

DUSA PHARMACEUTICALS INC

Form 10-Q

November 03, 2008

**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, 2008**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number: 001-31533**

**DUSA PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

01887  
(Zip Code)

(978) 657-7500

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of October 31, 2008, the registrant had 24,078,452 shares of Common Stock, no par value per share, outstanding.

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

	Page Number
<u><b>PART I. FINANCIAL INFORMATION</b></u>	
<u>Item 1. Financial Statements</u>	
- <u>Condensed Consolidated Balance Sheets at September 30, 2008 (Unaudited) and December 31, 2007</u>	3
- <u>Condensed Consolidated Statements of Operations for the three and nine-month periods ended September 30, 2008 and 2007 (Unaudited)</u>	4
- <u>Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2008 and 2007 (Unaudited)</u>	5
- <u>Notes to the Condensed Consolidated Financial Statements (Unaudited)</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	26
<u>Item 4. Controls and Procedures</u>	26
<u><b>PART II. OTHER INFORMATION</b></u>	
<u>Item 1. Legal Proceedings</u>	27
<u>Item 1A. Risk Factors</u>	28
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	41
<u>Item 3. Defaults Upon Senior Securities</u>	41
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	41
<u>Item 5. Other Information</u>	41
<u>Item 6. Exhibits</u>	41
<u>SIGNATURES</u>	42
<u>Exhibit Index</u>	

**Table of Contents**

**PART I.**  
**ITEM 1. FINANCIAL STATEMENTS**

**DUSA PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)**

	September 30, 2008	December 31, 2007
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 5,225,879	\$ 4,713,619
Marketable securities	15,004,901	18,311,650
Accrued interest receivable	140,454	97,243
Accounts receivable, net of allowance for doubtful accounts of \$89,000 and \$158,000 in 2008 and 2007, respectively	1,911,968	2,667,178
Inventory	2,999,468	2,672,105
Prepaid and other current assets	1,739,689	1,843,873
<b>TOTAL CURRENT ASSETS</b>	<b>27,022,359</b>	<b>30,305,668</b>
Restricted cash	173,385	170,510
Property, plant and equipment, net	2,034,357	2,142,658
Deferred charges and other assets	193,258	273,404
<b>TOTAL ASSETS</b>	<b>\$ 29,423,359</b>	<b>\$ 32,892,240</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 554,955	\$ 1,213,867
Accrued compensation	1,040,243	491,529
Other accrued expenses	3,210,876	3,322,642
Deferred revenue	873,505	1,256,494
<b>TOTAL CURRENT LIABILITIES</b>	<b>5,679,579</b>	<b>6,284,532</b>
Deferred revenues	4,051,249	2,918,850
Warrant liability	486,964	1,262,600
Other liabilities	266,657	319,736
<b>TOTAL LIABILITIES</b>	<b>10,484,449</b>	<b>10,785,718</b>
<b>COMMITMENTS AND CONTINGENCIES (NOTE 17)</b>		
<b>SHAREHOLDERS EQUITY</b>		
Capital Stock	151,652,941	151,648,943

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in Series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding: 24,078,452 and 24,076,110 shares of common stock, no par, at September 30, 2008 and December 31, 2007, respectively

Additional paid-in capital	6,928,164	5,885,353
Accumulated deficit	(139,860,271)	(135,600,484)
Accumulated other comprehensive income	218,076	172,710
TOTAL SHAREHOLDERS EQUITY	18,938,910	22,106,522
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 29,423,359	\$ 32,892,240

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

	Three-months ended September 30,		Nine-months ended September 30,	
	2008	2007	2008	2007
Product revenues and royalties	\$ 5,726,071	\$ 5,784,194	\$21,767,810	\$19,323,232
Cost of product revenues and royalties	1,462,028	1,573,897	4,950,039	5,506,540
<b>GROSS MARGIN</b>	<b>4,264,043</b>	<b>4,210,297</b>	<b>16,817,771</b>	<b>13,816,692</b>
Operating Costs:				
Research and development	1,487,816	1,225,462	5,049,327	4,328,475
Marketing and sales	2,967,431	2,887,370	9,520,865	9,727,660
General and administrative	1,911,028	2,110,766	6,603,989	7,966,791
Impairment charge related to contingent consideration	1,500,000		1,500,000	
Net gain from settlement of litigation	650		(282,775)	
<b>TOTAL OPERATING COSTS</b>	<b>7,866,925</b>	<b>6,223,598</b>	<b>22,391,406</b>	<b>22,022,926</b>
<b>LOSS FROM OPERATIONS</b>	<b>(3,602,882)</b>	<b>(2,013,301)</b>	<b>(5,573,635)</b>	<b>(8,206,234)</b>
Other income, net	114,260	135,519	538,212	480,117
Gain on change in fair value of warrants	651,767		775,636	
<b>NET LOSS</b>	<b>\$ (2,836,855)</b>	<b>\$ (1,877,782)</b>	<b>\$ (4,259,787)</b>	<b>\$ (7,726,117)</b>
<b>BASIC AND DILUTED NET LOSS PER COMMON SHARE</b>	<b>\$ (0.12)</b>	<b>\$ (0.10)</b>	<b>\$ (0.18)</b>	<b>\$ (0.40)</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED</b>	<b>24,078,610</b>	<b>19,495,067</b>	<b>24,078,546</b>	<b>19,487,594</b>

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

	Nine-months ended September 30,	
	2008	2007
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (4,259,787)	\$ (7,726,117)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of premiums and discounts on marketable securities	(95,139)	(157,401)
Realized loss on sales of marketable securities	42,989	2,533
Share-based compensation	1,042,811	1,146,120
Impairment charge related to contingent consideration	1,500,000	
Inventory reserve	88,947	6,000
Depreciation and amortization	441,829	512,471
Gain on change in fair value of warrants	(775,636)	
Deferred revenues recognized	(761,302)	(481,051)
Changes in other assets and liabilities impacting cash flows used in operations:		
Accounts receivable	1,093,357	343,489
Accrued interest receivable	(43,211)	75,612
Inventory	(416,310)	(1,092,824)
Prepaid and other current assets	(233,963)	570,076
Deferred charges and other assets	80,146	(74,618)
Accounts payable	(658,912)	71,864
Accrued compensation and other accrued expenses	686,948	(1,691,490)
Deferred revenues	1,510,712	1,839,088
Other liabilities	(53,083)	95,195
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(809,604)</b>	<b>(6,561,053)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Cash paid for contingent consideration	(1,750,000)	(500,000)
Purchases of marketable securities	(22,964,544)	(12,560,937)
Proceeds from maturities and sales of marketable securities	26,368,809	17,546,115
Restricted cash	(2,875)	(4,008)
Purchases of property, plant and equipment	(333,526)	(223,451)
<b>NET CASH PROVIDED BY INVESTING ACTIVITIES</b>	<b>1,317,864</b>	<b>4,257,719</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from exercise of options	4,000	40,650
<b>NET CASH PROVIDED BY INVESTING ACTIVITIES</b>	<b>4,000</b>	<b>40,650</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>		
	512,260	(2,262,684)
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>4,713,619</b>	<b>3,267,071</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 5,225,879</b>	<b>\$ 1,004,387</b>

See the accompanying Notes to the Condensed Consolidated Financial Statements.

5

---



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

The Condensed Consolidated Balance Sheet as of September 30, 2008, the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2008 and 2007 and the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2008 and 2007 of DUSA Pharmaceuticals, Inc. (the Company or DUSA ) have been prepared in accordance with accounting principles generally accepted in the United States of America ( U.S. GAAP ). These condensed consolidated financial statements are unaudited but include all normal recurring adjustments, which management of the Company believes to be necessary for fair presentation of the periods presented. The results of the Company s operations for any interim period are not necessarily indicative of the results of the Company s operations for any other interim period or for a full year.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements should be read in conjunction with the Consolidated Financial Statements and Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2007 filed with the Securities and Exchange Commission. The balance sheet as of December 31, 2007 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

**2) NEW ACCOUNTING PRONOUNCEMENTS**

In 2007, the Financial Accounting Standards Board ( FASB ) issued Statement No. 141(R), *Business Combinations* ( SFAS 141(R) ). SFAS 141(R) amends FASB Statement No. 141 and provides revised guidance for recognizing and measuring assets acquired and liabilities assumed in a business combination. SFAS 141(R) also requires that transaction costs in a business combination be expensed as incurred. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS 141(R) will impact the Company s accounting for business combinations, if any, completed beginning January 1, 2009.

In 2007, the FASB also issued Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* ( SFAS 160 ). SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. This new consolidation method will significantly change the accounting for transactions with minority interest holders. The provisions of this standard are effective beginning January 1, 2009. The adoption of this standard is not expected to have an effect on the Company s consolidated financial position and results of operations.

In March 2008, the FASB issued Statement No. 161 ( SFAS 161 ), *Disclosures about Derivative Instruments and Hedging Activities, as an amendment to SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities*. SFAS 161 requires that objectives for using derivative instruments be disclosed in terms of underlying risk and accounting designation. The fair value of derivative instruments and their gains and losses will need to be presented in tabular format in order to present a more complete picture of the effects of using derivative instruments. SFAS 161 is effective for financial statements issued for periods beginning after November 15, 2008. The Company is currently evaluating the impact of adopting this pronouncement.

**3) FAIR VALUE MEASUREMENTS**

Effective January 1, 2008, the Company implemented Statement of Financial Accounting Standard No. 157, *Fair Value Measurements* ( SFAS 157 ), for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. The adoption of SFAS 157 did not have an impact on the Company s financial results. As defined in SFAS 157, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly

**Table of Contents**

transaction between market participants at the measurement date. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

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

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

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

Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, volatility factors, prepayment speeds, default rates, loss severity, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace. Financial instruments in this category include corporate debt, government-backed securities and the warrant liability. Level 3 is comprised of financial instruments whose fair value is estimated based on internally developed models or methodologies utilizing significant inputs that are generally less readily observable.

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2008, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	Level 2
Assets:	
United States government-backed securities	\$ 10,729,000
Corporate debt securities	4,276,000
Total assets	\$ 15,005,000
Liabilities:	
Warrant liability	\$ 487,000
Total liabilities	\$ 487,000

**4) WARRANTS**

On October 29, 2007, the Company sold, through a private placement, 4,581,043 shares of its common stock and warrants to purchase 1,145,259 shares of common stock with an exercise price of \$2.85. The warrants have a 5.5 year term and became exercisable on April 30, 2008. The warrants are recorded as a derivative liability at fair value. Upon issuance of the warrants on October 29, 2007, the Company recorded the warrant liability at its initial fair value of \$2.0 million. Warrants that are classified as a liability are revalued at each reporting date until the warrants are exercised or expire with changes in the fair value reported in the Condensed Consolidated Statements of Operations as gain or loss on fair value of warrants. At September 30, 2008, the aggregate fair value of these warrants decreased to \$0.5 million from \$1.3 million at December 31, 2007. The non-cash gains recorded during the three and nine-month periods ended September 30, 2008 were \$652,000 and \$776,000, respectively.

**Table of Contents**

Assumptions used for the Black-Scholes option-pricing models as of September 30, 2008 and December 31, 2007 are as follows:

	September 30, 2008	December 31, 2007
Expected volatility	70.0%	67.3%
Remaining contractual term (years)	4.58	5.33
Risk-free interest rate	2.98%	3.45%
Expected dividend yield	0%	0%
Common stock price	\$ 1.15	\$ 2.07

**5) MARKETABLE SECURITIES**

The Company's investment securities consist of securities of the U.S. government and its agencies and investment-grade corporate bonds. The Company has classified all investment securities as available-for-sale and recorded such investments at fair market value. Since the Company's investments are managed by a third-party investment advisor pursuant to a discretionary arrangement, for securities with unrealized losses at September 30, 2008 and December 31, 2007, which totaled \$71,000 and \$16,000, respectively, an other-than-temporary impairment was considered to have occurred and the cost basis of such securities were written down to their fair values with the amount of the write-down included in earnings as unrealized losses. As of September 30, 2008, current yields range from 2.25% to 6.44% and maturity dates range from October 2008 to January 2013. The fair value and cost of marketable securities at September 30, 2008 and December 31, 2007 are as follows:

	September 30, 2008		
	Amortized cost	Unrealized gains	Fair value
United States government-backed securities	\$10,520,460	\$208,576	\$10,729,036
Corporate securities	4,266,365	9,500	4,275,865
<b>Total marketable securities available-for-sale</b>	<b>\$14,786,825</b>	<b>\$218,076</b>	<b>\$15,004,901</b>

	December 31, 2007		
	Amortized cost	Unrealized gains	Fair value
United States government-backed securities	\$16,429,249	\$162,619	\$16,591,868
Corporate securities	1,709,691	10,091	1,719,782
<b>Total marketable securities available-for-sale</b>	<b>\$18,138,940</b>	<b>\$172,710</b>	<b>\$18,311,650</b>

The change in net unrealized gains and losses on such securities for the three and nine-month periods ended September 30, 2008 was \$58,042 and \$45,366, respectively, as compared to (\$94,000) and (\$106,000) for the three and nine-month periods ended September 30, 2007, and have been recorded in accumulated other comprehensive income, which is reported as part of shareholders' equity in the Condensed Consolidated Balance Sheets.

