

DUSA PHARMACEUTICALS INC

Form 10-Q

November 09, 2012

[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: September 30, 2012

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)

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

New Jersey
(State of Other Jurisdiction of

22-3103129
(I.R.S. Employer

Incorporation or Organization)

Identification No.)

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

01887
(Zip Code)

(978) 657-7500

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

Large accelerated filer Accelerated filer

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

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

As of November 7, 2012, the registrant had 25,027,683 shares of Common Stock, no par value per share, outstanding.

Table of Contents

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>Consolidated Balance Sheets at September 30, 2012 and December 31, 2011 (Unaudited)</u>	3
- <u>Consolidated Statements of Operations for the three and nine-month periods ended September 30, 2012 and 2011 (Unaudited)</u>	4
- <u>Consolidated Statements of Comprehensive Income for the three and nine-month periods ended September 30, 2012 and 2011 (Unaudited)</u>	5
- <u>Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2012 and 2011 (Unaudited)</u>	6
- <u>Notes to the Consolidated Financial Statements (Unaudited)</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	20
<u>Item 4. Controls and Procedures</u>	20
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	22
<u>Item 1A. Risk Factors</u>	22
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
<u>Item 3. Defaults Upon Senior Securities</u>	30
<u>Item 4. Mine Safety Disclosures</u>	31
<u>Item 5. Other Information</u>	31
<u>Item 6. Exhibits</u>	31
<u>SIGNATURES</u>	32
<u>Exhibit Index</u>	33
<u>EX-31.A</u>	
<u>EX-31.B</u>	
<u>EX-32.A</u>	
<u>EX-32.B</u>	
<u>EX-101 INSTANCE DOCUMENT</u>	
<u>EX-101 SCHEMA DOCUMENT</u>	
<u>EX-101 CALCULATION LINKBASE DOCUMENT</u>	
<u>EX-101 LABELS LINKBASE DOCUMENT</u>	
<u>EX-101 PRESENTATION LINKBASE DOCUMENT</u>	
<u>EX-101 DEFINITION LINKBASE DOCUMENT</u>	

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

	September 30, 2012	December 31, 2011
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 28,735,654	\$ 24,423,682
Marketable securities, at fair value	3,570,620	3,791,942
Accounts receivable, net of allowance for doubtful accounts of \$43,000 and \$50,000 in 2012 and 2011, respectively	2,772,034	3,729,303
Inventory	3,779,433	2,823,173
Prepaid and other current assets	901,602	1,380,763
Current assets of discontinued operations		38,671
TOTAL CURRENT ASSETS	39,759,343	36,187,534
Restricted cash	176,145	175,810
Property, plant and equipment, net	1,654,794	1,601,101
Deferred charges and other assets	64,855	57,833
TOTAL ASSETS	\$ 41,655,137	\$ 38,022,278
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 1,285,895	\$ 803,639
Accrued compensation	1,317,226	2,351,342
Other accrued expenses	2,926,186	2,459,562
Current liabilities of discontinued operations	161,922	851,775
TOTAL CURRENT LIABILITIES	5,691,229	6,466,318
Deferred revenues	893,233	900,769
Warrant liability	4,525,605	2,216,763
Other liabilities	137,473	157,238
TOTAL LIABILITIES	11,247,540	9,741,088
COMMITMENTS AND CONTINGENCIES (NOTE 9)		
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; of which 40,000 were designated junior Series A preferred shares. Issued and outstanding: 25,027,683 and 24,649,614 shares of common shares, no par, at September 30, 2012 and December 31, 2011, respectively	151,853,161	151,985,930
Additional paid-in capital	12,459,574	10,606,654
Accumulated deficit	(133,910,660)	(134,336,998)

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Accumulated other comprehensive income	5,522	25,604
TOTAL SHAREHOLDERS EQUITY	30,407,597	28,281,190
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 41,655,137	\$ 38,022,278

See the accompanying Notes to the Consolidated Financial Statements.

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

	Three months ended		Nine months ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
Product revenues	\$ 9,740,247	\$ 9,373,673	\$ 34,887,038	\$ 30,026,616
Cost of product revenues	1,508,767	1,412,137	5,356,713	4,513,854
GROSS MARGIN	8,231,480	7,961,536	29,530,325	25,512,762
Operating costs:				
Research and development	1,697,659	1,307,054	5,955,299	3,739,472
Marketing and sales	3,353,545	3,352,535	11,988,075	10,614,332
General and administrative	2,906,932	2,318,572	8,864,383	7,321,606
TOTAL OPERATING COSTS	7,958,136	6,978,161	26,807,757	21,675,410
INCOME FROM OPERATIONS	273,344	983,375	2,722,568	3,837,352
Other income	7,729	9,065	12,612	45,052
(Loss) gain on change in fair value of warrants	(1,702,542)	2,569,154	(2,308,842)	(495,216)
(LOSS) INCOME FROM CONTINUING OPERATIONS	(1,421,469)	3,561,594	426,338	3,387,188
(LOSS) INCOME FROM DISCONTINUED OPERATIONS		(54,699)		625,402
NET (LOSS) INCOME	\$ (1,421,469)	\$ 3,506,895	\$ 426,338	\$ 4,012,590
BASIC NET (LOSS) INCOME PER SHARE CONTINUING OPERATIONS	\$ (0.06)	\$ 0.14	\$ 0.02	\$ 0.14
DISCONTINUED OPERATIONS	\$	\$	\$	\$ 0.03
BASIC NET (LOSS) INCOME PER SHARE	\$ (0.06)	\$ 0.14	\$ 0.02	\$ 0.16
DILUTED NET (LOSS) INCOME PER SHARE CONTINUING OPERATIONS	\$ (0.06)	\$ 0.13	\$ 0.02	\$ 0.13
DISCONTINUED OPERATIONS	\$	\$	\$	\$ 0.02
DILUTED NET (LOSS) INCOME PER SHARE	\$ (0.06)	\$ 0.13	\$ 0.02	\$ 0.15

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

WEIGHTED AVERAGE COMMON SHARES OUTSTANDING, BASIC	25,009,793	24,649,364	24,893,967	24,492,137
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING, DILUTED	25,009,793	26,442,251	26,978,359	26,385,140

See the accompanying Notes to the Consolidated Financial Statements.

Table of Contents**DUSA PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (UNAUDITED)**

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
NET (LOSS) INCOME	\$ (1,421,469)	\$ 3,506,895	\$ 426,338	\$ 4,012,590
Change in net unrealized gains on marketable securities, available-for-sale	(5,856)	(15,800)	(20,082)	(43,969)
COMPREHENSIVE (LOSS) INCOME	\$ (1,427,325)	\$ 3,491,095	\$ 406,256	\$ 3,968,621

See the accompanying Notes to the Consolidated Financial Statements.

