

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

DUSA PHARMACEUTICALS INC

Form 10-Q

May 10, 2006

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended: March 31, 2006  
-----

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

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

Commission file number: 001-31533  
-----

DUSA PHARMACEUTICALS, INC.  
(Exact Name of Registrant as Specified in Its Charter)

-----  
New Jersey 22-3103129  
-----  
(State of Other Jurisdiction of Incorporation or Organization) (I.R.S. Employer Identification No.)

25 Upton Drive, Wilmington, MA 01887  
-----  
(Address of Principal Executive Offices) (Zip Code)

(978) 657-7500  
-----  
(Registrant's Telephone Number, Including Area Code)

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

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

Yes  No

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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

Large Accelerated Filer [    ]      Accelerated Filer [X]      Non-accelerated Filer [    ]

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

As of May 8, 2006, the registrant had 19,025,300 shares of Common Stock, no par value per share, outstanding.

### PART I.

#### ITEM 1. FINANCIAL STATEMENTS

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

	MARCH 31, 2006 -----
ASSETS	
CURRENT ASSETS	
Cash and cash equivalents	\$ 4,282,713
Marketable securities	18,976,838
Accrued interest receivable	233,651
Accounts receivable, net	2,126,853
Inventory	3,538,794
Deferred acquisition costs	--
Prepays and other current assets	1,159,297
TOTAL CURRENT ASSETS	----- 30,318,146
Restricted cash	145,983
Property, plant and equipment, net	3,002,981
Intangible assets	17,057,961
Goodwill	5,772,505
Deferred charges and other assets	230,522
TOTAL ASSETS	----- \$ 56,528,098 =====
LIABILITIES AND SHAREHOLDERS' EQUITY	
CURRENT LIABILITIES	
Accounts payable	\$ 1,221,374
Accrued compensation	717,616
Other accrued expenses	3,392,076
Deferred revenue	72,111

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

TOTAL CURRENT LIABILITIES	5,403,177
Other liabilities	205,677
TOTAL LIABILITIES	5,608,854
COMMITMENTS AND CONTINGENCIES (NOTE 13)	
SHAREHOLDERS' EQUITY	
Capital Stock	
Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding: 19,448,192 and 17,041,197 shares of common stock, no par, at March 31, 2006 and December 31, 2005, respectively	142,868,571
Additional paid-in capital	2,353,981
Accumulated deficit	(94,177,779)
Accumulated other comprehensive loss	(125,529)
TOTAL SHAREHOLDERS' EQUITY	50,919,244
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 56,528,098

See the accompanying Notes to the Condensed Consolidated Financial Statements.

2

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

	THREE MONTHS ENDED MAR 2006	2005
Product Revenues	\$ 4,750,520	\$ 3,360,000
Cost of Product Revenues and Royalties	1,790,759	2,000,000
Gross Margin	2,959,761	1,360,000
Operating Costs		
Research and Development	1,510,731	1,590,000
In-process Research and Development	1,600,000	1,600,000
Marketing and Sales	2,690,684	2,780,000
General and Administrative	2,070,291	1,680,000
Total Operating Costs	7,871,706	6,060,000
Loss from Operations	(4,911,945)	(4,690,000)
Other Income		

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Other Income, net	271,636	36
	-----	-----
Net Loss	\$ (4,640,309)	\$ (4,33
	=====	=====
Basic and Diluted Net Loss per Common Share	\$ (0.26)	\$
	=====	=====
Weighted Average Number of Common Shares Outstanding, Basic and Diluted	17,629,292	16,90
	=====	=====

See the accompanying Notes to the Condensed Consolidated Financial Statements.

3

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

	THREE MONTHS E
	2006
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES	
Net loss	\$ (4,640,309)
Adjustments to reconcile net loss to net cash used in operating activities:	
Amortization of premiums and accretion of discounts marketable securities available for sale	27,214
Depreciation and amortization	488,253
In-process research and development charge	1,600,000
Stock-based compensation	318,195
Gain on sale of marketable securities	(14,015)
Changes in other assets and liabilities impacting cash flows from operations (net of impact of acquisition):	
Accrued interest receivable	119,798
Accounts receivable	(41,555)
Inventory	109,294
Prepaid and other current assets	(469,831)
Deferred charges and other assets	11,934
Accounts payable	(316,150)
Accrued compensation and other accrued expenses	(816,343)
Deferred revenue	(22,172)
Other liabilities	107
	-----
NET CASH USED IN OPERATING ACTIVITIES	(3,645,580)
	-----
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES	
Cash paid for acquisition, net of cash received	(7,767,006)
Purchases of marketable securities	(1,059,725)
Proceeds from maturing and sales of marketable securities	12,619,393
Restricted cash	(1,442)

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Purchases of property, plant and equipment	(112,558)
	-----
NET CASH PROVIDED BY INVESTING ACTIVITIES	3,678,662
	-----
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES	
Proceeds from exercise of options	38,956
	-----
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	72,038
	-----
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,210,675
	-----
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 4,282,713
	=====

See the accompanying Notes to the Condensed Consolidated Financial Statements.