**6) BUSINESS ACQUISITION**

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius Laboratories, Inc. The Company agreed to pay additional consideration in future periods to the former Sirius shareholders based upon the achievement of total cumulative sales milestones for the Sirius products over the period ending 50 months from the

**Table of Contents**

date of close. The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments are, as follows:

Cumulative Sales Milestone:	Additional Consideration:
\$25.0 million	\$1.5 million
\$35.0 million	\$1.0 million
\$45.0 million	\$1.0 million
Total	\$3.5 million

The first cumulative sales milestone was achieved during the three-month period ended September 30, 2008, and accordingly a cash payment in the amount of \$1.5 million was paid to the former Sirius shareholders during the period. The payment made during the third quarter of 2008 was recorded initially as goodwill and then subsequently deemed impaired and expensed during the same period as described below.

Goodwill impairment is determined using a two-step process. The first step of the goodwill impairment test is used to identify potential impairment by comparing the fair value of a reporting unit with the net book value (or carrying amount), including goodwill. If the fair value of the reporting unit exceeds the carrying amount, goodwill of the reporting unit is considered not impaired and the second step of the impairment test is unnecessary. If the carrying amount of the reporting unit exceeds the fair value, the second step of the goodwill impairment test is performed to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of the reporting unit's goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess. The implied fair value of goodwill is determined in the same manner as the amount of goodwill recognized in a business combination. Accordingly, the fair value of the reporting unit is allocated to all of the assets and liabilities of that unit as if the reporting unit had been acquired in a business combination and the fair value of the reporting unit was the purchase price paid to acquire the reporting unit. The fair value of the Company's Non-PDT reporting unit was determined using an income approach. Under the income approach, the fair value of a reporting unit is calculated based on the present value of estimated future cash flows. The present value of future cash flows uses our estimates of revenue for the reporting unit, driven by assumed growth rates and estimated costs as well as appropriate discount rates.

In performing the first step of the goodwill impairment test, management determined there was an indicator of impairment in the Non-PDT goodwill because the carrying value of the reporting unit exceeded its estimated fair value. In performing the second step of the goodwill impairment test, the Company allocated the estimated fair values of the Non-PDT reporting unit determined in step one of the impairment test, to the assets and liabilities as if a new acquisition were being accounted for in accordance with SFAS 141. Determining the fair value of the reporting unit under the first step of the goodwill impairment test and determining the fair value of individual assets and liabilities of a reporting unit under the second step of the goodwill impairment test is judgmental in nature and often involves the use of significant estimates and assumptions. Since the fair value of the Non-PDT reporting unit was derived from projected revenues associated solely with developed technologies, which were identified as intangible assets in the original purchase accounting allocation and subsequently written down to zero in 2006, the fair value of the reporting unit was hypothetically all allocated to developed technologies, with no remaining value to assign to goodwill. The result was a full write-down of the Company's goodwill balance.

If the remaining sales milestones are attained, they will be paid in either common stock or cash, at the Company's sole discretion.

**7) 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-backed securities and investment-grade corporate bonds. The Company is also exposed to concentration of credit risk related to accounts receivable that are generated from its distributors and customers. To manage credit risk, the Company performs regular credit evaluations of its customers and provides allowances for

**Table of Contents**

potential credit losses, when applicable. Concentrations in the Company's total revenues for the three and nine-months ended September 30, 2008 and 2007, and accounts receivable as of September 30, 2008 and December 31, 2007 are as follows:

	% of revenue		% of revenue		% of accounts receivable	
	Three-months ended September 30, 2008	September 30, 2007	Nine-months ended September 30, 2008	September 30, 2007	September 30, 2008	December 31, 2007
Customer A	1%	2%	2%	5%	4%	5%
Customer B	1%	14%	9%	12%	1%	10%
Customer C		16%	8%	17%	1%	12%
Customer D		7%	4%	6%	1%	7%
Customer E	4%		3%		2%	26%
Customer F	8%		2%		16%	1%
Other customers	86%	61%	72%	60%	75%	39%
Total	100%	100%	100%	100%	100%	100%

The Company is dependent upon sole-source suppliers for a number of its products. There can be no assurance that these suppliers will be able to meet the Company's future requirements for such products or parts or that they will be available at favorable terms. Any extended interruption in the supply of any such products or parts or any significant price increase could have a material adverse effect on the Company's operating results in any given period.

In April 2008, the Company was notified by Actavis Totowa, LLC, the manufacturer of Nicomide<sup>®</sup>, that Actavis would cease manufacturing several prescription vitamins, including Nicomide<sup>®</sup>, due to continuing discussions with the U.S. Food and Drug Administration (FDA). As the Company previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, the Company stopped the sale and distribution of Nicomide<sup>®</sup> as a prescription product in June 2008. The Company is relabeling its remaining supply of product as a non-prescription dietary supplement in compliance with the Dietary Supplement Health and Education Act (DSHEA). The Company is in discussions with the FDA regarding new labeling, including use of the trademark. The Company is actively searching for a source of supply for the DSHEA product. The Company expects both the price and volume of the Nicomide<sup>®</sup> DSHEA labeled product to be considerably less than historic Nicomide<sup>®</sup> levels.

On August 12, 2008, the Company entered into a worldwide non-exclusive patent License Agreement to its patent covering Nicomide<sup>®</sup> (the License Agreement) with River's Edge Pharmaceuticals, LLC and an amendment to its Settlement Agreement with River's Edge. See Note 17 below. The amendment to the Settlement Agreement allows River's Edge to manufacture and market a prescription product that could be substitutable for Nicomide<sup>®</sup> pursuant to the terms of the License Agreement and changes certain payment obligations of River's Edge for sales of its substitutable product. In consideration for granting the license, the Company will be paid a share of the net revenues, as defined in the License Agreement, of River's Edge's licensed product sales under the License Agreement. At the same time, the Company is also considering the possible sale of the product and the related patent.

**8) INVENTORY**

Inventory consisted of the following:

September 30, 2008	December 31, 2007
-----------------------	----------------------

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Finished goods	\$1,260,000	\$1,625,000
BLU-U <sup>®</sup> evaluation units	322,000	131,000
Work in process	785,000	409,000
Raw materials	632,000	507,000
Total	\$2,999,000	\$2,672,000



**Table of Contents**

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

**9) OTHER ACCRUED EXPENSES**

Other accrued expenses consisted of the following:

	September 30, 2008	December 31, 2007
Research and development costs	\$ 162,000	\$ 293,000
Marketing and sales costs	212,000	334,000
Reserve for sales returns and allowances	519,000	546,000
Accrued FDA fees	589,000	
Reserve for chargebacks and rebates	110,000	200,000
Other product related costs	748,000	873,000
Legal and other professional fees	493,000	484,000
Employee benefits	266,000	236,000
Other expenses	112,000	357,000
<b>Total</b>	<b>\$3,211,000</b>	<b>\$3,323,000</b>

**10) SHARE-BASED COMPENSATION**

Total share-based compensation expense, related to all of the Company's share-based awards, recognized for the three and nine-month periods ended September 30, 2008 and 2007 included the following line items:

	Three-months ended		Nine-months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Cost of product revenues	\$ 18,000	\$ 25,000	\$ 59,000	\$ 75,000
Research and development	70,000	94,000	260,000	280,000
Marketing and sales	88,000	115,000	61,000	134,000
General & administrative	177,000	194,000	662,000	657,000
<b>Share-based compensation expense</b>	<b>\$353,000</b>	<b>\$ 428,000</b>	<b>\$1,042,000</b>	<b>\$ 1,146,000</b>

The weighted-average estimated fair values of employee stock options granted during the three and nine-month periods ended September 30, 2008 and 2007 were \$1.42 and \$2.01 per share, respectively, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	Three-months ended		Nine-months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Volatility-directors and officers	70.2%	62.2%	70.2%	62.2%
Volatility-non-officer employees	70.8%	62.2%	70.8%	%
Risk-free interest rate	2.98-3.61%	4.70%	2.98-3.61%	4.53%
Expected dividend yield	0%	0%	0%	0%

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Expected life-directors and officers	6.3 years	5.9 years	6.3 years	5.9 years
Expected life-non-officer employees	5.9 years	5.5 years	5.9 years	5.5 years

---

**Table of Contents**

A summary of stock option activity is as follows:

	Nine-months ended September 30, 2008	Weighted average exercise price
Outstanding, beginning of period	2,855,125	\$ 10.76
Options granted	309,500	2.17
Options forfeited	(16,000)	7.43
Options expired	(122,625)	11.04
Options exercised	(2,500)	1.60
Outstanding, end of period	3,023,500	\$ 9.90
Exercisable, end of period	2,262,939	\$ 11.68
Options vested and expected to vest, end of period	2,937,106	\$ 10.08

The weighted average remaining contractual term was approximately 4.54 years for stock options outstanding and approximately 3.93 years for stock options exercisable as of September 30, 2008.

The total intrinsic value (the excess of the market price over the exercise price) was \$0 for stock options outstanding and exercisable as of September 30, 2008. The total intrinsic value for stock options exercised in 2008 was \$1,000. The total intrinsic value for stock options vested/expected to vest was approximately \$0 as of September 30, 2008. During the second quarter of 2008, the Company issued 102,000 shares of restricted stock to its officers. The shares of restricted stock vest over 4 years at a rate of 25% per year. The stock was valued at \$2.20 on the date of grant.

**11) BASIC AND DILUTED NET LOSS PER SHARE**

Basic net loss per common share is based on the weighted-average number of shares outstanding during each period. For the three and nine-month periods ended September 30, 2008, and 2007, stock options, non-vested restricted stock, warrants and rights totaling approximately 4,521,000 and 3,264,000 shares, respectively, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive.

**12) SEGMENT REPORTING**

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

Three-months ended		Nine-months ended	
September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007

## REVENUES

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

PDT drug and device product revenues	\$5,157,000	\$3,489,000	\$16,416,000	\$12,107,000
Non-PDT product revenues	569,000	2,295,000	5,352,000	7,216,000
Total revenues	5,726,000	5,784,000	21,768,000	19,323,000
COSTS OF REVENUES				
PDT drug and device cost of product revenues	1,146,000	1,155,000	3,589,000	3,608,000
Non-PDT cost of product revenues	316,000	419,000	1,361,000	1,898,000
Total costs of product revenues	1,462,000	1,574,000	4,950,000	5,506,000

12

---

**Table of Contents**

	Three-months ended		Nine-months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
<b>GROSS MARGIN</b>				
PDT drug and device product gross margin	4,011,000	2,334,000	12,827,000	8,499,000
Non-PDT product gross margin	253,000	1,876,000	3,991,000	5,318,000
<b>Total gross margin</b>	<b>\$4,264,000</b>	<b>\$4,210,000</b>	<b>\$16,818,000</b>	<b>\$13,817,000</b>

During the three-month periods ended September 30, 2008 and 2007, the Company derived revenues from the following geographies based on the location of the customer (as a percentage of product revenues):

	Three-month period ended		Nine-month period ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
United States	93%	98%	93%	97%
Canada	1%	2%	2%	3%
Korea	4%		3%	
Other	2%		2%	
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

Asset information by reportable segment is not reported to or reviewed by the chief operating decision maker and, therefore, the Company has not disclosed asset information for each reportable segment.