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

	Nine months ended September 30,	
	2012	2011
CASH FLOWS PROVIDED BY OPERATING ACTIVITIES		
Net income	\$ 426,338	\$ 4,012,590
Less: income from discontinued operations		(625,402)
Net income from continuing operations	426,338	3,387,188
Adjustments to reconcile net income to net cash provided by operating activities:		
Accretion of premiums and discounts on marketable securities	(51)	(13,288)
Share-based compensation	1,852,920	884,290
Depreciation and amortization	442,689	332,254
Loss on change in fair value of warrants	2,308,842	495,216
Deferred revenues recognized	(7,536)	(1,720,997)
Changes in other assets and liabilities impacting cash flows from operations:		
Accounts receivable	957,269	1,034,091
Inventory	(956,260)	(906,936)
Prepaid and other assets	472,139	595,970
Accounts payable, accrued compensation and other accrued expenses	(85,236)	(370,386)
Other liabilities	(19,765)	(19,331)
NET CASH PROVIDED BY OPERATING ACTIVITIES FROM CONTINUING OPERATIONS	5,391,349	3,698,071
NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES FROM DISCONTINUED OPERATIONS	(651,182)	343,035
NET CASH PROVIDED BY OPERATING ACTIVITIES	4,740,167	4,041,106
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES		
Purchases of marketable securities	(1,998,709)	(1,499,337)
Proceeds from maturities and sales of marketable securities	2,200,000	11,115,000
Restricted cash	(335)	(834)
Purchases of property, plant and equipment	(496,382)	(271,078)
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES FROM CONTINUING OPERATIONS	(295,426)	9,343,751
NET CASH PROVIDED BY INVESTING ACTIVITIES FROM DISCONTINUED OPERATIONS		750,000
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES	(295,426)	10,093,751
CASH FLOWS (USED IN) PROVIDED BY FINANCING ACTIVITIES		
Stock option exercises	375,797	515,689
Settlements of restricted stock for tax withholding obligations	(508,566)	(233,757)
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(132,769)	281,932
NET INCREASE IN CASH AND CASH EQUIVALENTS	4,311,972	14,416,789

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Decrease (increase) in cash and cash equivalents from discontinued operations	651,182	(1,093,035)
Increase in cash and cash equivalents from continuing operations	4,963,154	13,323,754
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	24,423,682	8,884,402
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 28,735,654	\$ 23,301,191

See the accompanying Notes to the Consolidated Financial Statements.

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

The Consolidated Balance Sheet as of September 30, 2012, the Consolidated Statements of Operations and Comprehensive Income for the three and nine-month periods ended September 30, 2012 and 2011, and the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2012 and 2011 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 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 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, 2011 filed with the Securities and Exchange Commission. The balance sheet as of December 31, 2011 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*

The Company's financial instruments at September 30, 2012 and December 31, 2011 consisted primarily of cash and cash equivalents, accounts receivable, marketable securities, accounts payable, and a warrant liability. The Company believes the carrying value of accounts receivable and accounts payable approximates their fair values due to their short-term nature.

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. The warrant liability was recorded initially at its fair value using the Black-Scholes option-pricing model and is revalued 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.

Table of Contents

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 September 30, 2012			
	Carrying Value	(Level 1)	(Level 2)	(Level 3)
Assets				
Cash and cash equivalents	\$ 28,736,000	\$ 28,736,000	\$	\$
United States government-backed securities	3,354,000		3,354,000	
Certificate of Deposit Restricted Cash	176,000	176,000		
Corporate debt securities	217,000		217,000	
Total assets at fair value	\$ 32,483,000	\$ 28,912,000	\$ 3,571,000	\$
Liabilities				
Warrant liability	\$ 4,526,000			\$ 4,526,000
Total liabilities at fair value	\$ 4,526,000	\$	\$	\$ 4,526,000

	Fair Value Measurements at December 31, 2011			
	Carrying Value	(Level 1)	(Level 2)	(Level 3)
Assets				
Cash and cash equivalents	\$ 24,424,000	\$ 24,424,000		
United States government-backed securities	3,569,000		3,569,000	
Certificate of Deposit Restricted Cash	176,000	176,000		
Corporate debt securities	223,000		223,000	
Total assets at fair value	\$ 28,392,000	\$ 24,600,000	\$ 3,792,000	
Liabilities				
Warrant liability	\$ 2,217,000			\$ 2,217,000
Total liabilities at fair value	\$ 2,217,000	\$	\$	\$ 2,217,000

The Company reviewed the level classifications of its investments at September 30, 2012 compared to December 31, 2011 and determined that there were no significant transfers between levels in the nine-month period ended September 30, 2012.

The table below includes a rollforward of the balance sheet amounts for the three and nine-month periods ended September 30, 2012 and 2011 for the warrant liability, which is classified as Level 3.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)					
Three-Month Period Ended September 30, 2012					
Fair Value at July 1, 2012	Total Unrealized Loss Recognized in Statement of	Purchases, Sales Issuances, Settlements, net	Transfers In and/or Out of Level 3	Fair Value at September 30, 2012	Change in Unrealized Losses

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

	Operations					
Warrant Liability	\$ 2,823,000	\$ 1,703,000	\$	\$	\$ 4,526,000	\$ (1,703,000)

Nine-month Period Ended September 30, 2012

	Total					
	Unrealized					
	Loss					
	Recognized					
	Fair Value	in	Purchases,	Transfers	Fair Value at	Change in
	at	Statement Of	Sales	In	September 30,	Unrealized
	January 1, 2012	Operations	Issuances,	and/or	2012	Losses
			Settlements,	Out of		
			net	Level 3		
Warrant Liability	\$ 2,217,000	\$ 2,309,000	\$	\$	\$ 4,526,000	\$ (2,309,000)

Table of Contents

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

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

Nine-month Period Ended September 30, 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 September 30, 2011	Change in Unrealized Losses
Warrant Liability	\$ 1,204,000	\$ 495,000	\$	\$	\$ 1,699,000	\$ (495,000)

Marketable Securities

The Company's marketable securities consist of the following:

September 30, 2012

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government-backed securities	\$ 3,350,000	\$ 4,000	\$	\$ 3,354,000
Corporate securities	215,000	2,000		217,000
Total marketable securities	\$ 3,565,000	\$ 6,000	\$	\$ 3,571,000

December 31, 2011

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government-backed securities	\$ 3,551,000	\$ 18,000	\$	\$ 3,569,000
Corporate securities	215,000	8,000		223,000
Total marketable securities	\$ 3,766,000	\$ 26,000	\$	\$ 3,792,000

The decrease in net unrealized gains on such securities for the three and nine-month periods ended September 30, 2012 were \$6,000 and \$20,000, as compared to \$16,000 and \$44,000 in the comparable 2011 periods. Unrealized gains have been recorded as a component of comprehensive income (loss) in the Consolidated Statements of Comprehensive Income and are reported as part of shareholders' equity in the Consolidated Balance Sheets. There were no realized losses on sales of marketable securities for the three and nine-month periods ended September 30, 2012 and 2011. As of September 30, 2012, current yields range from 0.1% to 4.7% and maturity dates range from October 2012

to January 2013.

Common Stock Warrants

Upon issuance of the warrants on October 29, 2007, the Company recorded the warrant liability at its initial fair value of \$1,950,000. Warrants that are classified as a liability are measured at each reporting date until the warrants are exercised or expire with changes in the fair value reported in the Company's Consolidated Statements of Operations as gain or loss on fair value of warrants. Assumptions used for the Black-Scholes option-pricing models in determining the fair value as of September 30, 2012 and December 31, 2011, include the exercise price of \$2.85 per share, and the following:

	September 30, 2012	December 31, 2011
Expected volatility	53%	61%
Remaining contractual term (years)	0.6	1.3
Risk-free interest rate	0.1%	0.2%
Expected dividend yield	0%	0%
Common stock price	\$ 6.79	\$ 4.38

Table of Contents**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 key components for its products. There can be no assurance that these suppliers will be able to meet the Company's future requirements for such components or parts or that they will be available at favorable terms.

