 2011, the weighted average rate of return on our investments was 1.14%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of March 31, 2011, the fair market value of the portfolio would decline by approximately \$77,000. Declines in interest rates could, over time, reduce our interest income.

Derivative Financial Instruments

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

Currency Exchange Rates

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

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

ITEM 4. CONTROLS AND PROCEDURES

We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2011. There have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2011 that have materially affected, or are reasonably likely to materially affect, DUSA's internal control over financial reporting.

Forward-Looking Statements Safe Harbor

This report, including the Management's Discussion and Analysis of Financial Condition and Results of Operations, contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 21E of the Securities Exchange Act of 1934 which represent our expectations or beliefs concerning future events, including, but not limited to our beliefs regarding off-label use, our intention to announce a price increase on an annual basis in the fourth quarter of each year, beliefs regarding softness in the international markets, beliefs regarding improved gross margins on Kerastick® from further volume growth and price increases in the United States, expectations regarding general and administrative costs, beliefs regarding our liquidity and capital resources, ability to raise funds through financing transactions and on reasonable terms, expectations regarding the payment of remaining milestones to former Sirius shareholders, beliefs regarding the effects of inflation, our expectations regarding the potential for reduction of headcount, curtailment of variable expenses, expectations regarding the initiation of and

timing of our BASDI clinical trial, beliefs regarding the future development of Levulan® and other potential indications, expectations concerning manufacture of the BLU-U® in our facility, intention to pursue licensing, marketing, co-promotion, other arrangements, additional business or new technologies, expectations regarding additional market expansion, the impact on our market share of Galderma's promotion of Metvixia®, expectations regarding the confidentiality of our proprietary information, beliefs regarding regulatory approvals, filings, timelines and environmental compliance, beliefs concerning patent disputes or patents issued to third parties, beliefs regarding litigation and the costs thereof, ability and intentions to obtain, secure, defend and enforce our patents, beliefs regarding the impact of a third-party's regulatory compliance status and fulfillment of contractual obligations, expectations of decreases in the prices we charge for our products, our beliefs regarding the market for our products and our product candidate, expected use of cash resources, beliefs regarding research and development programs, beliefs regarding investments and economic conditions including the impact of our customer's failure to meet our payment terms, expectations regarding outstanding options and warrants, beliefs regarding the effect of reimbursement policies on sales, revenues and market acceptance of our therapies, expectations for research and development programs and