**13) COMPREHENSIVE LOSS**

For the three and nine-month periods ended September 30, 2008 and 2007, comprehensive loss consisted of the following:

	Three-month period ended		Nine-month period ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
<b>NET LOSS</b>	<b>\$(2,836,855)</b>	<b>\$(1,877,782)</b>	<b>\$(4,259,787)</b>	<b>\$(7,726,117)</b>
Change in net unrealized gains on marketable securities available-for-sale	58,042	94,312	45,366	106,316
<b>COMPREHENSIVE LOSS</b>	<b>\$(2,778,813)</b>	<b>\$(1,783,470)</b>	<b>\$(4,214,421)</b>	<b>\$(7,619,801)</b>

**14) STIEFEL AGREEMENT**

In January 2006, as amended in September 2007, DUSA licensed to Stiefel the exclusive Latin American rights to market Levulan® PDT. The Company manufactures and supplies finished product for Stiefel, which the Company began shipping in September 2007. In consideration for the transaction, Stiefel agreed to pay the Company as follows:

(i) \$375,000 upon launch of the product in either Mexico or Argentina; (ii) \$375,000 upon receipt of acceptable pricing approval in Brazil; (iii) two installments of \$375,000 each for cumulative end-user sales in Brazil totaling 150,000 units and 300,000 units, and (iv) two installments of \$375,000 each for cumulative sales in countries excluding Brazil totaling 150,000 units and 300,000 units. Stiefel launched the product in October 2007 in Mexico and Argentina and in April 2008 in Brazil. The Company is deferring and recognizing approval and sales milestones as product revenues on a straight-line basis, beginning on the date the milestone is achieved through the fourth quarter of 2015, which is the term of the Stiefel Agreement. Stiefel pays a fixed price per unit for the inventory as well as a royalty based on a percentage of the net sales price to end-users. During the launch phase, the Company's policy is to defer revenues upon shipment and recognize revenues based on end-user demand. At

**Table of Contents**

September 30, 2008 and December 31, 2007 the total revenues deferred associated with shipments to Stiefel were \$402,000 and \$206,000, respectively. Deferred revenues at September 30, 2008 and December 31, 2007 associated with milestone payments received from Stiefel are \$643,000 and \$345,000, respectively. The agreement with Stiefel also establishes minimum purchase quantities over the first five years following regulatory approval.

**15) DAEWOONG AGREEMENT**

In January 2007, the Company licensed to Daewoong the exclusive rights to market Levulan<sup>®</sup> PDT in certain Asian countries. The Company manufactures and supplies finished product for Daewoong, which the Company began shipping in October 2007. In consideration for the transaction, Daewoong agreed to pay the Company as follows: (i) \$1.0 million upon contract signing; (ii) \$1.0 million upon achieving regulatory approval in Korea; and (iii) two installments of \$750,000 each for cumulative end-user sales totaling 200,000 units and 500,000 units. Daewoong launched the product in November 2007 in Korea. The Company is deferring and recognizing the up-front and regulatory approval milestones as product revenues on a straight-line basis, beginning with product launch in the territory through the fourth quarter of 2016, which is the term of the Daewoong Agreement. Daewoong pays a fixed price per unit for the inventory and an Excess Purchase Price, as defined in the Agreement, if the Average Selling Price to end-users during any calendar quarter exceeds a certain threshold. During the launch phase, the Company's policy is to defer revenues upon shipment and recognize revenues based on end-user demand. At September 30, 2008 and December 31, 2007 the total revenues deferred associated with shipments to Daewoong were \$1,203,000 and \$762,000, respectively. Deferred revenues at September 30, 2008 and December 31, 2007 associated with milestone payments received from Daewoong are \$1,695,000 and \$1,848,000. The agreement with Daewoong also establishes minimum purchase quantities over the first five years following regulatory approval.

**16) DEFERRED COMPENSATION PLAN**

In October 2006, the Company adopted the DUSA Pharmaceuticals, Inc. Non-Qualified Deferred Compensation Plan (the Plan), a non-qualified supplemental retirement plan maintained primarily for the purpose of providing deferred compensation for a select group of management or highly compensated employees and members of the Board of Directors of the Company (the Participants). Participants may defer up to 80% of their compensation. A Participant will be 100% vested in all of the amounts he or she defers as well as in the earnings attributable to a Participant's deferred account. A Participant may elect to receive distributions from the deferred account at various times, either in a lump sum or in up to ten annual installments. Included in other liabilities at September 30, 2008 and December 31, 2007 is \$95,000 and \$127,000, respectively, representing the Company's obligation under the Plan. DUSA's obligation to pay the Participant an amount from his or her deferred account is an unsecured promise and benefits shall be paid out of the general assets of the Company. The Company has purchased corporate owned life insurance to serve as the funding vehicle for the Plan. The cash surrender value of the life insurance policy is recorded in deferred charges and other assets and totaled \$96,000 and \$124,000 at September 30, 2008 and December 31, 2007, respectively.

**17) COMMITMENTS AND CONTINGENCIES****LEGAL MATTERS:****RIVER'S EDGE LITIGATION SETTLEMENT**

As part of the settlement of litigation between DUSA and River's Edge Pharmaceuticals, LLC in October 2007, the parties entered into a Settlement Agreement and Mutual Release (the Settlement Agreement) to dismiss the lawsuit brought by DUSA against River's Edge asserting a number of claims arising out of River's Edge's alleged infringement of the Company's Nicomid<sup>®</sup> patent, U.S. Patent No. 6,979,468, under which DUSA has marketed, distributed and sold Nicomide<sup>®</sup>. As part of the terms of this agreement, River's Edge agreed to pay to DUSA \$25.00 for every bottle of NIC 750 above 5,000 bottles that is substituted for Nicomide<sup>®</sup> after September 30, 2007. The net gain from settlement of litigation for the three and nine month periods ended September 30 is (\$650) and \$282,775, respectively. In the accompanying Consolidated Statement of Operations the net gain on settlement is recorded as a separate component of operating expenses.

On August 12, 2008, the Company entered into a worldwide non-exclusive patent License Agreement to its patent covering Nicomide<sup>®</sup> with River's Edge Pharmaceuticals, LLC and an amendment to its Settlement Agreement with River's Edge. The amendment to the Settlement Agreement allows River's Edge to manufacture and market a prescription product that could be substitutable for Nicomide<sup>®</sup> pursuant to the terms of the License Agreement and





**Table of Contents**

changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, the Company will be paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement. At the same time, we are also considering the possible sale of the product and the related patent. Royalty revenues recorded pursuant to the License Agreement are recorded in Product Revenues in the accompanying Condensed Consolidated Statements of Operations.

The Company has not accrued any amounts for potential contingencies as of September 30, 2008.

**18) SUBSEQUENT EVENTS**

In October 2008, the Company was notified that Winston Laboratories, Inc. had filed a demand for arbitration against the Company. The demand for arbitration arises out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement (together, the Agreement ) and claims that DUSA breached the Agreement. Winston Laboratories is claiming damages in excess of \$2.0 million. The Company plans to defend itself vigorously and has not recorded any liability pursuant to the claim at September 30, 2008. For more information about our agreements with Winston Laboratories, see Management s Discussion and Analysis of Financial Condition and Results of Operations Contractual Obligations and Other Commercial Commitments.

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

We are a vertically integrated dermatology company that is developing and marketing Levulan PDT and other products for common skin conditions. Our currently marketed products include among others Levulan® Kerastick® 20% Topical Solution with photodynamic therapy, the BLU-U® brand light source, and certain products acquired in the March 10, 2006 merger with Sirius Laboratories, Inc., including ClindaReach®.

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

The Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® were launched in the United States, or U.S., in September 2000 for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp under a former dermatology collaboration. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. In addition, in September 2003 we received clearance from the United States Food and Drug Administration, or FDA, to market the BLU-U® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions. Sirius Laboratories, Inc., or Sirius, a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Nicomide®, its key product, is a vitamin-mineral product currently prescribed by dermatologists. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008. We are relabeling our remaining supply of product as a non-prescription dietary supplement in compliance with the Dietary Supplement Health and Education Act, or DSHEA. We are in discussions with the FDA regarding new labeling, including use of the trademark. We are actively searching for a source of supply for the DSHEA product. We expect both the price and volume of the Nicomide® DSHEA labeled product to be considerably less than historic Nicomide® levels.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide®, or License Agreement, with River s Edge Pharmaceuticals, LLC, or River s Edge, and an amendment to our Settlement Agreement with River s Edge. See Note 17 of the Notes to Condensed Consolidated Financial

Statements. The amendment to the Settlement Agreement allows Rivers Edge to manufacture

**Table of Contents**

and market a prescription product that could be substitutable for Nicomide<sup>®</sup> pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we will be paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement. At the same time, we are also considering the possible sale of the product and related patent.

We are responsible for manufacturing our Levulan<sup>®</sup> Kerastick<sup>®</sup> and for the regulatory, sales, marketing, and customer service of our Levulan<sup>®</sup> Kerastick<sup>®</sup>, and other related activities for all of our products. Our current objectives include increasing the sales of our products in the United States, Canada, Latin America, and Korea, launching Levulan<sup>®</sup> with our partners in additional Latin American countries and Asia, and continuing our efforts of exploring partnership opportunities for Levulan<sup>®</sup> PDT for dermatology in Europe and Japan.

To further these objectives, we entered into a marketing and distribution agreement with Stiefel Laboratories, Inc. in January 2006 granting Stiefel an exclusive right to distribute the Levulan<sup>®</sup> Kerastick<sup>®</sup> in Mexico, Central and South America. On March 5, 2008, Stiefel notified us that the Brazilian authorities had published the final pricing for the product which is acceptable to Stiefel and to us. Stiefel launched the product in Brazil in April 2008. In light of the unexpected delay in receiving acceptable final pricing in Brazil, in 2007 we amended certain terms of the original Stiefel agreement to reflect our plans to launch in other Latin American countries prior to Brazil. The product was launched in Argentina, Chile, Colombia and Mexico during the fourth quarter of 2007. Similarly, in January 2007, we entered into a marketing and distribution agreement with Daewoong Pharmaceutical Co., Ltd. and Daewoong s wholly owned subsidiary, DNC Daewoong Derma & Plastic Surgery Network Company, together referred to as Daewoong, granting Daewoong exclusive rights to distribute the Levulan<sup>®</sup> Kerastick<sup>®</sup> in certain Asian countries. In the fourth quarter of 2007, the Korean Food and Drug Administration, or KFDA, approved Levulan<sup>®</sup> Kerastick<sup>®</sup> for PDT for the treatment of actinic keratosis, and Daewoong launched our product in Korea. Recently, we granted Daewoong the right to distribute our product in Japan on a named-patient basis to test this market.

We believe that issues related to reimbursement negatively impacted the economic competitiveness of our therapy with other AK therapies and hindered its adoption in the past. Though we believe that current Centers for Medicare and Medicaid Services, or CMS, reimbursement levels allow us to be competitive, we continue to support efforts to improve reimbursement levels to physicians. Most major private insurers have approved coverage for our AK therapy; however some private insurers still do not provide adequate coverage. When we learn of these issues, we educate the insurers and are often able to facilitate a change in their coverage policy. We believe that with potential future improvements, along with our education and marketing programs, a more widespread adoption of our therapy should occur over time. We intend to seek reimbursement coverage for use of our BLU-U to treat acne following the analysis of the results of our Phase IIB clinical trial. See the section below entitled "Research and Development Costs" .

We are developing Levulan<sup>®</sup> PDT and PD under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen s University, Kingston, Ontario, Canada. We also own or license certain other patents relating to methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA<sup>®</sup>, DUSA Pharmaceuticals, Inc.<sup>®</sup>, Levulan<sup>®</sup>, Kerastick<sup>®</sup>, BLU-U<sup>®</sup>, Nicomide<sup>®</sup>, Nicomide-T<sup>®</sup>, ClindaReach<sup>®</sup>, Meted<sup>®</sup>, and Psoriacap<sup>®</sup> are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Numerous other trademark applications are pending.

As of September 30, 2008, we had an accumulated deficit of approximately \$140,000,000. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable on a sustainable basis. We expect to continue to incur operating losses until sales of our products increase substantially. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our PDT therapy by the medical and consumer constituencies.

**CRITICAL ACCOUNTING POLICIES**

Our accounting policies are disclosed in Note 2 of the Notes to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2007. Since all of these accounting policies do not require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting

policies with our Audit Committee. Other than the adoption of SFAS 157 effective January 1, 2008 as

**Table of Contents**

disclosed in footnote 3 to the accompanying condensed consolidated financial statements, there have been no changes to our critical accounting policies in the three or nine-month periods ended September 30, 2008.