4) INVENTORY

Inventory consisted of the following:

	September 30, 2012	December 31, 2011
Finished goods	\$ 1,959,000	\$ 1,110,000
BLU-U [®] evaluation units	164,000	225,000
Work in process	226,000	291,000
Raw materials	1,430,000	1,197,000
Total	\$ 3,779,000	\$ 2,823,000

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

5) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	September 30, 2012	December 31, 2011
Research and development costs	\$ 697,000	\$ 323,000
Marketing and sales costs	342,000	249,000
Other product related costs	739,000	918,000
Legal and other professional fees	586,000	363,000
Employee benefits	356,000	368,000
Other expenses	206,000	239,000
Total	\$ 2,926,000	\$ 2,460,000

6) SHARE-BASED AWARDS

Total share-based compensation expense, related to all of the Company's share-based awards, recognized for the three and nine-month periods ended September 30, 2012 and 2011 included the following line items:

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

	Nine-months ended			
	Three-months ended		September 30,	
	September 30,		September 30,	
	2012	2011	2012	2011
Cost of product revenues	\$ 33,000	\$ 14,000	\$ 89,000	\$ 39,000
Research and development	74,000	39,000	205,000	106,000
Marketing and sales	115,000	57,000	321,000	164,000
General and administrative	449,000	202,000	1,238,000	575,000
Share-based compensation expense	\$ 671,000	\$ 312,000	\$ 1,853,000	\$ 884,000

Table of Contents*Stock Options*

The weighted-average estimated fair value of employee stock options granted during the nine-month period ended September 30, 2012 was \$3.95 per share, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	Three-months ended September 30, 2012	Nine-months ended September 30, 2012
Expected volatility	77.4%	77.9%
Risk-free interest rate	0.8%	1.0%
Expected dividend yield	0%	0%
Expected life-directors and officers (years)	6.14	6.14
Expected life-non-officer employees (years)	5.57	5.57

A summary of stock option activity for the nine-month period ended September 30, 2012 is as follows:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, beginning of period, January 1, 2012	2,811,225	\$ 3.97		
Options granted	141,300	\$ 6.06		
Options forfeited	(21,350)	\$ 5.32		
Options expired	(10,625)	\$ 9.73		
Options exercised	(150,676)	\$ 2.49		
Outstanding, end of period	2,769,874	\$ 4.13	3.40	\$ 9,305,000
Exercisable, end of period	2,070,776	\$ 4.59	2.94	\$ 6,497,000
Options vested and expected to vest, end of period	2,714,242	\$ 4.12	3.36	\$ 9,166,000

At September 30, 2012 total unrecognized estimated compensation cost related to stock options was \$874,000 which is expected to be recognized over a weighted average period of 1.8 years.

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, or for members of the Board of Directors, which vest 25% immediately and 25% per year for 3 years thereafter. The changes in unvested common stock during 2012 and 2011 are as follows:

	2012	2011
Outstanding, beginning of period,	900,750	586,000
Shares granted	966,000	506,000
Shares vested	(317,750)	(191,250)

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Outstanding, end of period	1,549,000	900,750
Weighted average grant date fair value of shares vested during period	\$ 2.85	\$ 1.88
Weighted average grant date fair value of shares granted during period	\$ 6.14	\$ 4.42
Weighted average grant date fair value of unvested shares, end of period	\$ 5.04	\$ 3.08
Weighted average remaining years to vest	2.82	2.73

At September 30, 2012 total unrecognized estimated compensation cost related to non-vested common shares was \$6,253,000, which is expected to be recognized over a weighted average period of 2.8 years.

7) BASIC AND DILUTED NET INCOME PER SHARE

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

Table of Contents

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Weighted average common shares outstanding-basic	25,009,793	24,649,364	24,893,967	24,492,137
Stock options, warrants and unvested shares of common stock		1,792,887	2,084,392	1,893,003
Weighted average common shares outstanding-diluted	25,009,793	26,442,251	26,978,359	26,385,140

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

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Stock options	2,770,000	902,000	951,000	894,000
Unvested shares of common stock	1,549,000	42,000	687,000	14,000
Warrants	1,145,000			
Total	5,464,000	944,000	1,638,000	908,000

8) DISCONTINUED OPERATIONS

At December 31, 2011, the Company ceased marketing and selling its remaining Non-PDT products, primarily ClindaReach® and Meted®. The former Non-PDT Drug Products segment is now reflected as discontinued operations in the accompanying financial statements for all periods presented.

The following is a summary of income from discontinued operations for the three and nine-month periods ended September 30, 2012 and 2011:

	Three months ended September 30,		Nine months ended September 30,			
	2012	2011	2012	2011		
Revenues	\$	\$	74,000	\$	\$	266,000
Cost of revenues			124,000			377,000
Gross Margin			(50,000)			(111,000)
Operating Expenses:						
Selling, general and administrative			5,000			14,000
Gain on sale of assets						(750,000)
Total operating expenses			5,000			(736,000)
Income from discontinued operations	\$	\$	(55,000)	\$	\$	625,000

The Company includes only revenues and costs directly attributable to the discontinued operations, and not those attributable to the ongoing entity. Accordingly, no general corporate overhead costs have been allocated to the Non-PDT operations for purposes of discontinued operations reporting.

Table of Contents

The following is a summary of assets and liabilities associated with discontinued operations at September 30, 2012 and December 31, 2011:

	September 30, 2012	December 31, 2011
Assets from discontinued operations:		
Accounts receivable, net of allowance for doubtful accounts	\$	\$ 39,000
Total assets from discontinued operations	\$	\$ 39,000
Liabilities from discontinued operations:		
Accounts payable	\$ 3,000	\$ 3,000
Sales returns reserve	51,000	252,000
Deferred revenues	78,000	78,000
Payment due to former Sirius shareholders		250,000
Non-PDT license payable		250,000
Other	30,000	19,000
Total liabilities from discontinued operations	\$ 162,000	\$ 852,000

The following is a summary of net cash (used in) provided by operating activities from discontinued operations for the nine-month periods ended September 30, 2012 and 2011:

	Nine-month periods ended September 30,	
	2012	2011
Income from discontinued operations	\$	\$ 625,000
Decrease in assets	39,000	151,000
Increase (decrease) in liabilities	(690,000)	317,000
Gain on sale of assets		(750,000)
Net cash (used in) provided by operating activities from discontinued operations	\$ (651,000)	\$ 343,000
Proceeds from sale of assets		750,000
Net cash provided by investing activities from discontinued operations	\$	\$ 750,000

The Company establishes an accrual in an amount equal to its estimate of Non-PDT products expected to be returned. The Company determines the estimate of the sales return accrual primarily based on historical experience regarding sales and related returns and incorporating other factors that could impact sales returns in the future. These other factors include, for example, levels of inventory in the distribution channel, estimated shelf life and product discontinuances. The Company's policy is to accept returns of Non-PDT products when product is within six months of expiration. The Company considers all of these factors and adjusts the accrual periodically to reflect actual experience.

A summary of activity in the Company's sales returns reserve accounts is as follows:

Provision

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

	Balance at January 1, 2012		Actual Returns or Credits	Balance at September 30, 2012
Sales returns reserve	\$ 252,000	\$	\$ (201,000)	\$ 51,000

	Balance at January 1, 2011	Provision	Actual Returns or Credits	Balance at September 30, 2011
Sales returns reserve	\$ 125,000	\$ 162,000	\$ (49,000)	\$ 238,000

Table of Contents**9) COMMITMENTS AND CONTINGENCIES****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 \$271,000 and \$266,000 for the nine-month periods ended September 30, 2012 and 2011, respectively. Future minimum payments under lease arrangements at September 30, 2012 are as follows:

Years Ending December 31,	Operating Lease Obligations
2012	\$ 98,000
2013	396,000
2014	367,000
Total	\$ 861,000

The Company has not accrued amounts for any other potential contingencies as of September 30, 2012.