4

DUSA PHARMACEUTICALS, INC.  
 NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

-----

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of March 31, 2006, and the Condensed Consolidated Statements of Operations and Cash Flows for the three months ended March 31, 2006 and 2005 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, 2005 filed with the Securities and Exchange Commission. The balance sheet as of December 31, 2005 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. Certain amounts for 2005 have been reclassified to conform to the current year presentation. Such reclassifications had no impact on the net loss or shareholders' equity for any period presented.

2) SIGNIFICANT ACCOUNTING POLICIES

Accounting policies newly adopted or updated since the filing of the Company's Annual Report on Form 10-K

Revenue Recognition

PDT Drug and Device Products. Revenues on the Kerastick (R) and BLU-U(R)

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

product sales are recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and collection is probable. Product sales made through distributors, historically, have been recorded as deferred revenue until the product was sold by the distributors to the end users because we did not have sufficient history with our distributors to be able to reliably estimate returns. Beginning in the first quarter of 2006, we began recognizing revenue as product is sold to distributors because we believe we have sufficient history to reliably estimate returns from distributors as of January 1, 2006. The effect of this change in estimate was to recognize additional revenue of approximately \$34,000 during the three months ended March 31, 2006. Certain device units are held by physicians for a trial period. No revenue is recognized on these units until the physician elects to purchase the equipment and all other revenue recognition criteria are met.

Non-PDT Drug Products. We recognize revenue for these products in accordance with SAB No. 101, "Revenue Recognition in Financial Statements", as amended by SAB No. 104, "Revenue Recognition." Our accounting policy for revenue recognition has a substantial impact on our reported results and relies on certain estimates that require difficult, subjective and complex judgments on the part of management. We recognize revenue for sales when

5

DUSA PHARMACEUTICALS, INC.  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

---

substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment to wholesale customers, with the exceptions described below. Revenue is recognized net of revenue reserves, which consists of allowances for discounts, returns, rebates chargebacks and fees paid to wholesalers under distribution service agreements.

In the case of sales made to wholesalers as a result of incentives and that are in excess of the wholesaler's ordinary course of business inventory level, substantially all the risks and rewards of ownership do not transfer upon shipment and, accordingly, such sales are recorded as deferred revenue and the related costs as deferred cost of revenue until the product is sold through to the wholesalers' customers on a FIFO basis.

### Sales Return Accrual

We account for sales returns in accordance with SFAS No, 48 by establishing an accrual in an amount equal to our estimate of sales recorded for which the related products are expected to be returned. We determine the estimate of the sales return accrual primarily based on historical experience regarding sales returns, but also by considering other factors that could impact sales returns. These factors include levels of inventory in the distribution channel, estimated shelf life, product recalls, product discontinuances, price changes of competitive products, introductions of generic products and introductions of competitive new products. It is our policy to accept returns of Non-PDT Drug products when product is within six months of expiration. We consider all of these factors and adjust the accrual periodically to reflect actual experience.

### Goodwill and Other Intangible Assets

Goodwill and intangible assets with indefinite lives are no longer amortized but are reviewed annually for impairment or more frequently if impairment indicators arise. Separable intangible assets that are not deemed to have indefinite lives will continue to be amortized over their useful lives.

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

### Stock-Based Compensation

Prior to January 1, 2006, we used the intrinsic value-based method to account for employee stock option awards under the provisions of Accounting Principles Board Opinion ("APB") No. 25, and to provide disclosures based on the fair value method in the Notes to the Consolidated Financial Statements as permitted by Statement of Financial Accounting Standards ("SFAS") No. 123, as amended. Stock or other equity-based compensation for non-employees is accounted for under the fair value-based method as required by SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and other related interpretations. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost is recognized and charged to operations over the service period which, in the case of stock options, is generally the vesting period.

6

DUSA PHARMACEUTICALS, INC.  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

---

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123(R), "Share-Based Payment," a revision of SFAS Statement No. 123. We adopted SFAS 123(R) effective January 1, 2006, using the modified prospective application method, and beginning with the first quarter of 2006, we measure all employee share-based compensation awards using a fair value based method and record share-based compensation expense in our financial statements if the requisite service to earn the award is provided.