**RESULTS OF OPERATIONS THREE AND NINE-MONTH PERIODS ENDED SEPTEMBER 30, 2008  
VERSUS THREE AND NINE-MONTH PERIODS ENDED SEPTEMBER 30, 2007**

**REVENUES** Total revenues for the three and nine-month periods ended September 30, 2008 were \$5,726,000 and \$21,768,000, respectively, as compared to \$5,784,000 and \$19,323,000 in 2007, and were comprised of the following:

	Three-months ended September 30,		INCREASE/ (DECREASE)	Nine-months ended September 30,		INCREASE/ (DECREASE)
	2008	2007		2008	2007	
<b>PDT PRODUCT</b>						
<b>REVENUES</b>						
<b>LEVULAN®</b>						
<b>KERASTICK®</b>						
<b>PRODUCT</b>						
<b>REVENUES</b>						
United States	\$4,374,000	\$2,923,000	\$ 1,451,000	\$13,720,000	\$10,108,000	\$ 3,612,000
Canada	72,000	143,000	(71,000)	449,000	536,000	(87,000)
Korea	186,000		186,000	710,000		710,000
Rest of World	99,000		99,000	289,000		289,000
Subtotal Levulan® Kerastick® product revenues	4,731,000	3,066,000	1,665,000	15,168,000	10,644,000	4,524,000
<b>BLU-U®</b>						
<b>PRODUCT</b>						
<b>REVENUES</b>						
United States	376,000	423,000	(47,000)	1,198,000	1,369,000	(171,000)
Canada					94,000	(94,000)
Korea	50,000		50,000	50,000		50,000
Subtotal BLU-U® product revenues	426,000	423,000	3,000	1,248,000	1,463,000	(215,000)
<b>TOTAL PDT</b>						
<b>PRODUCT</b>						
<b>REVENUES</b>	5,157,000	3,489,000	1,668,000	16,416,000	12,107,000	4,309,000
<b>TOTAL</b>						
<b>NON-PDT DRUG</b>						
<b>PRODUCT</b>						
<b>REVENUES</b>	569,000	2,295,000	(1,726,000)	5,352,000	7,216,000	(1,864,000)
<b>TOTAL</b>						
<b>PRODUCT</b>						
<b>REVENUES</b>	\$5,726,000	\$5,784,000	\$ (58,000)	\$21,768,000	\$19,323,000	\$ 2,445,000

For the three and nine-month periods ended September 30, 2008, total PDT Drug and Device Products revenues, comprised of revenues from our Kerastick® and BLU-U® products, were \$5,157,000 and \$16,416,000, respectively. This represents an increase of \$1,668,000, or 48%, and \$4,309,000, or 36%, over the comparable 2007 totals of \$3,489,000 and \$12,107,000, respectively. The incremental revenue was driven primarily by increased Kerastick® revenues. Our strategy to focus our sales and marketing resources on medical dermatologists and hospitals has been a key factor in the year-over-year growth in our PDT Drug and Device Products segment.

For the three and nine-month periods ended September 30, 2008, Kerastick® revenues were \$4,731,000, and \$15,168,000, respectively, representing a \$1,665,000, or 54%, and \$4,524,000, or 43%, increase over the comparable 2007 totals of \$3,066,000 and \$10,644,000, respectively. Kerastick® unit sales to end-users were 44,668 and 145,256, for the three and nine-month periods ended September 30, 2008, respectively, including on a year-to-date basis 5,700 sold in Canada and 10,692 sold in Korea. This represents an increase from 30,108 and 104,364 Levulan® Kerastick® units sold in the three and nine-month periods ended September 30, 2007, respectively, including on a year-to-date basis 7,098 sold in Canada and 0 sold in Korea since the product was not yet approved. Our average net selling price for the Kerastick® increased to \$102.79 per unit for the first nine months of 2008 from \$101.89 per unit for the first nine months of 2007. Our average net selling price for the Kerastick® in the United States increased to \$110.15 per unit in 2008 from \$103.82 per unit in 2007. This increase was almost fully offset by the averaging of the lower sales prices we receive under our international distribution agreements with Daewoong and Stiefel. The increase in 2008 Kerastick® revenues was driven mainly by increased sales volumes in the United States and internationally, through our distribution agreements with Stiefel and Daewoong, along with the slight increase in our average unit selling price. We expect our average selling price in the United States to increase with the implementation of a 3% price increase, which was effective October 1, 2008 and an expected additional price increase effective January 1, 2009. For the three and nine-month periods ended September 30, 2008, BLU-U® revenues were \$426,000 and \$1,248,000, respectively, representing a \$3,000, or a

**Table of Contents**

0% increase, and \$215,000, or a 15% decrease over the comparable 2007 totals of \$423,000 and \$1,463,000, respectively. The decrease in year-to-date 2008 BLU-U<sup>®</sup> revenues was driven by decreased overall sales volumes, offset in part by an increase in our average selling price. In the three and nine-month periods ended September 30, 2008, there were 57 and 154 units sold, respectively, versus 60 and 181 units sold, respectively, in the comparable 2007 periods. 149 of the units sold in 2008 were sold in the United States with 5 sold in Korea. The 2007 total consists of 165 sold in the United States and 16 sold in Canada. In 2008 on a year-to-date basis, our average net selling price for the BLU-U<sup>®</sup> increased to \$7,820 from \$7,596 in 2007. Our BLU-U<sup>®</sup> evaluation program allows customers to take delivery for a limited number of BLU-U<sup>®</sup> units for a period of up to four months for private practitioners and up to one year for hospital clinics, before a purchase decision is required. At September 30, 2008, there were approximately 90 units in the field pursuant to this evaluation program, compared to 31 units in the field at December 31, 2007. Since a significant majority of the units placed in the field under our evaluation program result in sales, we expect to continue this program. The increase in BLU-U<sup>®</sup> units in the field should result in increased Kerastick<sup>®</sup> sales, since customers with BLU-U<sup>®</sup> units purchase more Kerastick<sup>®</sup> units than customers without BLU-U<sup>®</sup> units. 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. At current sales volumes, we have approximately 6 months of finished BLU-U<sup>®</sup> units in inventory. Our third party manufacturer of the BLU-U<sup>®</sup> received a warning letter from FDA concerning certain observations at its facility. While we do not believe that these observations directly relate to the BLU-U<sup>®</sup>, we may be required to use our Wilmington, Massachusetts facility which was approved for the manufacture of BLU-U<sup>®</sup> units in 2005 to manufacture the BLU-U<sup>®</sup> if our third-party manufacturer does not rectify the issues stated in the warning letter in time to satisfy our needs.

Total Non-PDT Product revenues for the three and nine-month periods ended September 30, 2008 were \$569,000 and \$5,352,000, respectively, compared to \$2,295,000 and \$7,216,000, respectively, for the comparable 2007 periods. The substantial majority of the Non-PDT product revenues were from sales of Nicomide<sup>®</sup> and Nicomide<sup>®</sup> related royalties. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide<sup>®</sup>, that Actavis would cease manufacturing several prescription vitamins, including Nicomide<sup>®</sup>, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide<sup>®</sup> as a prescription product in June 2008. We are relabeling our remaining supply of product as a non-prescription dietary supplement in compliance with DSHEA. We are in discussions with the FDA regarding new labeling, including use of the trademark. We are actively searching for a source of supply for the DSHEA product. We expect both the price and volume of the Nicomide<sup>®</sup> DSHEA labeled product to be considerably less than historic Nicomide<sup>®</sup> levels.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide<sup>®</sup> with River s Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River s Edge. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide<sup>®</sup> pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we will be paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement. At the same time, we are also considering the possible sale of the product and related patent. Nicomide<sup>®</sup> sales in 2008 were negatively impacted by residual levels of NIC 750, that were substituted for Nicomide<sup>®</sup>, remaining in the distribution channel subsequent to the settlement with River s Edge. The Settlement Agreement is described in Note 17 to the Condensed Consolidated Financial Statements.

The increase in our total revenues on a year-to-date basis results from increased PDT segment revenues in the United States, as well as our PDT product launches in Korea and the rest of the world. However, we must increase sales significantly from these levels in order for us to become profitable. We remain confident that sales should continue to increase through increased consumption of our PDT segment products by our existing customers, as well as the addition of new customers. We expect to be able to grow our PDT segment revenues in the United States during 2008, due in part to the 18% percent increase in reimbursement of our PDT-related procedure fee, which became effective January 1, 2008, as well as our price increase, which was effective October 1, 2008, and the expected additional price

increase effective January 1, 2009. Although we expect growth in our PDT segment revenues, a portion of our customer base, i.e., those focusing on the cosmetic market, are more susceptible to the uncertain economic conditions facing the country at present, and reduced sales to that customer base could be expected until the economy recovers. We expect our Non-PDT revenues for the remainder of 2008 to be significantly negatively impacted since we are no longer manufacturing and marketing Nicomide® as a prescription product. We are evaluating alternative manufacturing, labeling and distribution strategies in order to maintain Nicomide® on the market and we are also considering opportunities to sell the product. Also see the section entitled Risk Factors Any Failure to Comply with Government Regulations in the United States and Elsewhere Will Limit Our Ability to Market Our Products And Become Profitable.



**Table of Contents**

**COST OF PRODUCT REVENUES** Cost of product revenues for the three and nine-month periods ended September 30, 2008 were \$1,462,000 and \$4,950,000 as compared to \$1,574,000 and \$5,507,000 in the comparable periods in 2007. A summary of the components of cost of product revenues and royalties is provided below:

	Three-months ended September 30,		Increase/ (Decrease)
	2008	2007	
Levulan® Kerastick® cost of product revenues and royalties			
Direct Levulan® Kerastick® product costs	\$ 547,000	\$ 433,000	\$ 114,000
Other Levulan® Kerastick® production costs including internal costs assigned to support products	2,000	231,000	(229,000)
Royalty and supply fees (1)	197,000	138,000	59,000
Subtotal Levulan® Kerastick® cost of product revenues and royalties	746,000	802,000	(56,000)
BLU-U® cost of product revenues			
Direct BLU-U® product costs	205,000	133,000	72,000
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	195,000	219,000	(24,000)
Subtotal BLU-U® cost of product revenues	400,000	352,000	48,000
<b>TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>1,146,000</b>	<b>1,154,000</b>	<b>(8,000)</b>
Non-PDT cost of product revenues and royalties	316,000	420,000	(104,000)
<b>TOTAL COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>\$1,462,000</b>	<b>\$1,574,000</b>	<b>\$(112,000)</b>
	Nine-months ended September 30,		Increase/ (Decrease)
	2008	2007	
Levulan® Kerastick® cost of product revenues and royalties			
Direct Levulan® Kerastick® product costs	\$ 1,778,000	\$ 1,508,000	\$ 270,000
Other Levulan® Kerastick® production costs including internal costs assigned to support products	5,000	386,000	(381,000)
Royalty and supply fees (1)	668,000	486,000	182,000
Subtotal Levulan® Kerastick® cost of product revenues and royalties	2,451,000	2,380,000	71,000
BLU-U® cost of product revenues			
Direct BLU-U® product costs	553,000	555,000	(2,000)
	585,000	673,000	(88,000)

Other BLU-U<sup>®</sup> product costs including internal costs assigned to support products; as well as costs incurred to ship, install and service the BLU-U<sup>®</sup> in physicians offices

Subtotal BLU-U <sup>®</sup> cost of product revenues	1,138,000	1,228,000	(90,000)
<b>TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>3,589,000</b>	<b>3,608,000</b>	<b>(19,000)</b>
Non-PDT cost of product revenues and royalties	1,361,000	1,899,000	(538,000)
<b>TOTAL COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>\$ 4,950,000</b>	<b>\$ 5,507,000</b>	<b>\$ (557,000)</b>

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

**Table of Contents**

**MARGINS** Total product margins for the three and nine-month periods ended September 30, 2008 were \$4,264,000 and \$16,818,000, respectively, as compared to \$4,210,000 and \$13,817,000 for the comparable 2007 periods, as shown below:

	Three-months ended September 30,				INCREASE/ (DECREASE)
	2008		2007		
Levulan® Kerastick® gross margin	\$ 3,986,000	84%	\$ 2,263,000	74%	\$ 1,723,000
BLU-U® gross margin	25,000	6%	71,000	17%	(46,000)
Total PDT drug & device gross margin	\$ 4,011,000	78%	\$ 2,334,000	67%	\$ 1,677,000
Total Non-PDT gross margin	253,000	44%	1,876,000	82%	\$ (1,623,000)
<b>TOTAL GROSS MARGIN</b>	<b>\$ 4,264,000</b>	<b>74%</b>	<b>\$ 4,210,000</b>	<b>73%</b>	<b>\$ 54,000</b>

	Nine-months ended September 30,				INCREASE/ (DECREASE)
	2008		2007		
Levulan® Kerastick® gross margin	\$ 12,717,000	84%	\$ 8,264,000	78%	\$ 4,453,000
BLU-U® gross margin	110,000	9%	235,000	16%	(125,000)
Total PDT drug & device gross margin	\$ 12,827,000	78%	\$ 8,499,000	70%	\$ 4,328,000
Total Non-PDT gross margin	3,991,000	75%	5,318,000	74%	\$ (1,327,000)
<b>TOTAL GROSS MARGIN</b>	<b>\$ 16,818,000</b>	<b>77%</b>	<b>\$ 13,817,000</b>	<b>72%</b>	<b>\$ 3,001,000</b>

For the three and nine-month periods ended September 30, 2008, total PDT Drug and Device Product Margins were 78% for both periods versus 67% and 70%, respectively, for the same periods in 2007. The incremental margin was driven by positive margin gains on the Levulan® Kerastick®, partially offset by declines in BLU-U® margin.