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

10) SUBSEQUENT EVENTS**Merger with Sun Pharmaceutical**

On November 8, 2012, the Company entered into an Agreement and Plan of Merger with Sun Pharmaceutical Industries Limited (Sun) under which Sun will acquire the Company. Under the terms of the agreement, Sun, through a subsidiary, will commence a tender offer for all of the outstanding common stock of DUSA at a price of \$8.00 per share in cash. The transaction has a total cash value of approximately \$230 million. The closing of the tender offer will be subject to certain conditions, including the tender of a number of DUSA shares that represent at least a majority of the total number of DUSA's outstanding shares (assuming the exercise of all options and warrants and vesting of restricted shares), the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. Upon the completion of the tender offer, Sun will acquire all remaining shares through a second-step merger at the same price per share.

Warrant Exercise

On November 8, 2012, the Company received notice from a warrant holder that it intended to exercise warrants representing 333,166 shares of the Company's common stock. The exercise will result in the Company recording a loss in the fourth quarter of 2012 for the difference between the carrying value of the warrants at September 30, 2012 and the intrinsic value of the stock warrants on the date of exercise. The Company estimates the fourth quarter loss related to the warrant exercise to be approximately \$400,000. The Company will receive cash proceeds of approximately \$950,000 related to the exercise.

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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[®] photodynamic therapy, or PDT. Our marketed products include the Levulan[®] Kerastick[®] 20% Topical Solution with PDT and the BLU-U[®] brand light source.

We devote most of our resources to advancing the development and marketing of our Levulan[®] PDT technology platform. 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. 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.

We are marketing Levulan[®] PDT under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to our BLU-U[®] device, our Kerastick[®], 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[®], and BLU-U[®] 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 or have been granted.

We manufacture our Levulan[®] Kerastick[®] in our Wilmington, Massachusetts facility. We are responsible for the regulatory, sales, marketing, and customer service and other related activities for our Levulan[®] Kerastick[®] and BLU-U[®].

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, 2011. Since not all of these accounting policies require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting policies with our Audit Committee. There have been no changes to our critical accounting policies in the nine months ended September 30, 2012.

Table of Contents**RESULTS OF OPERATIONS THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2012 VERSUS SEPTEMBER 30, 2011**

Revenues Total revenues for the three and nine-month periods ended September 30, 2012 were \$9,740,000 and \$34,887,000, respectively, as compared to \$9,374,000 and \$30,027,000 in 2011, and were comprised of the following:

	Three months ended September 30,		Increase/ (Decrease)	Nine months ended September 30,		Increase/ (Decrease)
	2012	2011		2012	2011	
LEVULAN® KERASTICK® PRODUCT REVENUES						
United States	\$ 9,149,000	\$ 7,314,000	\$ 1,835,000	\$ 32,947,000	\$ 26,639,000	\$ 6,308,000
Canada	156,000	89,000	67,000	219,000	272,000	(53,000)
Korea (1)		1,516,000	(1,516,000)		1,720,000	(1,720,000)
Subtotal Levulan® Kerastick® product revenues	9,305,000	8,919,000	386,000	33,166,000	28,631,000	4,535,000
BLU-U® PRODUCT REVENUES						
United States	435,000	455,000	(20,000)	1,715,000	1,396,000	319,000
Canada				6,000		6,000
Subtotal BLU-U® product revenues	435,000	455,000	(20,000)	1,721,000	1,396,000	325,000
TOTAL PRODUCT REVENUES	\$ 9,740,000	\$ 9,374,000	\$ 366,000	\$ 34,887,000	\$ 30,027,000	\$ 4,860,000

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

For the three and nine-month periods ended September 30, 2012, total products revenues, comprised of revenues from our Kerastick® and BLU-U® products, were \$9,740,000 and \$34,887,000, respectively. This represents an increase of \$366,000 or 4%, and \$4,860,000, or 16%, over the comparable 2011 totals of \$9,374,000 and \$30,027,000, respectively. The increase in revenues was driven by increased Kerastick® revenues in the United States, offset in part by the acceleration of deferred revenues related to the termination of our Asia Pacific distribution agreement in 2011.

For the three and nine-month periods ended September 30, 2012, Kerastick® revenues were \$9,305,000, and \$33,166,000, respectively, representing a \$386,000, or 4%, and \$4,535,000, or 16%, increase over the comparable 2011 totals of \$8,919,000, and \$28,631,000, respectively. Kerastick® unit sales to end-users were 62,352 and 220,422 for the three and nine-month periods ended September 30, 2012, respectively, including on a year-to-date basis 218,322 sold in the United States and 2,100 sold in Canada. This represents an increase from 54,258 and 195,177 Kerastick® units sold in the three and nine-month periods ended September 30, 2011, respectively, including on a year-to-date basis 188,754 sold in the United States, 2,838 sold in Canada, and 3,585 sold in Korea. Our distributor arrangement for Korea was terminated during the third quarter of 2011. Our overall average net selling price for the Kerastick® increased to \$150.40 per unit for the first nine months of 2012 from \$138.82 per unit for the first nine months of 2011. The increase in 2012 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, offset in part by the acceleration of deferred revenues of \$1,379,000 related to the termination of our Asia Pacific distribution agreement in 2011. For the three and nine-month periods ended September 30, 2012, domestic Kerastick® revenues were \$9,149,000, and \$32,947,000, respectively, representing a \$1,835,000, or

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

25%, and \$6,308,000, or 24%, increase over the comparable 2011 totals of \$7,314,000, and \$26,639,000, respectively.

For the three and nine-month periods ended September 30, 2012, BLU-U[®] revenues were \$435,000 and \$1,721,000, respectively, representing a (\$20,000), or (4%), and \$325,000, or 23%, (decrease)/increase over the comparable 2011 totals of \$455,000 and \$1,396,000, respectively. On a year-to-date basis, the increase in BLU-U[®] revenues was due to an increase in our sales volumes, partially offset by a decrease in our overall average selling price. In the three and nine-month periods ended September 30, 2012, there were 61 and 241 units sold, respectively, versus 61 and 181 units sold, respectively, in the comparable 2011 periods. In 2012, on a year-to-date basis, our average net selling price for the BLU-U[®] decreased to \$7,060 from \$7,526 in 2011. The decrease in our average selling price from the prior year is a result of incentive discounting.

Table of Contents

Our BLU-U[®] evaluation program allows customers to take delivery for a limited number of BLU-U[®] units for a period of up to four months for private practitioners and up to one year for hospital clinics, before we require a purchase decision. At September 30, 2012, there were approximately 31 units in the field pursuant to this evaluation program, compared to 48 units in the field at December 31, 2011. 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. In addition, the Company offers active customers who own an out-of-warranty, non-current version of the BLU-U[®], the opportunity to purchase our latest model at a discounted price with the return of the older unit.

The increase in our total product revenues for the nine-month period ended September 30, 2012, compared to the comparable 2011 period, results primarily from increased Kerastick[®] and BLU-U[®] revenues in the United States, offset in part by the acceleration of deferred revenues related to the termination of our Asia Pacific distribution agreement in 2011. 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[®] PDT with 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. Additionally, our two Phase 2 clinical trials to study broad area, short incubation methods, one of which has been successfully completed, could encourage us to conduct further studies which, following additional larger Phase 3 clinical studies, could lead to enhancements to our current product label and allow us to market our therapy under a treatment method being adopted by the medical community.