Table of Contents

expenses, expectations for continuing operating losses and beliefs regarding competition, expectations regarding the adequacy and availability of insurance, expectations regarding sales and marketing costs and research and development costs, levels of interest income, beliefs regarding the need to and impact of raising additional funds to meet capital requirements and the potential dilution to our existing shareholders, beliefs regarding the potential for additional inspection and testing of our manufacturing facilities or additional FDA or legislative actions, beliefs regarding our manufacturing capabilities and impact on us if problems arise, beliefs regarding the dependence on key personnel, beliefs concerning product liability and insurance thereof, beliefs regarding our financial condition, results of operations cash flows and profitability, our beliefs regarding our sales and marketing efforts, beliefs regarding the adoption of our products, our beliefs regarding our compliance with applicable laws, rules and regulations, our beliefs regarding available reimbursement for our products and plans to seek improvement, our beliefs regarding the current and future preclinical and clinical development and testing of our potential products and technologies and the timing and costs thereof, beliefs regarding the volatility of our stock price, beliefs regarding the impact of our rights plan, beliefs regarding the impact of future sales of securities, expectations related to the change in revenues of our PDT and Non-PDT products, beliefs regarding market share, beliefs regarding the growth in our PDT segment revenues, expectations regarding our manufacturing facility or any facility of our contract manufacturers, beliefs regarding our Nasdaq Global Market listing, beliefs regarding Section 382 on our current and future NOLs, beliefs regarding our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income, beliefs regarding a future ownership change or change of control, beliefs regarding the outcome if some or all of our shares are sold into the public market over a short period of time, beliefs regarding our ability to sell equity securities or equity-related securities in the future, beliefs concerning safety procedures for hazardous materials, our compliance and risks of liability, beliefs regarding competitive products, beliefs concerning revenues, beliefs concerning Peplin s and Allumera s impact on the market penetration of our PDT products, beliefs regarding our capital resource needs, beliefs regarding the sufficiency of our cash, cash equivalents and marketable securities, beliefs regarding economic recovery, beliefs regarding the failure to comply with FDA or other governmental regulatory requirements and the impact of such failure, beliefs regarding the global credit and financial market conditions on our business, including reimbursement, beliefs regarding production yields, costs or quality of our products, beliefs regarding market acceptance of our products, beliefs regarding collaborations with outside scientists, beliefs regarding our products becoming non-competitive or obsolete, expectations for losses, beliefs regarding patent protection of our current and future indications and impact on competition, beliefs regarding financial benefits from patent protection, beliefs regarding the timing of pricing changes, beliefs regarding the purchasing patterns of our customers and our beliefs regarding our ability to be profitable each quarter and the affect of fluctuations in the demand for our product. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the timely development, FDA and foreign regulatory approval, and market acceptance of our products, environmental risks relating to our products, reliance on third-parties for the production, manufacture, sales and marketing of our products, the availability of products for acquisition and/or license on terms agreeable to us, sufficient sources of funds, the securities regulatory process, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by third-party payors, none of which can be assured. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors.

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

None.

ITEM 1A. RISK FACTORS

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

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

Risks Related To DUSA

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

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

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

Table of Contents

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

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

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

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

send warning letters,

impose fines and other civil penalties on us,

seize our products,

suspend our regulatory approvals,

cease the manufacture of our products,

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

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

require us to recall products,

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

impose restrictions on our operations, and/or

criminally prosecute us.

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

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

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

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

If A Competitive Product Is Successful Our Revenues Could Decline, And Our Ability To Achieve Profitability On A Quarterly Basis 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 of our 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 this product is directly competitive with our Levulan[®] Kerastick[®] product. Photocure sold Metvix/Metvixia to Galderma, S.A., a large dermatology company, in October 2009, and while we are entitled to royalties on net sales of Metvixia, Galderma has considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share and make it more difficult for us to achieve profitability on an ongoing basis. Metvixia's U.S. product revenues have not been significant to date. In addition, Leo Pharma, a Danish corporation that acquired Peplin[®] in 2009, has announced that in 2012 it will be launching PEP005 for the treatment of AKs. We have also become aware that Photocure has announced plans to launch an ALA ester-based product, Allumera[™], as a cosmetic, during the second quarter of 2011, which could cause disruption in the marketplace. These products could negatively impact the market penetration of our PDT

Table of Contents

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

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

We have approximately \$21,067,000 in cash, cash equivalents and marketable securities as of March 31, 2011. Our cash, cash equivalents and marketable securities should be sufficient for current operations for at least the next 12 months. Although we expect continued growth in our PDT segment revenues, we are susceptible to the uncertain economic conditions, particularly with our customer base in the U.S. and internationally where our product lacks reimbursement, and to increased competition particularly from Metvixia[®]. In addition, we expect our Non-PDT product revenues for 2011 to be reduced from 2010 levels since the AVAR[®] royalty period ended during the fourth quarter of 2010. If we are unable to continue to be profitable on an ongoing basis, we may have to reduce our headcount, curtail certain variable expenses, or raise funds through financing transactions.

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

We reported net losses of \$605,000 and \$424,000 for the three-month periods ended March 31, 2011 and 2010, respectively. Prior to 2010, we had a history of annual operating losses and we may incur losses in the future. We reported net income (loss) of \$2,703,000, \$(2,508,000) and \$(6,250,000) for the years ended December 31, 2010, 2009 and 2008, respectively. As of March 31, 2011, our accumulated deficit was approximately \$142,262,000. We expect to incur significant additional research and development and other costs including costs related to preclinical studies and clinical trials. Our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any of our existing or future products to be marketed by us or our distributors may exceed revenues in the future, which may result in future losses from operations.