### 3) BUSINESS ACQUISITION

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius Laboratories, Inc. (Sirius) in exchange for 2,396,245 shares of unregistered DUSA common stock and \$8 million in cash. Pursuant to the terms of the Merger Agreement, the actual number of shares that were issued in the transaction was derived by dividing \$17 million by the average closing price of the Company's shares over the 20 trading day period prior to the close, or \$7.094 per share. For accounting purposes, these shares are valued at \$7.30 per share, the average market price of the Company's common stock over the 5 day period beginning two days prior and ending two days subsequent to the public announcement of the signing of the First Amendment to the Merger Agreement. Sirius is a dermatology specialty pharmaceuticals company founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. The purchase of Sirius is intended to enable DUSA to expand its product portfolio, capitalize on cross-selling and marketing opportunities, increase its sales force size; as well as, provide a pipeline of new products. The aggregate purchase price, net of cash received of \$0.5 million, was approximately \$26.8 million, which consisted of \$17.2 million in shares of common stock, net of estimated registration costs of \$0.3 million, \$7.5 million in cash, \$0.3 million outstanding balance on line of credit, and transaction costs of \$1.8 million, which primarily consisted of fees for legal and financial advisory services. Of the 2,396,245 shares issued in the acquisition, 422,892 shares have been placed

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

in an escrow account established to secure the indemnification obligations of the shareholders of Sirius as set forth in the Merger Agreement. The escrow account is established for a period of two years and will be used to satisfy liability claims, if any, made by the Company. No amounts may be distributed from the liability escrow account unless and until any individual claim exceeds \$25,000 and cumulative claims exceed \$100,000.

The Company has agreed to pay additional consideration in future periods, based upon the attainment of defined operating objectives, including new product approvals or launches and the achievement of pre-determined total cumulative sales milestones for the Sirius products over the period ending 42 months from the date of close. The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments earned are, as follows:

CUMULATIVE SALES MILESTONE:	PAYMENT EARNED:
-----	-----
\$25.0 million	\$1.5 million
35.0 million	\$1.0 million
45.0 million	\$1.0 million
	-----
Total	\$3.5 million
	=====

7

DUSA PHARMACEUTICALS, INC.  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

-----

In addition, there are three milestones related to new product approvals and/or launches each in the amount of \$500,000 per milestone, or \$1.5 million in the aggregate, that will be paid if the milestones are achieved.

The Company will not accrue contingent consideration obligations prior to the attainment of the objectives. At March 31, 2006, the maximum potential future consideration pursuant to such arrangements, to be resolved over the period ending 42 months from the date of close, is \$5.0 million. If attained, a portion of the contingent consideration is payable in cash and a portion is payable in either common stock or cash, at the Company's sole discretion. Any such payments will result in increases in goodwill at time of payment.

The acquisition was accounted for using the purchase method of accounting and the results of operations of the acquired business since March 10, 2006, the date of acquisition, were included in the results of the Company. The purchase price allocation is preliminary and a final determination of required purchase accounting adjustments will be made upon the completion of the integration. The Company may incur costs in the future related to manufacturing concerns that were identified with the manufacturing of one of Sirius' product lines. There is also a risk that inventory of some of these products could become in short supply while such concerns are being addressed. The Company may seek indemnification for these potential costs and lost revenues through the liability escrow agreement, and may also seek indemnification from the



## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

manufacturer under the terms of the supply and development agreement. The total purchase consideration was allocated to the assets acquired and liabilities assumed at their estimated fair values as of the date of acquisition, as determined by management and, with respect to identified intangible assets, by management with the assistance of an appraisal provided by a third-party valuation firm. The excess of the purchase price over the amounts allocated to assets acquired and liabilities assumed has been recorded as goodwill. The goodwill is not deductible for tax purposes. The value of the goodwill from this acquisition can be attributed to a number of business factors including, but not limited to, expanded product portfolio, cross selling and marketing opportunities, increased sales force and a pipeline of new products.

8

DUSA PHARMACEUTICALS, INC.  
 NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

---

The following table summarizes the estimated fair value of the assets acquired and liabilities assumed at the date of acquisition:

	(IN THOUSANDS)
	-----
Total consideration:	
Common stock issued, net of estimated registration costs of \$295,000	\$ 17,203
Cash paid to stockholders	8,000
Balance on line-of-credit	251
Transaction costs accrued	412
Transaction costs paid	1,459
	-----
Total purchase consideration	27,325
	=====
Allocation of the purchase consideration	
Current assets (including cash of \$485), exclusive of inventory	2,513
Inventory	1,983
Fixed assets	109
Long-term assets	14
Identifiable intangible assets	17,160
In-process research and development	1,600
Goodwill	5,772
	-----
Total assets acquired	29,151
Fair value of liabilities assumed	(1,826)
	-----
Fair value of assets acquired and liabilities assumed	\$ 27,325
	=====

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

The following are identified intangible assets acquired and the respective estimated periods over which the assets will be amortized:

	AMOUNT (IN THOUSANDS)	WEIGHTED AVERAGE AMORTIZATION PERIOD (IN YEARS)
	-----	-----
Core/Developed Technology	\$17,160	3.78
In-process Research & Development	\$1,600	--

The core/developed technology, comprised of the combined value of Sirius' product lines and related patents, trademarks/trade names, as applicable, is being amortized over its useful life, based upon the pattern in which the expected benefits will be realized, or on a straight-line basis, whichever is greater. The values of the intangible assets acquired were determined using projections of revenues and expenses specifically attributed to the intangible assets. The income streams were then discounted to present value using estimated risk adjusted discount rates. The intangible assets were valued using the income approach, specifically the excess earnings method. The key assumptions used in valuing the intangible assets are discount rates of 17% for core/developed technology and 18% for in-process research and development and an assumed tax rate of 40%. The in-process research and development represents the estimated fair value based on risk-adjusted cash flows related to product development projects. At the date of

9

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

-----

acquisition, the development of these projects had not yet reached technological feasibility and the research and development in progress had no alternative future uses. Accordingly, these costs were expensed as of the acquisition date.