Kerastick® gross margins for the three and nine-month periods ended September 30, 2008 were 84% for both periods versus 74% and 78% for the comparable 2007 periods. The margin improvement in 2008 is mainly attributable to an increased average selling price in the U.S., overall lower cost of production due to increased manufacturing volumes, as well as amortization of milestone payments received. Our long-term goal is to achieve higher gross margins on Kerastick® sales which will be significantly dependent on increased volume.

BLU-U® margins for the three and nine-month periods ended September 30, 2008 were 6% and 9%, respectively, versus 17% and 16% for the comparable 2007 periods. The decrease in gross margin is a result of lower sales

volumes. Our strategy is to, at a minimum, breakeven on device sales in an effort to drive Kerastick® sales volumes. Non-PDT Product margins reflect the gross margin generated by the products acquired as part of our acquisition of Sirius. Gross margins for the three and nine-month periods ended September 30, 2008 were 44% and 75%, respectively, compared to 82% and 74%, respectively, in the comparable prior year periods. During the three and nine-month periods ended September 30, 2008, Non-PDT Product margins were negatively impacted by our discontinuance of sales of Nicomide® as a prescription product.

As stated above, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008. We expect both the price and volume of the Nicomide® DSHEA labeled product to be considerably less than historic Nicomide® levels, which will have a negative impact on our gross margins going forward.

**RESEARCH AND DEVELOPMENT COSTS** Research and development costs for the three and nine-month periods ended September 30, 2008 were \$1,488,000 and \$5,049,000 as compared to \$1,225,000 and \$4,328,000 in the comparable 2007 periods.

**Table of Contents**

On a year-to-date basis, the increase in 2008 compared to 2007 was due primarily to increased spending on our Phase IIB clinical trial on acne and a one-time \$0.6 million Prescription Drug User Fee Act (PDUFA) charge related to our approved AK indication. In October 2008, we announced the results from our Phase IIB clinical trial to compare the safety and efficacy of photodynamic therapy (PDT) using DUSA's BLU-U<sup>®</sup> brand light plus vehicle containing Levulan<sup>®</sup> (aminolevulinic acid HCl) to that of PDT using the BLU-U<sup>®</sup> plus vehicle without Levulan (the control group) in patients with moderate to severe facial acne vulgaris. While both groups showed a statistically significant reduction in lesions from baseline, the results did not demonstrate statistically significant difference between the control and Levulan PDT groups. Therefore, DUSA will not pursue further clinical development of Levulan PDT with BLU-U<sup>®</sup> for moderate to severe acne. However, we do expect to continue to support investigator initiated studies in moderate to severe acne with Levulan and various light sources. We intend to file a 510K application with the FDA for an expansion of our BLU-U<sup>®</sup> label to include severe acne and we have filed a patent application to cover certain inventions arising from the study.

In November 2004, we signed a clinical trial agreement with the National Cancer Institute (NCI) Division of Cancer Prevention (DCP) for the treatment of oral cavity dysplasia. The NCI DCP used its resources to file its own investigational new drug application with the FDA. DUSA and the NCI DCP worked together to prepare the overall clinical development plan for Levulan<sup>®</sup> PDT in this indication, starting with Phase I/II trials. A Phase I/II protocol has been developed, and a Phase I clinical trial was launched in April 2008. Our costs related to this study will be limited to providing Levulan<sup>®</sup>, leasing lasers and the necessary training for the investigators involved. All other costs of this study are the responsibility of the NCI DCP. We have options on any new intellectual property which may arise from this study. Researchers anticipate that the study will be completed within 12-24 months and, depending on the results, NCI may choose to move forward with a Phase II trial.

We are planning to initiate at least one site, before the end of 2008, of a DUSA-sponsored clinical trial, which we expect will include 36 to 40 patients, at up to six clinical sites across the United States for the treatment of actinic keratoses and chemoprevention of non-melanoma skin cancers in immunosuppressed solid organ transplant recipients, or SOTR, who have demonstrated that they are at risk of developing multiple squamous cell carcinomas. A clinical protocol has been finalized and the FDA is allowing us to initiate the study. An Orphan Drug Designation Application with respect to the chemoprevention indication is pending with the FDA and we expect a decision by FDA during the first quarter of 2009. We believe there is a significant potential market opportunity for an indication related to SOTR patients.

We have entered into a series of agreements for our research projects and clinical studies. As of September 30, 2008, future payments to be made pursuant to these agreements, under certain terms and conditions, total approximately \$1,581,000 over the next twelve months.

**MARKETING AND SALES COSTS** Marketing and sales costs for the three and nine-month periods ended September 30, 2008 were \$2,967,000 and \$9,521,000, respectively, as compared to \$2,887,000 and \$9,728,000 for the comparable 2007 periods. These costs consisted primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling \$2,128,000 and \$6,503,000 for the three and nine-month periods ended September 30, 2008, compared to \$2,010,000 and \$6,275,000 in the comparable periods in 2007. The remaining expenses consisted of tradeshow, miscellaneous marketing and outside consultants totaling \$839,000 and \$3,018,000 for the three and nine-month periods ended September 30, 2008, compared to \$877,000 and \$3,453,000 for the comparable 2007 periods. The decrease in this category on a year-to-date basis is due primarily to absence in 2008 of expenses incurred in 2007 related to the launch of ClindaReach<sup>®</sup>. We expect marketing and sales costs for the full year 2008 to be relatively flat in comparison to 2007.

**GENERAL AND ADMINISTRATIVE COSTS** General and administrative costs for the three and nine-month periods ended September 30, 2008 were \$1,911,000 and \$6,604,000, respectively, as compared to \$2,111,000 and \$7,966,000 for the comparable 2007 periods. The decrease is mainly attributable to decreases in legal expenses, which were incurred in 2007 due to the River's Edge litigation. General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period. We expect general and administrative costs to remain at lower levels in 2008 compared to 2007 since patent litigation with River's Edge has been settled. However, legal fees will increase due to the arbitration process which has been commenced by Winston

Laboratories. See Part II, Item 1 entitled Legal Proceedings .

**NET GAIN FROM SETTLEMENT OF LITIGATION** During the fourth quarter of 2007, we entered into a Settlement Agreement and Mutual Release with River s Edge Pharmaceuticals, LLC. Under the terms of the Settlement Agreement, River s Edge made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages and paid to DUSA \$25.00 for every prescription of NIC 750 above 5,000 prescriptions that were substituted for Nicomide® from September 30, 2007 through June 30, 2008. During the nine-month period ended September 30, 2008 damages for NIC 750 substituted for Nicomide® resulted in a net gain from settlement of

**Table of Contents**

litigation of \$283,000. The payments under the Settlement Agreement ceased due to an amendment signed on August 12, 2008, effective July 3, 2008.

**OTHER INCOME, NET** Other income for the three and nine-month periods ended September 30, 2008 was \$114,000 and \$538,000, respectively, from \$136,000 and \$480,000 during the comparable 2007 periods. The increase in the year-to-date total reflects an increase in our average investable cash balances during 2008 as compared to 2007 as a result of the October 2007 private placement. The decrease in the third quarter compared with the comparable period in 2007 was due to the recording in earnings of unrealized losses on our investment portfolio.

**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 decrease in the liability during the three and nine-month periods ended September 30, 2008 was \$652,000 and \$776,000, respectively, which resulted in a non-cash gain in both periods. The decrease in fair value was due primarily to a decrease in our stock price from December 31, 2007 to September 30, 2008.

**NET LOSS** For the three and nine-month periods ended September 30, 2008, we incurred net losses of \$2,837,000, or \$0.12 per share, and \$4,260,000, or \$0.18 per share, respectively, as compared to net losses \$1,878,000, or \$0.10 per share, and \$7,726,000, or \$0.40 per share for the comparable 2007 periods. Our decreased net losses were the result of the factors described above. Net losses are expected to increase, at least in the short-term, due, in part to the fact that we are no longer manufacturing or marketing Nicomide<sup>®</sup> as a prescription product. Net losses are expected to continue until such time as our PDT revenues increase to levels which offset the cost of our sales force, marketing initiatives, and other business support functions.

**LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2008, we had approximately \$20,231,000 of cash and cash equivalents and marketable securities available-for-sale, comprised of \$5,226,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$15,005,000. We believe that our resources will be sufficient to meet our cash requirements for at least the next twelve months. We have invested our funds in liquid investments, so that we will have ready access to these assets, as needed, for the funding of development plans on a short-term and long-term basis. As of September 30, 2008, these securities had a weighted average yield of 3.8% and maturity dates ranging from October 2008 to January 2013. Our net cash used in operations for the nine-month period ended September 30, 2008 was \$810,000 versus \$6,561,000 for the comparable prior year period. The year-over-year improvement is primarily attributable to growth in revenues and gross margins in our PDT operating segment. As of September 30, 2008, working capital (total current assets minus total current liabilities) was \$21,343,000, as compared to \$24,021,000 as of December 31, 2007. Total current assets decreased by \$3.3 million during the nine-month period ended September 30, 2008 due primarily to decreases in marketable securities and accounts receivable, offset by increases in inventory and cash and cash equivalents. Total current liabilities decreased by \$0.6 million during the same period due primarily to decreases in accounts payable and deferred revenue, offset by an increase in accrued compensation. In response to the instability in the global financial markets, we have regularly reviewed our marketable securities holdings, and have reduced or avoided investing in securities deemed to have increased risk. We do not hold any asset-backed or auction rate securities.

Since our inception, we have generated significant losses while we have advanced our product candidates into preclinical and clinical trials, development and commercialization. We have funded our operations primarily through public offerings, private placements of equity securities and payments received under our collaboration agreements. We expect to incur significant additional research and development and other costs including costs related to preclinical studies and clinical trials. Our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any of our existing or future products to be marketed by us or our collaborators may exceed revenues in the future, which may result in continued losses from operations.

**Table of Contents**

We agreed to pay additional consideration to the former shareholders of Sirius in future periods, based upon the attainment of pre-determined total cumulative sales milestones for the Sirius products. The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments which may be paid in cash or DUSA shares, as DUSA may determine, are as follows:

Cumulative Sales Milestone:	Additional Consideration:
\$25.0 million	\$1.5 million
\$35.0 million	\$1.0 million
\$45.0 million	\$1.0 million
Total	\$3.5 million

The first cumulative sales milestone was achieved during the three-month period ended September 30, 2008, and a cash payment in the amount of \$1.5 million was paid to the former Sirius shareholders during the period. The payment made during the third quarter of 2008 was recorded initially as goodwill and then subsequently deemed impaired and expensed during the same period.

We may seek to further expand or enhance our business by using our resources to acquire by license, purchase or other arrangements, additional businesses, new technologies, or products in the field of dermatology. For 2008, we are focusing primarily on increasing the sales of the Levulan<sup>®</sup> Kerastick<sup>®</sup> and the BLU-U<sup>®</sup>. DUSA has no off-balance sheet financing arrangements.

**CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS*****ACTAVIS TOTOWA, LLC***

Under an agreement dated May 18, 2001, and amended on February 8, 2006, the former Sirius entered into an arrangement for the supply of Nicomide<sup>®</sup> with Amide Pharmaceuticals, Inc., now known as Actavis Totowa, LLC. The agreement was assigned to us as part of the Sirius merger. The agreement expires on February 8, 2009. Actavis Totowa has received several warning letters from the FDA regarding certain regulatory observations. In April 2008, we were notified by Actavis that Actavis would cease manufacturing several prescription vitamins, including Nicomide<sup>®</sup>, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide<sup>®</sup> as a prescription product in June 2008. We are relabeling our remaining supply of product as a non-prescription dietary supplement in compliance with DSHEA. We are in discussions with the FDA regarding new labeling, including use of the trademark. We are actively searching for a source of supply for the DSHEA product. We expect both the price and volume of the Nicomide<sup>®</sup> DSHEA labeled product to be considerably less than historic Nicomide<sup>®</sup> levels.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide<sup>®</sup> with River s Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River s Edge. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide<sup>®</sup> pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we will be paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement. At the same time, we are also considering the possible sale of the product and related patent.