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

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

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

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

Global Credit And Financial Market Conditions May Affect Our Business.

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

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

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

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

Table of Contents

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® Product Or Indications.

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

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

delays in product development, clinical testing or manufacturing,

unplanned expenditures in product development, clinical testing or manufacturing,

failure in clinical trials or failure to receive regulatory approvals,

emergence of superior or equivalent products,

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

failure to achieve market acceptance.

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

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

Any potential Levulan® product will require the approval of the FDA before it can be marketed in the United States. Before an application to the FDA seeking approval to market a new drug, called an NDA, can be filed, a product must undergo, among other things, extensive animal testing and human clinical trials. The process of obtaining FDA approvals can be lengthy, costly, and time-consuming. Following the acceptance of an NDA, the time required for regulatory approval can vary and is usually one to three years or more. The FDA may require additional animal studies and/or human clinical trials before granting approval. Our Levulan® PDT products are based on relatively new technology. To our knowledge, the FDA has approved only four drugs for use in photodynamic therapy, including Levulan®. This factor may lengthen the approval process. We face much trial and error and we may fail at numerous stages along the way.

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

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

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

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

compositions and apparatus for those methods, and

unique physical forms of ALA.

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

The patents relating to methods of using ALA for detecting or treating disease, other than for acne and our approved indication for AKs of the face or scalp, started to expire in July 2009. With the newly allowed claims which issued on May 25, 2010, we now have additional claims that relate to our AK product, and these will not expire until 2019. The reexamination by the USPTO of one of the patents we license from PARTEQ, the licensor of our ALA patents, that cover our approved product until 2013, has successfully concluded with the confirmation of the validity of all of the patent's original claims and the addition of eight new claims.

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

Table of Contents

Some of the indications for which we may develop PDT therapies may not be covered by the claims in any of our existing patents. Even with the issuance of additional patents to us, other parties are free to develop other uses of ALA, including medical uses, and to market ALA for such uses, assuming that they have obtained appropriate regulatory marketing approvals. ALA in the chemical form has been commercially supplied for decades, and is not itself subject to patent protection. There are reports of third parties conducting clinical studies with ALA in countries outside the United States where PARTEQ does not have patent protection. In addition, a number of third parties are seeking patents for uses of ALA not covered by our patents. These other uses, whether patented or not, and the commercial availability of ALA, could limit the scope of our future operations because ALA products could come on the market which would not infringe our patents but would compete with our Levulan® product even though they are marketed for different uses.

Photocure ASA received FDA approval to market Metvixia® for treatment of AKs in July 2004, and this product is directly competitive with our Levulan® Kerastick® product. Photocure sold Metvix/Metvixia to Galderma, S.A., a large dermatology company, in October 2009, and while we are entitled to royalties on net sales of Metvixia, Galderma has considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share. Metvixia's U.S. product revenues have not been significant to date.

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

these persons or entities might breach the agreements,

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

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

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

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

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

product yields,

quality control,

component and service availability,

compliance with FDA regulations, and

the need for further FDA approval if manufacturers make material changes to manufacturing processes and/or facilities.

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

to quickly remedy the problem(s). Any of these problems could cause our sales to suffer and could increase costs.