The results of operations of Sirius have been included in the financial statements of the Company since March 10, 2006, the date of acquisition. The following table reflects unaudited pro forma results of operations of the Company for the three months ended March 31, 2006 and 2005 assuming that the Sirius acquisition had occurred on January 1, 2006 and January 1, 2005, respectively (in thousands, expect per share data):

FOR THE  
THREE MONTHS ENDED  
MARCH 31

-----

2006	2005
------	------

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

	-----	-----
Revenues	\$ 7,668,180	\$ 5,204,672
Net loss	(3,195,324)	(6,045,762)
Net loss per share	\$ (0.16)	\$ (0.31)

The pro-forma net loss and net loss per share for the three months ended March 31, 2006 and 2005 excludes the impact of a of \$1.6 million charge related to purchased in-process research and development from the Sirius acquisition due to its non-recurring nature.

4) GOODWILL AND INTANGIBLE ASSETS

Under Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets" ("SFAS No 142"), goodwill and certain intangible assets are deemed to have indefinite lives and are no longer amortized, but are reviewed at least annually for impairment. Other identifiable intangible assets are amortized over their estimated useful lives. SFAS No. 142 requires that goodwill be tested for impairment annually, utilizing the "fair value" methodology. The Company has adopted December 1st as the date of the annual impairment test for goodwill.

The following is a summary of goodwill and intangible assets as March 31, 2006 (in thousands):

	GROSS CARRYING VALUE	ACCUMULATED AMORTIZATION	NET BOOK VALUE
Goodwill	\$ 5,773	--	\$ 5,773
Amortizable intangible assets:			
Core/Developed Technology	17,160	(102)	17,058
Total	\$22,933	\$ (102)	\$22,831

-----

All goodwill is associated with the Non-Photodynamic Therapy (Non-PDT) Drug Products operating segment (see Note 11). Amortization expense, included in

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

marketing and sales in the accompanying Condensed Consolidated Statements of Operations, related to intangible assets was \$102,000 for the first quarter of 2006. Amortization expense related to intangible assets is expected to be approximately \$1.3 million for the remainder of 2006 and approximately \$2.8 million, \$3.3 million, \$3.4 million, \$3.2 million and \$1.3 million for the years ending December 31, 2007, 2008, 2009, 2010 and 2011, respectively.

### 5) MARKETABLE SECURITIES

The Company's investment securities consist of securities of the U.S. government and its agencies, and investment grade corporate bonds, all classified as available for sale. As of March 31, 2006, current yields range from 2.35% to 7.43% and maturity dates range from April 1, 2006 to June 15, 2008. The estimated fair value and cost of marketable securities at March 31, 2006 and December 31, 2005 are as follows:

	MARCH 31, 2006			
	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR VALUE
United States government securities	\$ 9,874,071	\$ 158	(\$ 82,774)	\$ 9,791,455
Corporate securities	9,228,296	213	(43,126)	9,185,383
	-----	-----	-----	-----
Total marketable securities available for sale	\$19,102,367	\$ 371	\$ (125,900)	\$18,976,838
	=====	=====	=====	=====

	DECEMBER 31, 2005			
	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR VALUE
United States government debt securities	\$19,857,171	\$ 3,732	(\$ 72,243)	\$19,788,660
Investment grade corporate debt securities	10,818,063	15,136	(42,373)	10,790,826
	-----	-----	-----	-----
Total marketable securities available for sale	\$30,675,234	\$ 18,868	(\$ 114,616)	\$30,579,486
	=====	=====	=====	=====

Net unrealized gains and losses on such securities as of March 31, 2006 and December 31, 2005 was (\$125,529) and (\$95,748), respectively, and has been recorded in accumulated other comprehensive income, which is reported as part of shareholder's equity in the Condensed Consolidated Balance Sheets.

Realized gains on sales of marketable securities were \$14,000 and \$5,000 for the three months ended March 31, 2006 and 2005, respectively.

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Because the Company has the ability and intent to hold its investments until a recovery of fair value, which may be maturity, the Company does not consider investments with unrealized losses to be other-than-temporarily impaired at March 31, 2006.

11

DUSA PHARMACEUTICALS, INC.  
 NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

### 6) CONCENTRATION OF CREDIT RISK

The Company invests cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. The Company manages the credit risk associated with its investments in marketable securities by investing in U.S. government securities and investment grade corporate bonds.