During 2012, our revenues in the United States grew as a result of increased demand for our Kerastick[®] and our BLU-U[®]. With respect to Kerastick[®] prices, we announced a price increase in the fourth quarter of 2011, which became effective January 1, 2012. 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 volumes in the fourth quarter of each year. Although we expect continued growth in revenues, we are susceptible to the uncertain economic conditions, particularly with our Canadian customer base where our product lacks reimbursement, and to increased competition, particularly from Medcis Pharmaceutical Corporation (or Medcis), who in December 2011 acquired Aldara[®], a topical AK product, and Zyclara[®], used to treat precancerous skin growths related to sun overexposure, and Leo Pharma, who in January 2012 received FDA approval for Picato[®] Gel, a topical product, to treat AKs on the face and scalp and on the extremities. In September 2012, Medcis agreed to be acquired by Valeant Pharmaceuticals International. Also, Galderma, S.A., a large dermatology company, holds a non-exclusive license from us to Metvixia[®], which was transferred to Galderma by PhotoCure ASA, our original licensee. This product received FDA approval for treatment of AKs in July 2004 and it is directly competitive with our Levulan[®] Kerastick[®] product. Metvixia[®] is commercially available in the U.S.; however, to our knowledge, product revenues have not been significant to date.

We recently decided to participate in voluntary government programs which will require us to pay specified rebates for products reimbursed by Medicaid and to provide discounts for Kerastick[®] units purchased by certain covered entities under section 340B of the Public Health Service Act (such as disproportionate share hospitals meeting certain criteria). The mandated Medicaid rebate is 23.1%, plus an additional amount for price changes relative to cost of living adjustments since the product's launch. Our participation in these programs could lead to some incremental revenues since we are not presently serving these coverage groups; however, our revenues will be negatively impacted by our actual rebate and discount experience. To date, we have had nominal inquiries pertaining to these programs and we do not expect that these rebates and discounts will have a material effect on our revenues.

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

Cost of Product Revenues Cost of product revenues for the three and nine-month periods ended September 30, 2012 were \$1,509,000 and \$5,357,000 as compared to \$1,412,000 and \$4,514,000 in the comparable periods in 2011. A summary of the components of cost of product revenues and royalties is provided below:

	Three months ended September 30,		
	2012	2011	Increase/ (Decrease)
Levulan[®] Kerastick[®] Cost of Product Revenues and Royalties			
Direct and indirect Levulan [®] Kerastick [®] Product Costs	\$ 632,000	\$ 642,000	\$ (10,000)
Royalties (1)	367,000	307,000	60,000
Subtotal Levulan [®] Kerastick [®] Cost of Product Revenues and Royalties	\$ 999,000	\$ 949,000	\$ 50,000

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

BLU-U[®] Cost of Product Revenues			
Direct BLU-U [®] Product Costs	\$ 256,000	\$ 245,000	\$ 11,000
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	254,000	218,000	36,000
Subtotal BLU-U [®] Cost of Product Revenues	\$ 510,000	\$ 463,000	\$ 47,000
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$ 1,509,000	\$ 1,412,000	\$ 97,000

Table of Contents

	Nine months ended September 30,		
	2012	2011	Increase/ (Decrease)
Levulan® Kerastick® Cost of Product Revenues and Royalties			
Direct and indirect Levulan® Kerastick® Product Costs	\$ 2,299,000	\$ 2,108,000	\$ 191,000
Royalties (1)	1,311,000	1,081,000	230,000
Subtotal Levulan® Kerastick® Cost of Product Revenues and Royalties	\$ 3,610,000	\$ 3,189,000	\$ 421,000
BLU-U® Cost of Product Revenues			
Direct BLU-U® Product Costs	\$ 1,012,000	\$ 727,000	\$ 285,000
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	\$ 735,000	598,000	137,000
Subtotal BLU-U® Cost of Product Revenues	\$ 1,747,000	\$ 1,325,000	\$ 422,000
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$ 5,357,000	\$ 4,514,000	\$ 843,000

1) Royalties reflect amounts paid to our licensor, PARTEQ.

Margins Total product margins for the three and nine-month periods ended September 30, 2012 were \$8,231,000 and \$29,530,000, respectively, as compared to \$7,962,000 and \$25,513,000 for the comparable 2011 periods, as shown below:

	Three months ended September 30,				Increase/ (Decrease)
	2012		2011		
Levulan® Kerastick® gross margin	\$ 8,306,000	89%	\$ 7,970,000	89%	\$ 336,000
BLU-U® gross margin	(75,000)	(17)%	(8,000)	(2)%	(67,000)
Total gross margin	\$ 8,231,000	85%	\$ 7,962,000	85%	\$ 269,000

	Nine months ended September 30,				Increase/ (Decrease)
	2012		2011		
Levulan® Kerastick® gross margin	\$ 29,556,000	89%	\$ 25,442,000	89%	\$ 4,114,000
BLU-U® gross margin	(26,000)	(1)%	71,000	5%	(97,000)
Total gross margin	\$ 29,530,000	85%	\$ 25,513,000	85%	\$ 4,017,000

Kerastick® gross margins for the three and nine-month periods ended September 30, 2012 and 2011 were 89% for all periods.

Our long-term goal is to achieve higher gross margins on Kerastick® sales. Our gross margin percentages could be negatively impacted by our recent decision to participate in voluntary government programs such as Medicaid and to provide discounts to certain covered entities under section 340B of the Public Health Service Act (such as disproportionate share hospitals meeting certain criteria). To date, we have had nominal inquiries pertaining to these programs and we do not expect that these rebates and discounts will have a material effect on our gross margins.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

BLU-U[®] margins for the three and nine-month periods ended September 30, 2012 were (17)% and (1)%, respectively, as compared to (2%) and 5% in the comparable 2011 periods. The decrease in gross margin percentage is a result of a decrease in our average selling price, partially offset by an increase in sales volumes on year-to-date basis. It is important for us to sell BLU-U[®] units in an effort to increase Kerastick[®] sales volumes, and accordingly, we often sell BLU-U[®] units at low profit margins.

Research and Development Costs Research and development costs for the three and nine-month periods ended September 30, 2012 were \$1,698,000 and \$5,955,000 as compared to \$1,307,000 and \$3,739,000 in the comparable 2011 periods. The increase in 2012 compared to 2011 was due primarily to increased spending related to 2 clinical trials, which were initiated in late 2011, as further described in the following paragraph. In addition, we are exploring potential new formulations for Levulan[®] as part of our product life cycle management activities.

A DUSA-sponsored Phase 2 clinical trial designed to study the broad area application and short drug incubation, or BASDI, method of using the Levulan[®] Kerastick[®] was initiated during the fourth quarter of 2011, and is being carried out at 13 clinical trial sites. Two hundred thirty-five (235) study subjects are enrolled in this trial, which has been closed to further accrual. The protocol objectives are to compare the

Table of Contents

effect of various incubation times (1, 2 or 3 hours) of broad area application, versus a 2 hour spot incubation on the safety and efficacy of Levulan® plus BLU-U® PDT versus vehicle plus BLU-U® for the treatment of multiple actinic keratoses of the face or scalp and to investigate the potential for reduction in AK occurrence in the treatment areas during a follow-up period of up to 6 months. We expect that preliminary results of this trial will be available by the end of 2012.

In addition to this BASDI clinical trial, another DUSA-sponsored clinical trial designed to study a BASDI method of using the Levulan® Kerastick® for the treatment of AKs on upper extremities was initiated during the fourth quarter of 2011. Seventy (70) subjects were enrolled in this study at 3 trial sites. The objective of the study was to compare the safety and efficacy of Levulan® Kerastick® plus BLU-U® PDT versus vehicle plus BLU-U® PDT on AKs of the upper extremities, and to evaluate the effect of occlusive dressing versus no occlusive dressing during incubation. We announced the results of this study on September 13, 2012. The results showed that at 12 weeks following PDT, the subjects that were treated with Levulan® plus occlusion demonstrated an 89% (p<0.0001) AK lesion clearance rate as compared to a 70% (p<0.0001) clearance rate for those treated without occlusion after up to two PDT treatments; subjects receiving vehicle plus occlusion and vehicle alone demonstrated 17% and 6% lesion clearance rates, respectively. The results of the study suggest that blue light-Levulan® PDT following a 3-hour incubation appears efficacious for AK lesion clearance of the upper extremities, and that incubation using an occlusive dressing significantly increases the efficacy of the procedure.