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

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

Based on an Internal Revenue Code, or IRC, Section 382 evaluation, we determined that we have experienced prior ownership changes, as defined under IRC Section 382, with the most recent change in ownership occurring in 2007 (the 2007 Ownership Change). Our pre-change NOL carryforwards are subject to an annual limitation of approximately \$2.2 million per year. Further, additional rules provide for the enhancement of the aforementioned annual limitation for the first five years after the ownership change. A loss corporation may increase its IRC Section 382 limitation by the amount of the net unrealized built-in gain, or NUBIG, recognized within five years of the ownership

Table of Contents

change. Our calculated aggregate amount of NUBIG enhancement is approximately \$4.3 million (i.e., approximately \$868,000 per year for the first five years after the ownership change). This NUBIG enhancement will be utilized in conjunction with the approximately \$2.2 million of IRC Section 382 base annual limitation, resulting in approximately \$3.0 million per year for the first five years after the ownership change. Based on these additional factors, we estimate that we will be able to utilize approximately \$54.3 million of our current net operating losses, provided that sufficient income is generated and no further ownership changes were to occur. However, it is reasonably possible that a future ownership change, which could be the result of transactions involving our common stock that are outside of our control (such as sales by existing shareholders), could occur during 2011 or thereafter. Future ownership changes could further restrict our utilization of our net operating losses and tax credits, reducing or eliminating the benefit of such net operating losses and tax credits. An ownership change occurs under IRC Section 382 if the aggregate stock ownership of certain shareholders increases by more than 50 percentage points over such shareholders' lowest percentage ownership during the testing period, which is generally three years.

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, and parts of Asia, where we have distributors. If our sales and marketing efforts fail, then sales of the Levulan[®] Kerastick[®], the BLU-U[®], and other products will be adversely affected, which would adversely affect our results of operations and financial condition.

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

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

- the effectiveness, or perceived effectiveness, of our product in comparison to competing products,
- the existence of any significant side effects, as well as their severity in comparison to any competing products,
- potential advantages over alternative treatments,
- the ability to offer our product for sale at competitive prices,
- relative convenience and ease of administration,
- the strength of marketing and distribution support, and
- sufficient third-party coverage or reimbursement.

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

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

therapy in their practices.

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

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

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

Additionally, if a third-party were to file a United States patent application, or be issued a patent claiming technology also claimed by us in a pending United States application(s), we may be required to participate in interference proceedings in the USPTO to determine the priority of

Table of Contents

the invention. A third-party could also request the declaration of a patent interference between one of our issued United States patents and one of its patent applications. Any interference proceedings likely would require participation by us and/or PARTEQ, which could involve substantial legal fees and result in a loss or lessening of our patent protection.

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

We are a small company with only 91 employees, including 1 part-time employee, as of March 31, 2011. We are highly dependent on several key officer/employees with specialized scientific and technical skills without whom our business, financial condition and results of operations would suffer, especially in the photodynamic therapy portion of our business. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very few people with their expertise could be hired. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain other qualified personnel in our specialty drug and light device areas.

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

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

Risks Related To Our Industry***Product Liability And Other Claims Against Us May Reduce Demand For Our Products Or Result In Damages.******We Are Subject To Risk From Potential Product Liability Lawsuits Which Could Negatively Affect Our Business.***

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

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

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

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

Well-known pharmaceutical, biotechnology and medical device companies are marketing well-established therapies for the treatment of AKs and acne. Doctors may prefer to use familiar methods, rather than trying our products.

Reimbursement issues affect the economic competitiveness of our products as compared to other more traditional therapies.

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

Table of Contents

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

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

On May 30, 2006, we entered into a patent license agreement with Photocure ASA whereby we granted a non-exclusive license to Photocure under the patents we license from PARTEQ, for esters of ALA. Furthermore, we granted a non-exclusive license to Photocure for its existing formulations of its Hexvix[®] and Metvix[®] (known in the United States as Metvixia[®]) products for any of our 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 this product is directly competitive with our Levulan[®] Kerastick[®] product, and its price is comparable to the price of Levulan[®]. Photocure sold Metvix/Metvixia to Galderma, S.A., a large dermatology company in October 2009, and while we are entitled to royalties on net sales of Metvixia, Galderma has considerably more resources than we have, which could significantly hamper our ability to maintain or increase our market share. Metvixia's U.S. product revenues have not been significant to date.