The Company is also exposed to concentration of credit risk related to accounts receivable that are generated from its distributors and customers. To manage credit risk, the Company performs regular credit evaluations of its customers' and provides allowances for potential credit losses, when applicable. Concentrations of credit risk in the Company's total revenues for the three-months ended March 31, 2006 and 2005, and accounts receivable as of March 31, 2006 and December 31, 2005 are as follows:

	% OF REVENUE			
	THREE-MONTHS ENDED		% OF ACCOUNTS RECEIVABLE	
	MARCH 31, 2006	MARCH 31, 2005	MARCH 31, 2006	DECEMBER 31, 2005
Third-party distributor A	12%	-	49%	-
Third-party distributor B	8%	13%	6%	6%
Third-party distributor C	3%	-	9%	-
Third-party distributor D	-	15%	-	-
Third-party other distributors	4%	-	8%	-
Direct customers	73%	72%	28%	94%
Total	100%	100%	100%	100%

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

### 7) INVENTORY

Inventory consisted of the following:

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

	MARCH 31, 2006	DECEMBER 31, 2005
	-----	-----
Finished goods	\$2,540,918	\$1,004,772
BLU-U(R) evaluation units	329,160	292,129
Work in process	197,795	60,805
Raw materials	470,921	503,087
	-----	-----
	\$3,538,794	\$1,860,793
	=====	=====

12

DUSA PHARMACEUTICALS, INC.  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

-----

BLU-U(R) commercial light sources placed in physicians' offices for an initial evaluation period are included in inventory until all revenue recognition criteria are met. The Company amortizes the cost of the evaluation units during the evaluation period to cost of goods sold using an estimated useful life for the equipment of 3 years.

8) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	MARCH 31, 2006	DECEMBER 31, 2005
	-----	-----
Research and development costs	\$ 360,439	\$ 347,220
Marketing and sales costs	358,907	173,092
Product related costs	930,408	667,388
Legal and other professional fees	1,319,795	488,401
Employee benefits	265,331	225,628
Other expenses	157,196	93,950
	-----	-----
	\$3,392,076	\$1,995,679
	=====	=====

9) STOCK-BASED COMPENSATION

Under the Company's 1996 Omnibus Plan ("Omnibus Plan"), as amended, the Company may grant stock-based awards to purchase up to a maximum of 20% of the Company's common stock outstanding or a maximum of 3,343,874 shares. The Omnibus Plan is administered by a committee ("Committee") established by the Board of Directors. The Omnibus Plan enables the Committee to grant non-qualified stock options ("NQS"), incentive stock options ("ISO"), stock appreciation rights, restricted stock, or other securities determined by the Company, to directors,

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

employees and consultants.

Non-Qualified Stock Options - All the NQSOs granted under the Omnibus Plan have an expiration period not exceeding ten years and are issued at a price not less than the market value of the common stock on the grant date. NQSO grants to employees become exercisable at a rate of one quarter of the total granted on each of the first, second, third and fourth anniversaries of the grant date, subject to satisfaction of certain conditions involving continuous periods of service. In addition, the Company initially grants each individual who agrees to become a director 15,000 NQSO to purchase common stock of the Company. Thereafter, each director reelected at an Annual Meeting of Shareholders will automatically receive an additional 10,000 NQSO on June 30 of each year. Grants to directors immediately vest on the date of the grant.

Incentive Stock Options - ISOs granted under the Omnibus Plan have an expiration period not exceeding ten years (five years for ISOs granted to employees who are also ten percent shareholders) and are issued at a price not less than the market value of the common stock on the grant date. These options become exercisable at a rate of one quarter of the total granted on each of the first, second, third and fourth anniversaries of the grant date, subject to satisfaction of certain conditions involving continuous periods of service.

13

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

A summary of stock option transactions for the Omnibus Plan follows:

	NUMBER OF SHARES (IN THOUSANDS)	WEIGHTED AVERAGE EXERCISE PRICE
	-----	-----
OUTSTANDING AT DECEMBER 31, 2005	2,850,250	\$11.85
Options granted	255,500	6.82
Options cancelled/forfeited/expired	(315,125)	8.18
Options exercised	(10,750)	3.62
OUTSTANDING AT MARCH 31, 2006	2,779,875	11.81
EXERCISABLE AT MARCH 31, 2006	1,930,381	\$13.19

The weighted average remaining contractual term was approximately 6.1 years for stock options outstanding and approximately 4.8 years for stock options exercisable as of March 31, 2006.

The total intrinsic value (the excess of the market price over the exercise price) was approximately \$2,030,000 and \$1,554,000 for stock options outstanding and exercisable, respectively, as of March 31, 2006. The total intrinsic value for stock options exercised in 2006 was approximately \$39,000. At March 31,

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

2006, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was \$4,024,479, which was expected to be recognized over a weighted average period of 2.4 years.

The amount of cash received from the exercise of stock options in 2006 was approximately \$39,000 and the related tax deduction was approximately \$12,000 in 2006.