We expect that the total cost of these trials will be approximately \$3.2 million once completed. Due to these studies, we expect research and development costs for 2012 to be increased from 2011 levels.

Marketing and Sales Costs Marketing and sales costs for the three and nine-month periods ended September 30, 2012 were \$3,354,000 and \$11,988,000, respectively, as compared to \$3,353,000 and \$10,614,000 for the comparable 2011 periods. These costs consisted primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses totaling \$2,711,000 and \$8,904,000 for the three and nine-month periods ended September 30, 2012, compared to \$2,701,000 and \$7,812,000 in the comparable 2011 periods. The increased spending on a year-to-date basis for 2012 in this category is due to increased headcount. The remaining expenses consisted of tradeshows, miscellaneous marketing and outside consultants totaling \$643,000 and \$3,084,000 for the three and nine-month periods ended September 30, 2012, compared to \$652,000 and \$2,802,000 for the comparable 2011 periods. The increase in this category on a year-to-date basis is due primarily to an increase in expenditures related to promotional activities. We expect marketing and sales costs for the full year 2012 to increase over 2011 levels, but to decrease as a percentage of revenues.

General and Administrative Costs General and administrative costs for the three and nine-month periods ended September 30, 2012 were \$2,907,000 and \$8,864,000, respectively, as compared to \$2,319,000 and \$7,322,000 for the comparable 2011 periods. The increase in 2012 is mainly attributable to compensation related charges and legal expenses. 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 2012, we expect general and administrative costs to increase compared with 2011, and also to increase as a percentage of revenues.

(Loss) Gain on Change in Fair Value of Warrants The warrants issued to investors in connection with the October 29, 2007 private placement were recorded initially at fair value and are marked to market each reporting period. The increase in the liability during the three and nine-month periods ended September 30, 2012 was \$1,703,000 and \$2,309,000, respectively, which resulted in non-cash losses in the respective periods. The change in fair value of the warrants is primarily due to changes in our stock price and a decreasing term to expiration. The exercise price of the warrants is \$2.85 per share and the warrants expire in April 2013.

Other Income, Net Other income for the three and nine-month periods ended September 30, 2012, decreased to \$8,000 and \$13,000, respectively, from \$9,000 and \$45,000, during the comparable 2011 periods. The decrease reflects a general decrease in interest rates over that timeframe.

(Loss) Income from Discontinued Operations (Loss) Income from discontinued operations was \$0 for the three and nine-month periods ended September 30, 2012, as compared to (\$55,000) and \$625,000 during the three and nine-month periods ended September 30, 2011, respectively. Discontinued operations reflect the results of our historically designated Non-PDT segment. See Note 8 in the Notes to the Consolidated Financial Statements for further discussion.

Net (Loss) Income For the three and nine-month periods ended September 30, 2012, our net (loss) income was (\$1,421,000), or (\$0.06) per share, and \$426,000, or \$0.02 per diluted share, respectively, as compared to \$3,507,000, or \$0.13 per diluted share, and \$4,013,000, or \$0.15 per diluted share for the comparable 2011 periods. The increase in our net loss, or decrease in our net income, is attributable to the reasons discussed above.

LIQUIDITY AND CAPITAL RESOURCES

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

At September 30, 2012, we had approximately \$32,306,000 of total liquid assets, comprised of \$28,736,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$3,570,000. We believe that our liquidity will be sufficient to meet our cash requirements for at least the next 12 months. As of September 30, 2012, our marketable securities had a weighted average yield to maturity of 1.06% and maturity dates ranging from October 2012 to January 2013. Our net cash generated from continuing operations for the nine-month period ended September 30, 2012 was \$5,391,000 versus \$3,698,000 for the comparable period in 2011. The year-over-year increase in cash generated from continuing operations is primarily attributable to the change in our (loss) income from continuing operations, adjusted for certain non-cash items such as the our (loss)/gain on the change in the fair value of our warrants and the recognition of \$1.7 million of deferred revenues in 2011. The increase in our investment in inventory for the 9 month period ended September 30, 2012 is to support our historically

Table of Contents

higher sales volumes in the fourth quarter of each year. Our net cash (used in) provided by operating activities from discontinued operations was (\$651,000) for the nine-month period ended September 30, 2012 versus \$343,000 for the comparable period in 2011. Our net cash used in investing activities was \$295,000 in 2012, which was primarily from net purchases of marketable securities and purchases of equipment. Our net cash used in financing activities in 2012 was \$133,000, resulting from the settlement of tax withholding obligations from restricted stock vestings, partially offset by proceeds from stock option exercises. As of September 30, 2012 working capital, which is our total current assets minus our total current liabilities, was \$34,068,000, as compared to \$29,721,000 as of December 31, 2011.

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.

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. Accordingly, we may also seek to raise funds through financing transactions. We cannot predict whether financing will be available at all or on reasonable terms.

We have no off-balance sheet financing arrangements.

Contractual Obligations and Other Commercial Commitments

PARTEQ Agreement

We license certain method of use patents underlying our Levulan[®] PDT system 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. 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 nine-month periods ended September 30, 2012 and September 30, 2011, actual royalties based on product sales were approximately \$1,311,000 and \$1,081,000, respectively. For the years ended December 31, 2011, 2010 and 2009, actual royalties based on product sales were approximately \$1,653,000, \$1,331,000 and \$1,019,000, respectively. Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$102,000 as of September 30, 2012).

National Biological Corporation Amended And Restated Purchase And Supply Agreement

On November 29, 2011, we and National Biological Corporation, or NBC, the primary manufacturer of our BLU-U[®] light source, entered into the 2011 Amended and Restated Purchase and Supply Agreement, or the 2011 NBC Agreement. The 2011 NBC Agreement includes similar terms and conditions to our Amended and Restated Purchase and Supply Agreement dated as of September 21, 2004, as amended, or the 2004 Agreement, which was due to expire on December 31, 2011. The 2011 NBC Agreement replaces the 2004 Agreement and has a term of 2 years through December 31, 2013. We have an option to further extend the term of the 2011 NBC Agreement for an additional 2 years if we purchase a certain number of units.

Bachem SA

Under an agreement dated December 24, 1993, Bachem SA, formerly 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 September 30, 2012, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$1,388,000. 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, 2012 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.

Table of Contents

Our contractual obligations and other commercial commitments to make future payments under contracts, including lease agreements, research and development contracts, manufacturing contracts, or other related agreements are as follows at September 30, 2012:

	Total	1 Year or less	2-3 Years	4-5 Years	After 5 Years
Operating lease obligations	\$ 861,000	\$ 395,000	\$ 466,000	\$	\$
Purchase obligations (1, 2)	2,645,000	2,343,000	302,000		
Minimum royalty obligations (3)	408,000	102,000	204,000	102,000	
Total obligations	\$ 3,914,000	\$ 2,840,000	\$ 972,000	\$ 102,000	\$

- 1) Research and development projects include various commitments including obligations for our studies 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 agreement with PARTEQ described above.
- Rent expense incurred under these operating leases was approximately \$271,000 and \$266,000 for the nine-month periods ended September 30, 2012 and 2011, respectively.

INFLATION

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

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

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

As of September 30, 2012, the weighted average rate of return on our investments was 1.06%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of September 30, 2012, the fair market value of the portfolio would decline by approximately \$5,000. 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

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

ITEM 4. CONTROLS AND PROCEDURES

We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2012.