***L. PERRIGO COMPANY***

On October 25, 2005, the former Sirius entered into a supply agreement with L. Perrigo Company, or Perrigo, for the exclusive manufacture and supply of a proprietary device/drug kit designed by Sirius pursuant to an approved abbreviated new drug application, or ANDA, owned by Perrigo. The agreement was assigned to us as part of the Sirius merger. We were responsible for all development costs and for obtaining all necessary regulatory approvals and



launched the product, ClindaReach®, in March 2007. Perrigo is entitled to royalties on net sales of the product, including certain minimum annual royalties, which commenced May 1, 2006, in the amount of \$250,000. The initial

**Table of Contents**

term of the agreement expires in July 2011 and may be renewed based on certain minimum purchase levels and other terms and conditions.

***MERGER WITH SIRIUS LABORATORIES, INC.***

In March 2006, we closed our merger to acquire all of the common stock of Sirius Laboratories Inc. in exchange for cash and common stock worth up to \$30,000,000. Of the up to \$30,000,000, up to \$5,000,000, (\$1,500,000 of which would be paid in cash, and \$3,500,000 of which would be paid in cash or common stock) was contingent on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. The portion of the contingent amounts related to product approvals or launch (i.e., up to \$1,500,000) has been satisfied according to the terms of the merger with payments totaling \$1,000,000. The first cumulative sales milestone was achieved during the three-month period ended September 30, 2008, and a cash payment in the amount of \$1,500,000 was paid to the former Sirius shareholders during the period.

***PHOTOCURE ASA***

On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby we granted a non-exclusive license to PhotoCure for esters of aminolevulinic acid, or ALA, under the patents we license from PARTEQ. ALA is the active ingredient in DUSA's Levulan<sup>®</sup> products. Furthermore, we granted a non-exclusive license to PhotoCure for its existing formulations of its Hexvix<sup>®</sup> and Metvix<sup>®</sup> (known in the United States as Metvixia<sup>®</sup>) products for any DUSA patents that may issue or be licensed by us in the future. PhotoCure received FDA approval to market Metvixia<sup>®</sup> for treatment of AKs in July 2004 and Metvixia<sup>®</sup> would be directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product should PhotoCure decide to begin marketing this product. While we are entitled to royalties from PhotoCure on its net sales of Metvixia<sup>®</sup>, this product may adversely affect our ability to maintain or increase our market.

***WINSTON LABORATORIES, INC.***

On or about January 30, 2006, Winston Laboratories, Inc., or Winston, and the former Sirius entered into a license agreement relating to a Sirius product, Psoriatec<sup>®</sup> (known by Winston as Micanol) revising a former agreement. The original 2006 Micanol License Agreement granted an exclusive license, with limitation on rights to sublicense, to all property rights, including all intellectual property and improvements, owned or controlled by Winston to manufacture, sell and distribute products containing anthralin, in the United States. On January 29, 2008, our wholly-owned subsidiary, Sirius, entered into the 2006 Micanol Transition License Agreement with Winston. The Transition License Agreement amends the original 2006 Micanol License Agreement which was due to expire pursuant to its terms on January 31, 2008. The parties entered into the Transition License Agreement to extend the term of the 2006 Micanol License Agreement to September 30, 2008 in order to allow DUSA to sell its last batch of product, to reduce the period of time that Sirius is required to maintain product liability insurance with respect to its distribution and sale of products containing anthralin after the termination of the Transition License Agreement and to confirm the allocation of certain costs and expenses relating to the product during and after the transition period. We pay royalties on net sales of Psoriatec<sup>®</sup>, but we are no longer required to pay Winston a minimum royalty to maintain the license. Psoriatec<sup>®</sup> is a product that is regulated under the FDA's marketed unapproved drug policy guide. As a result of discussions with the FDA, DUSA placed its Psoriatec<sup>®</sup> inventory on hold and notified the FDA (in July 2008) that DUSA would cease marketing Psoriatec<sup>®</sup> at the termination of its license agreement, which expired on September 30, 2008. In October 2008, Winston filed a notice demanding arbitration of claims relating to alleged breach of the agreements and seeking damages in excess of \$2,000,000. For more information, see Part II, Item 1 entitled "Legal Proceedings."

***PARTEQ AGREEMENT***

We license certain patents underlying our Levulan<sup>®</sup> PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations, or PARTEQ. Under the agreement, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ patent rights, to make, have made, use and sell certain products, including ALA. The agreement covers certain use patent rights. When we sell our products directly, we have agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where we have a sublicensee, we will pay 6% and 4% when patent rights do and do not exist, respectively, on our net selling price less the cost of goods for products sold to the sublicensee, and

6% of payments we receive on sales of products by the sublicensee. We are also obligated to pay to PARTEQ 5% of any lump sum sublicense fees received, such as milestone payments, excluding amounts designated by the sublicensee for future research and development efforts.

**Table of Contents**

Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$98,000 as of September 30, 2008). ***NATIONAL BIOLOGICAL CORPORATION AMENDED AND RESTATED PURCHASE AND SUPPLY AGREEMENT***

On June 21, 2004, we signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation, or NBC, the manufacturer of our BLU-U<sup>®</sup> light source. This agreement provides for the elimination of certain exclusivity clauses, permits us to order on a purchase order basis without minimums, and includes other modifications of the original agreement providing both parties greater flexibility related to the development and manufacture of light sources and the associated technology within the field of PDT. We paid \$110,000 to NBC upon execution of the agreement which is being amortized over the remaining term of the agreement, expiring December 31, 2008. An extension to this agreement is currently being negotiated.

***SOCHINAZ SA***

Under an agreement dated December 24, 1993, Sochinaz SA manufactures and supplies our requirements of Levulan<sup>®</sup> from its FDA approved facility in Switzerland. The agreement expires on December 31, 2009. While we can obtain alternative supply sources in certain circumstances, any new supplier would have to be inspected and qualified by the FDA.

***LEASE AGREEMENTS***

We have entered into lease commitments for office space in Wilmington, Massachusetts, Valhalla, New York, and Toronto, Ontario. The minimum lease payments disclosed below include the non-cancelable terms of the leases. We intend to sublease the offices in Toronto as we are closing that office as of October 31, 2008. The Valhalla lease expires on December 31, 2008 and will not be renewed as all functions are being consolidated in our Wilmington, Massachusetts facilities.

***RESEARCH AGREEMENTS***

We have entered into various agreements for research projects and clinical studies. As of September 30, 2008, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$1,288,000. Included in this future payment is a master service agreement, effective June 15, 2001, with Therapeutics, Inc., which is renewable on an annual basis, to engage Therapeutics to manage the clinical development of our products in the field of dermatology. The agreement was renewed on June 15, 2008 for a one year period. Therapeutics is entitled to receive a bonus valued at \$50,000, in cash or stock at our discretion, upon each anniversary of the effective date.

Our contractual obligations and other commercial commitments to make future payments under contracts, including lease agreements, research and development contracts, manufacturing contracts, or other related agreements are as follows at September 30, 2008:

	Total	1 Year or less	2-3 Years	4-5 Years	After 5 Years
Operating lease obligations (1)	\$ 1,779,000	\$ 454,000	\$ 936,000	\$ 389,000	\$
Purchase obligations (2, 3)	3,577,000	2,817,000	760,000		
Minimum royalty obligations (4)	1,053,000	348,000	509,000	196,000	
Total obligations	\$6,409,000	\$3,619,000	\$2,205,000	\$585,000	\$

1) Approximately \$74,000 of future operating lease

commitments relate to the Toronto and Valhalla offices, which will be closed during 2008.

- 2) Research and development projects include various commitments including remaining obligations for our Phase II clinical study for moderate to severe acne.
  
- 3) 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

**Table of Contents**

indication  
ranging from  
\$250,000 to  
\$1,250,000,  
depending on  
the regulatory  
phase of  
development of  
products under  
Therapeutics  
management.

- 4) Minimum  
royalty  
obligations  
relate to our  
agreements with  
PARTEQ,  
Winston and  
Perrigo  
described  
above.

Rent expense incurred under operating leases was approximately \$112,000 and \$333,000 for the three and nine-month periods ended September 30, 2008, respectively, compared to \$120,000 and \$360,000 for the comparable 2007 periods.

**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**

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

As of September 30, 2008, the weighted average rate of return on our investments was 3.88%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of September 30, 2008, the fair market value of the portfolio would decline by \$179,000. Declines in interest rates could, over time, reduce our interest income.

**ITEM 4. CONTROLS AND PROCEDURES**

We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2008.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, DUSA's internal control

over financial reporting.

**Forward-Looking Statements Safe Harbor**

This report, including the Management's Discussion and Analysis of Financial Condition and Results of Operations, contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 21E of the Securities Exchange Act of 1934 which represent our expectations or beliefs concerning future events, including, but not limited to management's statements regarding our strategies and core objectives for 2008, the results of our integration of Sirius Laboratories, Inc. with our business and matters relating thereto, our expectations concerning the introduction of generic substitutes for Nicomide® and such products' impact on sales of Nicomide®, our use of estimates and assumptions in the preparation of our financial statements and policies and impact on us of the adoption of certain accounting standards, the impact of compounding pharmacies, beliefs regarding estimates, management's beliefs regarding the unique nature of Levulan® and its use and potential use, expectations regarding the timing of results of clinical trials, future development of Levulan® and our other products and other potential indications, statements regarding the manufacture of Nicomide® in the future, beliefs concerning manufacture of the BLU-U®, intention to pursue licensing, marketing, co-promotion, collaboration or acquisition opportunities, status of clinical programs for all other indications and beliefs regarding potential efficacy and marketing, our beliefs regarding the safety, simplicity, reliability and cost-effectiveness of certain light sources, our expectations regarding product launches in other countries, expectations regarding additional market expansion, expectations for commercialization of Levulan® Kerastick® in Asian countries and a distribution agreement for Japan, expectations

**Table of Contents**

regarding the marketing and distribution of Levulan<sup>®</sup> Kerastick<sup>®</sup> by Daewoong Pharmaceutical Co., Ltd. and Stiefel Laboratories, Inc., beliefs regarding the clinical benefit of Levulan<sup>®</sup> PDT for acne and other indications, beliefs regarding the suitability of clinical data, expectations regarding the confidentiality of our proprietary information, statements of our intentions to seek additional U.S. and foreign regulatory approvals, and to market and increase sales outside the U.S., beliefs regarding regulatory classifications, filings, timelines, off-label use and environmental compliance, beliefs concerning patent disputes and litigation, intentions to defend our patent estate, the impact of a third-party's regulatory compliance and fulfillment of contractual obligations, and our anticipation that third parties will launch products upon receipt of regulatory approval, expectations of increases or decreases in the prices we charge for our products, our beliefs regarding the size of the market for our products and our product candidates, expectations of increases or decreases in cost of product sales, expected use of cash resources, requirements of cash resources for our future liquidity, beliefs regarding investments and economic conditions, expectations regarding outstanding options and warrants and our dividend policy, anticipation of increases or decreases in personnel, beliefs regarding the effect of reimbursement policies on revenues and acceptance of our therapies, expectations for future strategic opportunities and research and development programs and expenses, expectations for continuing operating losses and competition, including from Metvixia, expectations regarding the adequacy and availability of insurance, expectations regarding general and administrative costs, expectations regarding increased sales and marketing costs and research and development costs, levels of interest income and our capital resource needs, intention to raise additional funds to meet capital requirements and the potential dilution and impact on our business, potential for additional inspection and testing of our manufacturing facilities or additional FDA actions, beliefs regarding the adequacy of our inventory of Kerastick<sup>®</sup> and BLU-U<sup>®</sup> units and of Nicomide<sup>®</sup>, our manufacturing capabilities and the impact of inventories on revenues, beliefs regarding interest rate risks to our investments and effects of inflation, beliefs regarding the impact of any current or future legal proceedings or arbitration proceedings, dependence on key personnel, and beliefs concerning product liability insurance, the enforceability of our patents, the impact of generic products, our beliefs regarding our sales and marketing efforts, competition with other companies, the adoption of our products, and the outcome of such efforts, our beliefs regarding our sales and marketing efforts, our beliefs regarding the use of our products and technologies by third parties, our beliefs regarding our compliance with applicable laws, rules and regulations, our beliefs regarding available reimbursement for our products, our beliefs regarding the current and future clinical development and testing of our potential products and technologies and the costs thereof, the volatility of our stock price, the impact of our rights plan, the possibility that the holders of options and warrants will purchase our common stock by exercising these securities, timing and future development plans with respect to the NCI clinical trials, beliefs regarding legal strategies or regulatory authorities' actions to stop compounding pharmacies, expectations of price and volume of Nicomide<sup>®</sup> as a DSHEA-labeled product, expectations related to the change in revenues of our PDT and Non-PDT products, expectations regarding the payment of milestones to former Sirius shareholders, intention to sublease the Toronto offices, plans to re-launch Nicomide<sup>®</sup> under DSHEA compliant labeling, beliefs regarding market share, beliefs regarding profitability, beliefs regarding the change in growth in our PDT Drug and Device Products segment, expectations regarding the BLU-U<sup>®</sup> evaluation program and purchases of our products resulting therefrom, expectations regarding the development time-table for a DSHEA version of Nicomide<sup>®</sup> and beliefs regarding the quantities of re-labeled Nicomide<sup>®</sup>. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the timely development, FDA and foreign regulatory approval, and market acceptance of our products, environmental risks relating to our products, reliance on third-parties for the production, manufacture, sales and marketing of our products, the availability of products for acquisition and/or license on terms agreeable to us, sufficient sources of funds, the securities regulatory process, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by third-party payors, none of which can be assured. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors.