### Share-Based Compensation Information under FAS 123R

The fair value of stock options granted was estimated on the date of grant using a Black-Scholes option valuation model that uses the assumptions in the following table. The Company's employee stock options have various restrictions that reduce option value, including vesting provisions and restrictions on transfer and hedging, among others, and are often exercised prior to their contractual maturity.

14

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

---

The weighted-average estimated fair value of employee stock options granted during the three months ended March 31, 2006 was \$4.71 per share using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	THREE MONTHS ENDED MARCH 31, 2006
Volatility	63.7 %
Risk-free interest rate	4.69 %
Expected dividend yield	0 %
Expected life-directors and officers	8.5 years
Expected life-non-officer employees	6.3 years

The Company used a combination of historical and implied volatility of market-traded options in the Company's stock for the expected volatility assumption input to Black-Scholes model, consistent with the guidance in FAS 123R and the Securities and Exchange Commission's Staff Accounting Bulletin No. 107. Prior to the first quarter of fiscal 2006, the Company had used its historical stock price for purposes of its pro forma information. The decision to use a combination of historical and implied volatility data to estimate expected volatility was based upon the availability of actively traded options on the Company's stock and the Company's assessment that this is more representative of future stock price trends than historical volatility alone.

The risk-free interest rate assumption is based upon observed interest rates appropriate for the term of the Company's employee stock options. The expected life is based on the Company's historical option cancellation and employee exercise information. The expected life of employee stock options



## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

represents the weighted-average period the stock options are expected to remain outstanding post-vesting. In calculating the expected life of the options for 2006, the Company classified its grantee population into two groups, directors and officers and non-officer employees. As share-based compensation expense recognized in the Consolidated Statements of Operations for the first quarter of fiscal 2006 is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the first quarter of 2006, departure rates, defined as the annual percentage of options forfeited or exercised early due to departure, were estimated to be approximately 2.96% for officers and directors and 10.53% for non-officer employees based on historical experience. Prior to the first quarter of 2006, the Company had used a company-wide weighted average expected life of five years for grants in 2005, 2004 and 2003 and seven years for grants in 2002.

15

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

-----

Total estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the three months ended March 31, 2006 was comprised as follows:

	THREE MONTHS ENDED MARCH 31, 2005 -----
Cost of product revenues	\$ 19,000
Research and development	81,000
Selling and Marketing	69,000
General & Administrative	149,000
	-----
Share-based compensation expense	\$318,000
	-----
Net share-based compensation expense, per common share:	
Basic and diluted	\$ 0.02 =====

### Pro Forma Information under FAS 123 for Periods Prior to Fiscal 2006

Prior to adopting the provisions of FAS 123R, the Company recorded estimated compensation expense for employee stock options based upon their intrinsic value on the date of grant pursuant to Accounting Principles Board Opinion 25 (APB 25), "Accounting for Stock Issued to Employees" and provided the required pro forma disclosures of FAS 123. Because the Company established the exercise price based on the fair market value of the Company's stock at the date of grant, the stock options had no intrinsic value upon grant, and therefore no

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

estimated expense was recorded prior to adopting FAS 123R.

For purposes of pro forma disclosures under FAS 123 for the three months ended March 31, 2005, the estimated fair value of the stock options was amortized to expense over the stock options' vesting periods. The pro forma effects of recognizing estimated compensation expense under the fair value method on net loss and loss per common share for the three months ended March 31, 2005 were as follows:

16

DUSA PHARMACEUTICALS, INC.  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

	THREE MONTHS ENDED MARCH 31, 2005
Net loss, as reported	\$ (4,331,615)
Deduct: Share-based employee compensation expense determined under the fair value based method for all awards	(322,173)
	-----
Pro forma net loss	\$ (4,653,788)
	=====
Loss per common share:	
Basic and diluted loss per share-- as reported	\$ (0.26)
Basic and diluted loss per share -- pro forma	\$ (0.28)

The pro forma effects of estimated share-based compensation expense on net loss and loss per common share for the three months ended March 31, 2005 were estimated at the date of grant using the Black-Scholes option-pricing model based on the following assumptions (annualized percentages):

Volatility	72.4 %
Risk-free interest rate	4.14 %
Dividend yield	0.0 %
Expected life (years)	5.0

The Black-Scholes weighted average estimated fair value of stock options granted during the three months ended March 31, 2005 was \$6.95 per share.

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

### 10) BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per common share is based on the weighted-average number of shares outstanding during each period. For the three months ended March 31, 2006, and 2005, stock options, warrants and rights totaling approximately 3,080,000 and 3,386,000 shares, respectively, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive. The 2,396,245 shares issued in the Sirius acquisition, which includes 422,892 shares placed into the liability escrow account, are included in the weighted average number of shares outstanding from the date of issuance, March 10, 2006.