Table of Contents

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2012 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 our expectations regarding the potential for reduction of headcount, our desire to raise funds through financing transactions, management's beliefs regarding the nature of Levulan® and its potential uses, curtailment of variable expenses, expectations regarding 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, our expectations regarding product launches in other countries and territories expectations regarding additional market expansion, the impact on our market share resulting from Galderma's promotion of Metvix®, the approval of Leo Pharma's Picato® Gel, and Medicis' promotion of Aldara® and Zyclara®, expectations regarding the confidentiality of our proprietary information, beliefs regarding regulatory classifications, filings, timelines, off-label use, and environmental compliance, beliefs concerning patent disputes or patents issued to third parties, beliefs regarding the impact of litigation and ability to afford the costs, 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 increases or decreases in the prices we charge for our products and their margins, our beliefs regarding the size of the market for our products and our product candidate, expected use of cash resources, beliefs regarding requirements of cash resources for our future liquidity, and research and development programs, beliefs regarding investments and economic conditions including the impact of our customer's failure to meet our payment terms, expectations regarding outstanding options and warrants, anticipation of increases or decreases in personnel, beliefs regarding the effect of reimbursement policies on revenues and market acceptance of our therapies, expectations for future strategic opportunities and research and development programs and expenses, expectations for continuing operating losses and beliefs regarding competition, expectations regarding the adequacy and availability of insurance, expectations regarding general and administrative costs, expectations regarding sales and marketing costs and research and development costs, levels of interest income and our beliefs regarding the 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 actions, beliefs regarding our manufacturing capabilities, beliefs regarding interest rate risks to our investments and effects of inflation, beliefs regarding the impact of any current or future legal proceedings, beliefs regarding the dependence on key personnel, beliefs concerning product liability insurance, beliefs regarding the enforceability of our patents, beliefs regarding financial condition, results of operations and profitability, our beliefs regarding our sales and marketing efforts, beliefs regarding competition with other companies and effect on increased reimbursement, 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 clinical development and testing of our potential products and technologies and the costs thereof, beliefs regarding the volatility of our stock price, beliefs regarding the impact of our rights plan, beliefs regarding the impact of future sales of securities, expectations related to the change in revenues of our PDT products, beliefs regarding market share, beliefs regarding profitability, beliefs regarding the change in growth in our PDT Drug and Device Products segment, 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 our NUBIG enhancements, 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 regarding the impact that any manufacturing or supply problems could have on our sales, anticipation of future NDAs for Levulan® PDT, beliefs concerning safety procedures for hazardous materials, our compliance and risks of liability, beliefs regarding competitive products, beliefs concerning revenues, beliefs regarding our capital resource needs, beliefs regarding the sufficiency of our cash, cash equivalents and marketable securities, beliefs regarding instability in the international markets, 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, beliefs regarding cash flows, 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, beliefs regarding our inventory becoming obsolete or our inventory significantly changing in value, beliefs regarding patent protection our technology and from competition, beliefs regarding financial benefits from patent protection, beliefs regarding improved gross margins on Kerastick® from further volume growth and price increases in the United States, beliefs regarding the timing of pricing changes, beliefs regarding the purchasing patterns of our customers, our expectations regarding BASDI research and development costs, beliefs regarding our intention to announce a price increase on an annual basis in the fourth quarter of each year and our beliefs regarding our ability to remain profitable each quarter and the effect of fluctuations in the demand for our products during the year. 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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.

Table of Contents

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

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

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

Risks Related To DUSA

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

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

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

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

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

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

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

send warning letters,

impose fines and other civil penalties on us,

seize our products,

suspend our regulatory approvals,

cease the manufacture of our products,

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

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

require us to recall products,

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

impose restrictions on our operations, and/or

criminally prosecute us.

Table of Contents

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, or 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 remain profitable.

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

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

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

Galderma, S.A., a large dermatology company, holds a non-exclusive license from us on Metvixia[®], which was transferred to Galderma by PhotoCure ASA, our original licensee. This product received FDA approval for treatment of AKs in July 2004 and is directly competitive with our Levulan[®] Kerastick[®] product. To our knowledge, Metvixia's U.S. product revenues have not been significant to date. On December 2, 2011, Medicis acquired Aldara[®] and Zyclara[®], topical AK products used to treat precancerous skin growths related to sun overexposure. Medicis is being acquired by Valeant Pharmaceuticals International, Inc., which has significantly greater resources than we do. In addition, in January 2012, Leo Pharma, a Danish corporation, received FDA approval for Picato[®] Gel, a topical product, to treat AKs on the face and scalp and on the extremities. These products could negatively impact the market penetration of our PDT products.

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

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

We have approximately \$32,306,000 in cash, cash equivalents and marketable securities as of September 30, 2012. 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 potential increased competition from Metvixia[®], Picato[®] Gel, Aldara[®] and Zyclara[®]. 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.

Prior to 2010, we had a history of annual operating losses and we may incur quarterly losses in the future. As of September 30, 2012, our accumulated deficit was approximately \$133,911,000. 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 distributor, may exceed revenues in the future, which may result in future losses from operations.

We Have Only Two Marketed 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 Or Any Other Product.

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Except for Levulan® PDT for AKs, and the BLU-U® for acne, all of our other potential product candidates are being studied by independent investigators, or are at a very early stage of development, including our BASDI clinical studies and our new Levulan® formulation activities. Although results of our pilot study on the use of PDT for the upper extremities were very encouraging, these candidates are subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

delays in product development, clinical testing or manufacturing,

unplanned expenditures in product development, clinical testing or manufacturing,

failure in development efforts, clinical trials or failure to receive regulatory approvals,

Table of Contents

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 or label expansion 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, or a medical device, called either a PMA or 510(K) can be filed, a product must undergo, among other things, extensive 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 4 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 Cannot Assure You That We Will Be Able To Complete Our Broad Area Application And/Or Short Drug Incubation, Clinical Trials Successfully Within Any Specific Time Period, Or That The Results Of Such Clinical Trials Will Be As Expected.

We are currently conducting two clinical trials designed to study broad area application and/or short drug incubation methods, or BASDI methods, of using the Levulan[®] Kerastick[®]. Our FDA-approved labeling for Levulan[®] Kerastick[®] requires application of Levulan[®] to individual actinic keratoses, or AKs, lesions, but in these clinical trials a broad area application method is being utilized, where Levulan[®] is applied to an entire skin region. The first study is a Phase 2 study utilizing broad area application with 1, 2 and 3-hour (short) drug incubation for the treatment of AKs, of the face or scalp. The second study is a pilot clinical trial designed to study a BASDI method of using the Levulan[®] Kerastick[®] for the treatment of AKs on the upper extremities. Preliminary results of this second study were previously announced on September 13, 2012 and final results will be published shortly. Additional development and FDA approval is required before Levulan[®] could be marketed for these uses.

We do not know if development of the BASDI methods will be completed at all. We do not expect that the first BASDI clinical trial will produce statistically significant results as it is not powered for this purpose. Additionally, we do not know if the study will produce clinically meaningful trending information, results which are comparable to our current approved product label claims, or results which are commercially beneficial. Whether or not and how quickly we complete the first BASDI clinical trial is dependent, in part, upon the rate that clinical data can be collected, cleaned, locked and analyzed.

If we experience delays in completion of our BASDI clinical trials, we may incur additional costs and delays, and may not be able to complete our BASDI clinical trials on a cost-effective or timely basis. If enrolled patients do not complete the BASDI clinical trials as planned, we may need to delay or terminate the ongoing BASDI clinical trials and even if the BASDI clinical trials are completed, there is no guarantee they will produce positive trend results, all of which could negatively affect our business.

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

and sales of our products could be negatively impacted. Although positive reimbursement changes related to AK have been made, 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.