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

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

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

the ease of administration of our method of PDT,

the degree of generalized skin sensitivity to light,

the number of required doses,

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

the type and cost of our light systems.

Our primary competition in the acne market includes oral and topical antibiotics, other topical prescription and over-the-counter products, as well as various laser and non-laser light treatments. The market is highly competitive and other large and small companies have more 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 and 2010, our common stock traded at prices near and below \$1.00. If we do not continue to meet Nasdaq's applicable minimum listing standards, Nasdaq could delist us from the Nasdaq Global Market. If our common stock is delisted from the Nasdaq Global Market, we could seek to have our common stock listed on the Nasdaq Capital Market or other Nasdaq markets. However, delisting of our common stock from the Nasdaq Global Market could hinder your ability to sell, or obtain an accurate quotation for the price of, your shares of our common stock. Delisting could also adversely affect the perception among investors of DUSA and its prospects, which could lead to further declines in the market price of our common stock. Delisting may also make it more difficult and expensive for us to raise capital. In addition, delisting might subject us to a Securities and Exchange Commission rule that could adversely affect the ability of broker-dealers to sell or make a market in our common

stock, thus hindering your ability to sell your shares.

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

The price of our common stock has been highly volatile, which may create an increase in the risk of capital losses for our shareholders. From January 1, 2010 to March 31, 2011, the price of our stock has ranged from a low of \$1.32 to a high of \$5.30. The significant general market volatility in similar stage pharmaceutical and biotechnology companies also made the market price of our stock volatile.

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

The price of our common stock may be affected by the amount of quarterly shipments of our products to end-users. Since our PDT products are still in relatively early stages of adoption, and sales volumes are still low, a number of factors could affect product sales levels and growth

Table of Contents

rates in any period. These could include the level of penetration in new markets outside of the United States, the timing of medical conferences, sales promotion activities, and large volume purchases by our higher usage customers. In addition, seasonal fluctuations in the number of patients seeking treatment at various times during the year could impact sales volumes. These factors could, in turn, affect the volatility of our stock price.

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

As of April 15, 2011, there were outstanding options and warrants to purchase 4,172,000 shares of common stock, with exercise prices ranging from \$1.10 to \$15.90 per share for options, and \$2.85 per share for warrants. In addition, there were 882,000 shares of unvested common stock. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. Also, if some or all of such shares are sold into the public market over a short period of time, the value of all publicly traded shares could decline, as the market may not be able to absorb those shares at then-current market prices. Additionally, such sales may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all. The holders may exercise their securities during a time when we would likely be able to raise capital from the public on terms more favorable than those provided in these securities.

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

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

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

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. [REMOVED AND RESERVED].**ITEM 5. OTHER INFORMATION.**

On May 5, 2011, DUSA Pharmaceuticals, Inc. issued a press release announcing summary financial results for the fiscal quarter ended March 31, 2011. The press release issued in connection with such announcement is attached hereto as Exhibit 99.1.

Table of Contents

ITEM 6. EXHIBITS

EXHIBIT

NO.	DESCRIPTION OF EXHIBIT
3(a.1)	Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference.
3(a.2)	Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, and is incorporated herein by reference.
3(b)	By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant's current report on Form 8-K, filed on November 2, 2010, 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 May 5, 2011.

Table of Contents

SIGNATURES

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

DUSA Pharmaceuticals, Inc.

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

Dated: May 5, 2011

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

Dated: May 5, 2011

Table of Contents

EXHIBIT INDEX

- 3(a.1) Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference.
- 3(a.2) Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, and is incorporated herein by reference.
- 3(b) By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant's current report on Form 8-K, filed on November 2, 2009, and is incorporated herein by reference.
- 31(a) Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
- 31(b) Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
- 32(a) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32(b) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99.1 Press Release dated May 5, 2011.