17

DUSA PHARMACEUTICALS, INC.  
 NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

---

### 11) SEGMENT REPORTING

Beginning in the first quarter of 2006 with the acquisition of Sirius Laboratories, the Company has two reportable segments, Photodynamic Therapy (PDT) Drug and Device Products and Non-Photodynamic Therapy (Non-PDT) Drug Products. Operating segments are defined as components of the Company for which separate financial information is available to manage resources and evaluate performance regularly by the chief operating decision maker. The table below presents the revenues, costs of revenues and gross margins attributable to these operating segments for the periods presented. The Company does not allocate selling and marketing and general and administrative expenses to its business unit segments, because these activities are managed at a corporate level.

	QUARTER ENDED	
	MARCH 31, 2006	MARCH 31, 2005
<b>REVENUES</b>		
PDT Drug & Device Product Revenues	\$3,853,000	\$3,369,000
Non-PDT Drug Product Revenues	898,000	--
	4,751,000	3,369,000
	=====	=====
<b>COSTS OF REVENUES</b>		
PDT Drug & Device Cost of Product Revenues and Royalties	1,508,000	2,004,000
Non-PDT Drug Cost of Product Revenues and Royalties	283,000	--
	-----	-----

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Total Costs of Product Revenues and Royalties	1,791,000	2,004,000
	=====	=====
GROSS MARGINS		
PDT Drug and Device Product Gross Margin	2,344,000	1,365,000
Non-PDT Drug Product Gross Margin	616,000	--
	-----	-----
Total Gross Margins	\$2,960,000	\$1,365,000
	=====	=====

During the quarters ended March 31, 2006 and 2005, the Company derived revenues from the following geographies (as a percentage of product revenues):

	2006	2005
	----	----
United States	92%	87%
Canada	8%	13%
	---	---
Total	100%	100%

18

DUSA PHARMACEUTICALS, INC.  
 NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

---

Asset information by operating segment is not reported to or reviewed by the chief operating decision makers and, therefore, we have not disclosed asset information for each operating segment.

12) COMPREHENSIVE LOSS

For the three months ended March 31, 2006 and 2005, comprehensive loss consisted of the following:

	MARCH 31, 2006 (UNAUDITED)	MARCH 31, 2005 (UNAUDITED)
	-----	-----
NET LOSS	\$ (4,640,309)	\$ (4,331,615)
Change in net unrealized gains and losses on marketable securities available for sale	(29,781)	(227,816)
	-----	-----
COMPREHENSIVE LOSS	\$ (4,670,090)	\$ (4,559,431)

=====

Accumulated other comprehensive income consists of net unrealized gains and losses on marketable securities available for sale, which is reported as part of shareholders' equity in the Condensed Consolidated Balance Sheets.

13) COMMITMENTS AND CONTINGENCIES

LEGAL MATTERS:

River's Edge

On March 28, 2006, a lawsuit was filed by River's Edge Pharmaceuticals, LLC against us alleging, among other things, that, prior to the merger, Sirius Laboratories, Inc. agreed to authorize River's Edge to market a generic version of Nicomide(R), and that the United States patent covering Nicomide(R) issued to Sirius in December 2005 is invalid. The declaratory judgment suit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division. Nicomide is one of the key products DUSA acquired from Sirius in its Merger. River's Edge has also filed an application with the U.S. Patent and Trademark Office requesting reexamination of the Nicomide patent. On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that a River's Edge niacinamide product infringes U.S. patent 6,979,468. In response to a motion put forward with the filing by us, the Court granted an expedited hearing date of May 5, 2006 in order to hear arguments on a motion for preliminary injunction to enjoin River's Edge from selling its alternative product to Nicomide(R). The court has not yet ruled on this motion. An unfavorable ruling in the preliminary injunction hearing, allowing River's Edge niacinamide product to remain on the market for any significant length of time, could have a material impact on the Company's revenues, results of operations and liquidity.

The Company has not accrued any amounts for potential contingencies as of March 31, 2006, as these amounts are neither probable nor estimable.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

-----

14) SUBSEQUENT EVENT

In March 2006 the Board of Directors approved the 2006 Equity Compensation Plan (the "2006 Plan") and it has been submitted to shareholders for approval. If approved by the shareholders, the 2006 Plan will provide for the grant of incentive stock options, nonqualified stock options, stock awards, stock appreciation rights and other types of incentives to (i) our employees, consultants, and advisors; (ii) the employees, consultants, and advisors of the Company's parents, subsidiaries, and affiliates; and (iii) and the Company's non-employee directors. The maximum aggregate number of shares of the Company's common stock that may be issued under the 2006 Plan under any form of award may not exceed the lesser of: (i) 20% of the total number of shares of the Company's common stock issued and outstanding at any given time less the number of shares issued and outstanding under any other equity compensation plan of the Company at such time; or (ii) 3,888,488 shares less the number of shares issued and outstanding under any other equity compensation plan of the Company from time to time. The maximum number of shares of common stock that may be granted to any

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

individual during any calendar year is 300,000.