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



In October 2008, we were notified that Winston Laboratories, Inc. had filed a demand for arbitration against the Company. The demand for arbitration arises out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement, which we refer to together as the Agreement, and claims that DUSA breached the Agreement. Winston Laboratories is claiming damages in excess of \$2.0 million. The Company plans to defend itself vigorously and has not recorded any liability pursuant to the claim at September 30, 2008. For more

**Table of Contents**

information about our agreements with Winston Laboratories, see Management's Discussion and Analysis of Financial Condition and Results of Operations Contractual Obligations and Other Commercial Commitments.

**ITEM 1A. RISK FACTORS**

A description of the risk factors associated with our business is set forth below. This description includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1A of our 2007 Annual Report on Form 10-K for the year ended December 31, 2007 and in Item 1A of our Quarterly Report on Form 10-Qs for the quarters ended March 31, 2008 and June 30, 2008.

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 section of the Quarterly Report on Form 10-Q contains forward-looking statements of our plans, objectives, expectations and intentions. We use words such as anticipate, believe, expect, future, intend and similar expressions to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risk factors described below and elsewhere in this report. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this report.

**Risks Related To DUSA**

**We Are Not Currently Profitable And May Not Be Profitable In The Future Unless We Can Successfully Market And Sell Significantly Higher Quantities Of Our Products.**

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

If we do not generate sufficient revenues from our approved products, we may be forced to delay or abandon some or all of our product development programs. The pharmaceutical development and commercialization process is time consuming and costly, and any delays might result in higher costs which could adversely affect our financial condition. Without sufficient product sales, we would need alternative sources of funding. There is no guarantee that adequate funding sources could be found to continue the development of our potential products. We might be required to commit substantially greater capital than we have available to research and development of such products and we may not have sufficient funds to complete all or any of our development programs.

*Our Ability To Become Profitable Will Be Delayed Since We Will No Longer Promote Nicomide® As A Prescription Product And Since Other Generic Products Entered the Market.*

In March 2006, we acquired Nicomide® in connection with our merger with Sirius Laboratories, Inc. Our revenues from sales of Nicomide® will decrease significantly with our decision to cease marketing Nicomide® as a prescription product in response to discussions with the FDA. Assuming we launch Nicomide® as a dietary supplement which is compliant with current FDA regulations, our ability to become profitable will be more difficult.

In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the U.S. Food and Drug Administration. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008. We are relabeling our remaining supply of product as a non-prescription dietary supplement in compliance

**Table of Contents**

with DSHEA. We are in discussions with the FDA regarding new labeling, including use of the trademark. We are actively searching for a source of supply for the DSHEA product. We expect both the price and volume of the Nicomide® DSHEA labeled product to be considerably less than historic Nicomide® levels.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River s Edge. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we will be paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement. At the same time, we are also considering the possible sale of the product and related patent.

***We Have Not Yet Secured A Manufacturer for a DSHEA Nicomide® Product, And, As A Result, Our Revenues From Nicomide® Sales May Suffer.***

In April 2008, we were notified by the manufacturer of Nicomide that it was ceasing the manufacturing of several prescription vitamins, including Nicomide®. We are actively searching for a source of supply to manufacture a DSHEA-labeled version of Nicomide®. Since Actavis, the former manufacturer, owns certain proprietary assays and manufacturing processes relating to Nicomide®, it could take several months to develop the DSHEA version of Nicomide®. Although we believe we will have sufficient quantities of re-labeled Nicomide® product to meet the DSHEA market demand in the short-term, it is possible that we could go into a back-order situation and could lose market share while we redevelop the DSHEA product. We may not be able to locate a manufacturer on terms that are acceptable to us.

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

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

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

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

- control of marketing activities, including advertising and labeling.

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

- send warning letters, as received by the manufacturer of our BLU-U®,

- impose fines and other civil penalties on us,

- seize our products,

- suspend our regulatory approvals,

- cease the manufacture of our products, as Actavis Totowa is doing with Nicomide®,

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

**Table of Contents**

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

require us to recall products,

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

impose restrictions on our operations, and/or

criminally prosecute us.

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

Certain of the products acquired or licensed in connection with the Sirius merger including Nicomide<sup>®</sup>, are regulated by FDA under its marketed unapproved drugs compliance policy guide entitled, Marketed New Drugs without Approved NDAs or ANDAs. Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and/or bring these products into compliance with current FDA regulations. As result of discussions with the FDA, we stopped the sale and distribution of Nicomide<sup>®</sup> and Psoriatec<sup>®</sup> as prescription products in June 2008. We are relabeling a supply of Nicomide<sup>®</sup> product as a non-prescription dietary supplement in compliance with DSHEA for re-launch and are in discussions with FDA about appropriate DSHEA labeling, including use of the trademark. We are actively searching for a source of supply for the DSHEA product. Label changes eliminating references to medicinal benefits will limit the marketing claims we can make for Nicomide<sup>®</sup> and a change of product name, if required, could negatively affect our revenues and profits. We could experience a back-order situation if a manufacturer is not available in time to meet our supply needs which could also affect our revenues and profits. Our license agreement for Psoriatec<sup>®</sup> expired on September 30, 2008.

Manufacturing facilities are subject to ongoing periodic inspection by the FDA, including unannounced inspections. We cannot guarantee that our third-party supply sources, or our own Kerastick<sup>®</sup> facility, will continue to meet all applicable FDA regulations. If we, or any of our manufacturers, including without limitation, the manufacturer of the BLU-U<sup>®</sup>, who has received warning letters from the FDA, fail to maintain compliance with FDA regulatory requirements, it would be time consuming and costly to remedy the problem(s) or to qualify other sources. These consequences could have a significant adverse effect on our financial condition and operations. As part of our FDA approval for the Levulan<sup>®</sup> Kerastick<sup>®</sup> for AK, we were required to conduct two Phase IV follow-up studies. We successfully completed the first study; and submitted our final report on the second study to the FDA in January 2004. The FDA has requested additional information, which was provided to them in June 2008. We are awaiting their response. Additionally, if previously unknown problems with the product, a manufacturer or its facility are discovered in the future, changes in product labeling restrictions or withdrawal of the product from the market may occur. Any such problems could affect our ability to become profitable.

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

The costs of litigation or any proceeding relating to our intellectual property rights could be substantial even if resolved in our favor. Some of our competitors have far greater resources than we do and may be better able to afford the costs of complex patent litigation. For example, third-parties such as companies that have launched niacinamide products, may infringe one or more of our patents, and cause us to spend significant resources to enforce our patent rights. Also, in a lawsuit against a third-party for infringement of our patents in the United States, that third-party may challenge the validity of our patent(s). We cannot guarantee that a third-party will not claim, with or without merit, that our patents are not valid or that we have infringed their patent(s) or misappropriated their proprietary material. Defending these types of legal actions involve considerable expense and could negatively affect our financial results.



## **Table of Contents**

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 United States Patent and Trademark Office, or 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, could involve substantial legal fees and result in a loss or lessening of our patent protection.

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

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

While we completed a private placement raising net proceeds of approximately \$10.3 million in October 2007, we may need substantial additional funds to fully develop, manufacture, market and sell our potential products. We may obtain funds through other public or private financings, including equity financing, and/or through collaborative arrangements. We cannot predict whether any additional financing will be available at all or on acceptable terms. Depending on the extent of available funding, we may delay, reduce in scope or eliminate some of our research and development programs. We may also choose to license rights to third parties to commercialize products or technologies that we would otherwise have attempted to develop and commercialize on our own which could reduce our potential revenues.

The availability of additional capital to us is uncertain. There can be no assurance that additional funding will be available to us on favorable terms, if at all. Any equity financing, if needed, would likely result in dilution to our existing shareholders and debt financing, if available, would likely involve significant cash payment obligations and include restrictive covenants that restrict our ability to operate our business. Failure to raise capital if needed could materially adversely impact our business, our financial condition, results of operations and cash flows.

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

If we experience problems producing Levulan® Kerastick® units in our facility, or if any of our contract suppliers fail to supply our requirements for products, our business, financial condition and results of operations would suffer. Although we have received approval by the FDA to manufacture the BLU-U® and the Levulan® Kerastick® in our Wilmington, Massachusetts facility, at this time, with respect to the BLU-U®, we expect to utilize our own facility only as a back-up to our current third party manufacturer or for repairs unless we decide to manufacture in light of FDA's warning letter to our BLU-U® manufacturer.

In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008. We are relabeling our remaining supply of product as a non-prescription dietary supplement in compliance with DSHEA. We are in discussions with the FDA regarding new labeling, including use of the trademark. We are actively searching for a source of supply for the DSHEA product. We expect both the price and volume of the Nicomide® DSHEA labeled product to be considerably less than historic Nicomide® levels.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River's Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River's Edge. The amendment to the Settlement Agreement allows River's Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River's Edge for sales of its substitutable product. In consideration for granting the license, we will be paid a share of the net revenues, as defined in the License Agreement, of River's Edge's licensed product sales under the License Agreement. At the same time, we are also considering the possible sale of the product and related

patent.

**Table of Contents**

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.

**We Have Only Limited Experience Marketing And Selling Pharmaceutical Products And No Experience Marketing Dietary Supplements, As A Result, Our Revenues From Product Sales May Suffer.**

If we are unable to successfully market and sell sufficient quantities of our products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. We are responsible for marketing our products in the United States and the rest of the world, except Canada, Latin America and parts of Asia, where we have distributors. We are doing so without the experience of having marketed pharmaceutical products prior to 2000. In October 2003, DUSA began hiring a small direct sales force and we increased the size of our sales force to market our products in the United States. We do not have experience marketing dietary supplement products like Nicomide®. If our sales and marketing efforts fail, then sales of the Levulan® Kerastick®, the BLU-U®, Nicomide® and other products will be adversely affected.

**The Commercial Success Of Any Products 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 products that we may develop will be highly dependent upon the extent to which these products gain market acceptance among physicians, patients, health care payors, such as Medicare and Medicaid, private health insurers, including managed care organizations and group purchasing organizations, and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues, and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the effectiveness, or perceived effectiveness, of our products 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 products for sale at competitive prices;



**Table of Contents**

relative convenience and ease of administration;

the strength of marketing and distribution support; and

sufficient third-party coverage or reimbursement.

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

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan® Kerastick® for AK therapy will be limited. While we continue to support efforts to improve reimbursement levels to physicians and are working with the major private insurance carriers to improve coverage for our therapy, if our efforts are not successful, a broader adoption of our therapy and sales of our products could be negatively impacted. Although positive reimbursement changes related to AK were made in 2005, 2007 and again in 2008, 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, or stop covering products which are covered, including Nicomide®, our sales could be dramatically reduced.

**We Have Significant Losses And Anticipate Continued Losses**

We have a history of operating losses. We expect to have continued losses until sales of our products increase substantially. We incurred net losses of \$2,837,000 and \$4,260,000 for the three and nine-month periods ended September 30, 2008, respectively, and \$14,714,000 and \$31,350,000 for the years ended December 31, 2007 and 2006, respectively. As of September 30, 2008, our accumulated deficit was approximately \$140,000,000. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable on a sustainable basis.

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

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

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

methods of using ALA and its unique physical forms in combination with light,

compositions and apparatus for those methods, and

unique physical forms of ALA.

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

Some of the indications for which we may develop PDT therapies may not be covered by the claims in any of our existing patents. Even with the issuance of additional patents to DUSA, other parties are free to develop other uses of ALA, including medical uses, and to market ALA for such uses, assuming that they have obtained appropriate regulatory marketing approvals. ALA in the chemical form has been commercially supplied for decades, and is not

**Table of Contents**

itself subject to patent protection. There are reports of third-parties conducting clinical studies with ALA in countries outside the United States where PARTEQ, the licensor of our ALA patents, does not have patent protection. In addition, a number of third-parties are seeking patents for uses of ALA not covered by our patents. These other uses, whether patented or not, and the commercial availability of ALA, could limit the scope of our future operations because ALA products could come on the market which would not infringe our patents but would compete with our Levulan® products even though they are marketed for different uses.