Table of Contents

U.S. Health Care Reform Law And Other Legislative Developments Could Adversely Affect Our Business And Profitability.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA). As a result of this legislation, substantial changes could be made to the current system for paying for health care in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage.

Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of third-party payors and government programs, such as Medicare and Medicaid, the creation of a government-sponsored health care insurance source, or some combination of both, as well as other changes.

Although we cannot fully predict the many ways that health care reform might affect our business, the law imposes a 2.3% medical device excise tax on certain transactions, including many U.S. sales of medical devices, which we expect will include U.S. sales of our BLU-U®. This tax is scheduled to take effect in 2013. It is unclear whether and to what extent, if at all, other anticipated developments resulting from health care reform, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset this increased tax. If additional revenue does not materialize, or if our efforts to offset the excise tax through price increases, spending cuts or other actions are unsuccessful, the increased tax burden would adversely affect our revenue.

PPACA also requires pharmaceutical manufacturers to pay a 50% discount on drugs dispensed to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). We have entered into an agreement consistent with this provision, although we do not anticipate significant rebate claims since our products are not typically covered under Medicare Part D. We recently decided to participate in voluntary government programs which will require us to pay specified rebates for products reimbursed by Medicaid and to provide discounts for Kerastick® units purchased by certain covered entities under section 340B of the Public Health Service Act (such as disproportionate share hospitals meeting certain criteria). The mandated minimum Medicaid rebate and 340B program discount is 23.1%. Historically, we have had nominal sales inquiries through these programs. It is possible that by participating in these programs, our revenues could increase; however, ultimately, we do not expect that any incremental sales, rebates and discounts will have a material effect on our business, but we cannot be certain of the impact.

Finally, the law also requires drug manufacturers to pay an annual health care reform fee, which will be a portion of \$2.8 billion for 2012. Our fee is assessed in proportion to our share of sales to certain government programs, such as Medicare and Medicaid.

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.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Sales of our products are dependent, in large part, on reimbursement from government health and administration authorities, private health insurers, our distribution partner 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.

Table of Contents

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 components 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 Customers Ability To Meet Our Payment Terms, Our Cash Flow Would Be Adversely Affected And Our Ability To Continue To Be Profitable Could Be Jeopardized.

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

We Have 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 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 we license from PARTEQ, the licensor of our ALA patents, relating to methods of using ALA for detecting or treating disease, other than for acne and our approved indication for AKs of the face or scalp, started to expire in July 2009. The PARTEQ patent which covers our approved AK product expires in September 2013. Beyond September 2013 with the expiration of the PARTEQ patent, we will be more susceptible to certain types of competition. However, with a patent relating to use of our BLU-U[®], which issued in 2010, we now have additional claims that may mitigate some of the risk relating to our AK product, and these will not expire until June 2019. The 2010 patent contains method of treatment claims which cover our blue light technology and Levulan[®] for the treatment of actinic keratoses, and also contains claims that cover our blue light technology in conjunction with our Levulan[®] Kerastick[®].

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

Metvixia[®] was approved by the FDA as a treatment for AKs in July 2004, and this ALA-derived product is directly competitive with our Levulan[®] Kerastick[®] product. To our knowledge, Metvixia's U.S. product revenues have not been significant to date.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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 could independently develop or otherwise discover our trade secrets.

Table of Contents

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®, 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 are 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 3 years.

Based on an IRC Section 382 study we performed, we determined that we have experienced prior ownership changes, as defined under IRC Section 382, with the most recent change in ownership occurring in 2007. Our 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 5 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 5 years of the ownership change. The calculated aggregate amount of NUBIG enhancement for us is approximately \$4.3 million (i.e., approximately \$868,000 per year for the first 5 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 5 years after the ownership change. Based on these additional factors, we estimate that we will be able to utilize approximately \$49.9 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 2012 or thereafter. Future ownership changes could further restrict the utilization of our net operating losses and tax credits, reducing or eliminating the benefit of such net operating losses and tax credits. If such future ownership changes were to occur, it is possible that we could be required to pay federal income taxes in the

near-term.

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

If we are unable to successfully market and sell sufficient quantities of our products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. We directly market our products in the United States. In Canada, the only other country in which we market our products, we market Levulan[®] and the BLU-U[®] through a distributor. If our sales and marketing efforts fail, then sales of the Levulan[®] Kerastick[®], and the BLU-U[®] 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

Table of Contents

care organizations and group purchasing organizations, and the rest of 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.

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

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

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

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

We are a small company with only 99 employees as of September 30, 2012. 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. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very few people with their expertise could be hired. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain other qualified personnel in our specialty drug and light device areas.

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

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These scientists and advisors are not our employees and may have other commitments that limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services. In addition, although our advisors and

collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

Risks Related To Our Industry

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

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

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

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

We have used various hazardous materials, such as mercury in fluorescent tubes in our research and development activities. We are subject to federal, state and local laws and regulations which govern the use, manufacture, storage, handling and disposal of hazardous materials

Table of Contents

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

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

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

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

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

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

price reductions,

lower levels of third party reimbursements,

failure to achieve market acceptance, and

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

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

Galderma, S.A., a large dermatology company, holds a non-exclusive license from us to Metvixia[®], which was transferred to Galderma by PhotoCure ASA, our original licensee. This product received FDA approval for treatment of AKs in July 2004 and is directly competitive with our Levulan[®] Kerastick[®] product and its price is comparable to the price of Levulan[®]. To our knowledge, Metvixia's U.S. product revenues have not been significant to date. Also, Leo Pharma's Picato[®] Gel and Medicis' Aldara[®] and Zyclara[®], could negatively impact the market penetration of our PDT products.

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

We are aware of several companies commercializing and/or conducting research with ALA or ALA-related compounds, including: Galderma (Switzerland), medac GmbH and photonamic GmbH & Co. KG (Germany); Biofrontera (Germany), PhotoTherapeutics, Inc. (U.K.), and

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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: Valeant Pharmaceuticals International, Inc.; and Miravant Medical Technologies, Inc. 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.

Table of Contents

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 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, 2011 to September 30, 2012, the closing price of our stock has ranged from a low of \$2.39 to a high of \$6.99. The significant general market volatility in similar stage pharmaceutical and biotechnology companies also makes the market price of our stock volatile.

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

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

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

As of September 30, 2012, there were outstanding options and warrants to purchase 3,915,000 shares of common stock, with exercise prices ranging from \$1.10 to \$15.90 per share for options, and \$2.85 per share for warrants. In addition, there were approximately 1,549,000 shares of unvested common stock. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. Also, if some or all of such shares are sold into the public market over a short period of time, the value of all publicly traded shares could decline, as the market may not be able to absorb those shares at then-current market prices. Additionally, such sales may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all. The holders may exercise their securities during a time when we would likely be able to raise capital from the public on terms more favorable than those provided in these securities.

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

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

Effecting A Change Of Control Of DUSA Could 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. This plan and the rights which were exercisable under the plan expired on October 10, 2012.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

Table of Contents

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

- 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) Amended and Restated By-laws of the Registrant, filed as Exhibit 3(b) to the Registrant's Annual report on Form 10-K for the fiscal year ended December 31, 2011, filed on March 6, 2012, 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.
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase
- 101.LAB XBRL Taxonomy Extension Label Linkbase
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase
- 101.DEF XBRL Taxonomy Extension Definition Document

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: November 8, 2012

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

Dated: November 8, 2012

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)	Amended and Restated By-laws of the Registrant, filed as Exhibit 3(b) to the Registrant's Annual report on Form 10-K for the fiscal year ended December 31, 2011, filed on March 6, 2012, 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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Document