Nicomide® is covered by a United States patent which issued in December 2005. River s Edge Pharmaceuticals, LLC filed an application with the USPTO for the reexamination of the patent which was vacated by the USPTO on March 6, 2008. On October 28, 2007, we entered into a settlement agreement and mutual release to dismiss the lawsuit brought by DUSA against River s Edge, asserting a number of claims arising out of River s Edge s alleged infringement of U.S. Patent No. 6,979,468 under which DUSA has marketed, distributed and sold Nicomide®. Under the terms of the settlement agreement, River s Edge unconditionally acknowledged the validity and enforceability of the Nicomide® patent.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River s Edge. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we will be paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement.

Another company has launched a substitutable niacinamide product, which may cause us to again consider litigation and the validity of the Nicomide® patent could be tested again. Also, new products have been launched that are competing with Nicomide®. These events, together with our decision regarding the marketing of Nicomide will delay our ability to be profitable.

Furthermore, PhotoCure received FDA approval to market Metvixia® for treatment of AKs in July 2004, and this product, which would be directly competitive with our Levulan® Kerastick® product, could be launched at any time. While we are entitled to royalties from PhotoCure on its net sales of Metvixia®, this product which will be marketed in the U.S. by a large dermatology company, may adversely affect our ability to maintain or increase our Levulan® market.

While we attempt to protect our proprietary information as trade secrets through agreements with each employee, licensing partner, consultant, university, pharmaceutical company and agent, we cannot guarantee that these agreements will provide effective protection for our proprietary information. It is possible that:

these persons or entities might breach the agreements,

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

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

All of which could negatively impact our ability to be profitable.

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

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

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

**Table of Contents**

failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

delays in product development, clinical testing or manufacturing,

unplanned expenditures in product development, clinical testing or manufacturing,

failure in clinical trials or failure to receive regulatory approvals,

emergence of superior or equivalent products,

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

failure to achieve market acceptance.

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

***We Must Receive Separate Approval For Each Of Our Potential Products Before We Can Sell Them Commercially In The United States Or Abroad.***

All of our potential Levulan<sup>®</sup> products will require the approval of the FDA before they can be marketed in the United States. If we fail to obtain the required approvals (as we did for the product we were developing with Altana) for these products our revenues will be limited. Before an application to the FDA seeking approval to market a new drug, called an NDA, can be filed, a product must undergo, among other things, extensive animal testing and human clinical trials. The process of obtaining FDA approvals can be lengthy, costly, and time-consuming. Following the acceptance of an NDA, the time required for regulatory approval can vary and is usually one to three years or more. The FDA may require additional animal studies and/or human clinical trials before granting approval. Our Levulan<sup>®</sup> PDT products are based on relatively new technology. To the best of our knowledge, the FDA has approved only three drugs for use in photodynamic therapy, including Levulan<sup>®</sup>. 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 approval for any of our potential products. 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<sup>®</sup> PDT or photodetection, known as PD, is safe and effective for any new use we are studying as we experienced with our recent acne study. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy.

In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide<sup>®</sup>, that Actavis would cease manufacturing several prescription vitamins, including Nicomide<sup>®</sup>, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide<sup>®</sup> as a prescription product in June 2008. We are relabeling our remaining supply of product as a non-prescription dietary supplement in compliance with DSHEA. We are in discussions with the FDA regarding new labeling, including use of the trademark. We are actively searching for a source of supply for the DSHEA product. We expect both the price and volume of the Nicomide<sup>®</sup> DSHEA labeled product to be considerably less than historic Nicomide<sup>®</sup> levels.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide<sup>®</sup> with River s Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River s Edge. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide<sup>®</sup> pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we will be paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed



**Table of Contents**

product sales under the License Agreement. At the same time, we are also considering the possible sale of the product and related patent.

***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 88 employees, including 4 part-time employees, as of September 30, 2008. We are highly dependent on several key officer/employees with specialized scientific and technical skills without whom our business, financial condition and results of operations would suffer, especially in the photodynamic therapy portion of our business. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very few people with their expertise could be hired. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain other qualified personnel in our specialty drug and light device areas.

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

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

**Risks Related To Our Industry**

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

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

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

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

We have used various hazardous materials, such as mercury in fluorescent tubes in our research and development activities. We are subject to federal, state and local laws and regulations which govern the use, manufacture, storage, handling and disposal of hazardous materials and specific waste products. Now that we have established our own production line for the manufacture of the Kerastick<sup>®</sup>, we are subject to additional environmental laws and regulations. We believe that we are in compliance in all material respects with currently applicable environmental laws and regulations. However, we cannot guarantee that we will not incur significant costs to comply with environmental laws and regulations in the future. We also cannot guarantee that current or future environmental laws or regulations will not materially adversely affect our operations, business or assets. In addition, although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials.

**Table of Contents**

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 Some Or All Of Our Programs Or Potential Products Noncompetitive Or Obsolete.***

Well-known pharmaceutical, biotechnology and medical device companies are marketing well-established therapies for the treatment of many of the same conditions that we are seeking to treat, including AKs, acne and rosacea.

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 medical conditions for which we are developing treatments. Our industry is subject to rapid, unpredictable and significant technological change. Competition is intense. Our competitors may succeed in developing products that are safer or more effective than ours. Many of our competitors have substantially greater financial, technical and marketing resources than we have. In addition, several of these companies have significantly greater experience than we do in developing products, conducting preclinical and clinical testing and obtaining regulatory approvals to market products for health care.

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

price reductions,

lower levels of third-party reimbursements,

failure to achieve market acceptance, and

loss of market share, any of which could adversely affect our business. Further, we cannot give any assurance that developments by our competitors or future competitors will not render our technology obsolete.

On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby DUSA granted a non-exclusive license to PhotoCure under the patents DUSA licenses from PARTEQ, for esters of ALA. Furthermore, DUSA granted a non-exclusive license to PhotoCure for its existing formulations of its Hexvix<sup>®</sup> and Metvix<sup>®</sup> (known in the United States as Metvixia<sup>®</sup>) products for any DUSA patents that may issue or be licensed by DUSA in the future. PhotoCure received FDA approval to market Metvixia for treatment of AKs in July 2004 and it would be directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product should PhotoCure decide to begin marketing this product. While we are entitled to royalties from PhotoCure on its net sales of Metvixia, this product, which will be marketed in the U.S. by a large dermatology company which may start to market Metvixia at any time, would adversely affect our ability to maintain or increase our market.

***We Have Learned That Some Compounding Pharmacies Are Producing A Form Of Aminolevulinic Acid HCl And Are Marketing It To The Medical Community.***

We are aware that there are compounding pharmacies that market compounded versions of aminolevulinic acid HCl as an alternative to our Levulan<sup>®</sup> product. Since December 2004, we have filed lawsuits against compounding pharmacies, chemical suppliers and a light device company and several physicians alleging violations of the Lanham Act for false advertising and trademark infringement, and of United States patent law. All of the lawsuits have been settled or ended favorably to us. While we believe that certain actions of compounding pharmacies and others go

**Table of Contents**

beyond the activities which are permitted under the Food, Drug and Cosmetic Act and have advised the FDA and local health authorities of our concerns, we cannot be certain that our legal strategy will be successful in curbing the practices of these companies or that regulatory authorities will intervene to stop their activities. In addition, there may be other compounding pharmacies which are following FDA guidelines, or others conducting illegal activities of which we are not aware, which may be negatively impacting our sales revenues.

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

We are aware of several companies commercializing and/or conducting research with ALA or ALA-related compounds, including: medac GmbH and photonamic GmbH & Co. KG (Germany); Biofrontera, PhotoTherapeutics, Inc. (U.K.) and PhotoCure ASA (Norway) which entered into a marketing agreement with Galderma S.A. for countries outside of Nordic countries for certain dermatology indications. We also anticipate that we will face increased competition as the scientific development of PDT and PD advances and new companies enter our markets. Several companies are developing PDT agents other than Levulan<sup>®</sup>. These include: QLT Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); and Pharmacyclics, Inc. (U.S.). There are many pharmaceutical companies that compete with us in the field of dermatology, particularly in the acne and rosacea markets.

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound for PDT treatment of AKs and basal cell carcinoma in the European Union, New Zealand, Australia and countries in Scandinavia.

PhotoCure's marketing partner, a large dermatology company, could begin to market its product in direct competition with Levulan<sup>®</sup> in the U.S., at any time, under the terms of our patent license agreement and we may lose market share. Axcan Pharma Inc. has received FDA approval for the use of its product, PHOTOFRIN<sup>®</sup>, for PDT in the treatment of high grade dysplasia associated with Barrett's Esophagus. Axcan is the first company to market a PDT therapy for this indication for which we designed our proprietary sheath device and have conducted pilot clinical trials.

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

the ease of administration of our method of PDT,

the degree of generalized skin sensitivity to light,

the number of required doses,

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

the type and cost of our light systems.

Our primary competition in the acne and rosacea markets 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. We are also aware of new products that were launched recently which will compete with Nicomide<sup>®</sup> which could negatively impact our market share. The entry of new products from time to time would likely cause us to lose market share.

**Table of Contents**

**Risks Related To Our Stock**

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

As of October 31, 2008, there were outstanding options and warrants to purchase 4,419,000 shares of common stock, with exercise prices ranging from \$1.60 to \$31.00 per share, and from \$2.85 to \$6.00 per share, respectively. In addition, there are 102,000 shares of restricted stock that have not yet vested. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. The holders are likely to exercise their securities when we would probably be able to raise capital from the public on terms more favorable than those provided in these securities.

***Our Results Of Operations And General Market Conditions For Specialty Pharmaceutical And Biotechnology Stocks Could Result In Sudden Changes In The Market Value Of Our Stock.***

The price of our common stock has been highly volatile. These fluctuations create a greater risk of capital losses for our shareholders as compared to less volatile stocks. From January 1, 2007 to October 31, 2008, the price of our stock has ranged from a low of \$0.87 to a high of \$5.00. Factors that contributed to the volatility of our stock during this period included:

quarterly levels of product sales;

clinical trial results;

general market conditions;

patent litigation;

increased marketing activities or press releases; and

changes in third-party payor reimbursement for our therapy.

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

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

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



**Table of Contents**

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

In order for our common stock to trade on the Nasdaq Global Market, we must continue to meet the listing standards of that market. Among other things, those standards require that our common stock maintain a minimum closing bid price of at least \$1.00 per share. Recently, our common stock has traded at prices near and below \$1.00. On October 16, 2008, Nasdaq suspended the enforcement of rules requiring a minimum \$1.00 closing bid price. The suspension will remain in effect through January 16, 2009. If we do not continue to meet Nasdaq's applicable minimum listing standards, Nasdaq could delist us from the Nasdaq Global Market. If our common stock is delisted from the Nasdaq Global Market, we could seek to have our common stock listed on the Nasdaq Capital Market or other Nasdaq markets. However, delisting of our common stock from the Nasdaq Global Market could hinder your ability to sell, or obtain an accurate quotation for the price of, your shares of our common stock. Delisting could also adversely affect the perception among investors of DUSA and its prospects, which could lead to further declines in the market price of our common stock. Delisting would also make it more difficult and expensive for us to raise capital. In addition, delisting might subject us to an 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 Would Be Difficult, Which May Discourage Offers For Shares Of Our Common Stock.***

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

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

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

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

**Table of Contents**

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

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

None.

**ITEM 5. OTHER INFORMATION.**

None.

**ITEM 6. EXHIBITS.**

**EXHIBIT**

<b>NO.</b>	<b>DESCRIPTION OF EXHIBIT</b>
3(a.1)	Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference.
3(a.2)	Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, and is incorporated herein by reference
3(b)	By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant's current report on Form 8-K, filed on November 2, 2007, and is incorporated herein by reference.
10(a)	License Agreement between the Registrant and River's Edge Pharmaceuticals LLC entered into August 12, 2008 portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
31(a)	Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
31(b)	Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
32(a)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32(b)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1	Press Release dated November 3, 2008

**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 3, 2008

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

Dated November 3, 2008

**Table of Contents**

**EXHIBIT INDEX**

- 3(a.1) Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference.
- 3(a.2) Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, and is incorporated herein by reference.
- 3(b) By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant's current report on Form 8-K, filed on November 2, 2007, and is incorporated herein by reference.
- 10(a) License Agreement between the Registrant and River's Edge Pharmaceuticals LLC entered into August 12, 2008 portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
- 31(a) Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
- 31(b) Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
- 32(a) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32(b) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99.1 Press Release dated November 3, 2008.