20

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

#### OVERVIEW

DUSA is an integrated dermatology specialty pharmaceutical company focused primarily on the development and marketing of our Levulan(R) Photodynamic Therapy (PDT) technology platform, and complementary dermatology products. Our current marketed products include Levulan(R) Kerastick(R) 20% Topical Solution with PDT, the BLU-U(R) light source, Nicomide(R), Nicomide-T(R) and the AVAR(R) line of products. We acquired Nicomide(R), Nicomide-T(R), the AVAR(R) line of products, among others, and certain product candidates in early stages of development, which target the treatment of acne vulgaris and acne rosacea, as well as psoriasis, in connection with our recent merger with Sirius Laboratories, Inc., or Sirius, which was completed on March 10, 2006.

Our drug, Levulan(R) brand of aminolevulinic acid HCl, or ALA, is being used with light, for use in a broad range of medical conditions. When we use Levulan(R) and follow it with exposure to light to treat a medical condition, it is known as Levulan(R) photodynamic therapy, or Levulan(R) PDT. When we use Levulan(R) and follow it with exposure to light to detect medical conditions it is known as Levulan(R) photodetection, or Levulan(R) PD.

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

Sirius, a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. We believe this acquisition will allow us to expand our product portfolio, capitalize on cross-selling and marketing opportunities, increase our sales force size, as well as provide a pipeline of new products.

Nicomide(R) is an oral prescription vitamin supplement, and Nicomide-T(R) is a topical cosmetic product. Both products target the acne and acne rosacea markets. Acne rosacea is a condition that primarily affects the skin of the face and typically first appears between the ages of 30 and 60 as a transient flushing or blushing on the nose, cheeks, chin or forehead, progressing in many patients to a papulopustular form clinically similar to acne vulgaris (inflammatory acne). Given its resemblance to inflammatory acne, and the general public's limited knowledge of rosacea, the condition is frequently mistaken by patients as adult acne. If untreated, rosacea has the tendency to worsen over time, although it can also wax and wane. The AVAR line of products include a number of leave-on and cleanser formulations of sodium sulfacetamide and sulphur, a drug combination long known to have anti-acne, anti-inflammatory properties.

We are a vertically integrated company, primarily responsible for regulatory, sales, marketing, customer service, manufacturing of our Kerastick(R), and other related product activities. Our current objectives include increasing the sales of our non-PDT products in the United States and our PDT products in the United States, Canada and Latin America, integrating the operations of Sirius, continuing our efforts of exploring partnership opportunities for Levulan(R) PDT for non-dermatology indications, and for dermatology in Europe and elsewhere, and continuing our clinical development programs for our Levulan(R) PDT facial photodamage and moderate to severe acne indications. 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(R) Kerastick(R) in Mexico, Central and South America. During 2004 we signed clinical trial agreements with the National Cancer Institute, or NCI, Division of Cancer Prevention, or DCP, for the clinical development of Levulan(R) PDT for the treatment of high-grade dysplasia, or HGD, within Barrett's Esophagus, or BE, and oral cavity dysplasia treatment, and are working with the NCI DCP to advance the development of these programs. In addition, we continue to support independent investigator trials to advance research in the use and applicability of Levulan(R) PDT for other indications in dermatology, and selected internal indications.

We are developing Levulan(R) 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 Levulan(R) and related processes and improvements.

In the United States, AVAR(R), AVAR Green(R), AVAR-e(R), AVAR-e Green(R), AVAR Cleanser(R), BLU-U(R), DUSA(R), DUSA Pharmaceuticals, Inc.(R), Levulan(R), Kerastick(R), METED(R), Nicomide(R), Nicomide-T(R), Psoriacap(R) and Psoriatec(R) 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.

Historically, we devoted most of our resources to fund research and development efforts in order to advance the Levulan(R) PDT/PD technology platform. In addition, we are continuing to evaluate and develop several potential products that we acquired in our merger with Sirius which target patients with acne.

As of March 31, 2006, we had an accumulated deficit of approximately \$94,178,000. 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, increase sales of the Sirius products.

We operate in a highly regulated and competitive environment. Our competitors include larger fully integrated pharmaceutical companies and biotechnology companies. Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals, and greater manufacturing and sales and marketing capabilities than we do.

Marketing and sales activities since the October 2003 launch of our sales force have resulted in significant additional revenues as well as expenses. Kerastick(R) unit sales to end-users were 32,934 and 28,704 for the three months ended March 31, 2006 and 2005, respectively, consisting of 28,080 and 24,900 units sold in the U.S., and 4,854 and 3,804 units sold in Canada, in the three months ended March 31, 2006 and 2005, respectively.

The net number of BLU-U(R) units placed in doctors' offices during the three months ended March 31, 2006 and 2005 was 104 and 131, respectively, including 6 and 31 placed in Canada in the three months ended March 31, 2006 and 2005, respectively. As of March 31, 2006 and December 31, 2005 there were 1,441 and 1,337 units in doctor's offices, consisting of 1,240 and 1,142 in the U.S. and 201 and 195 in Canada, respectively. In addition, during 2005 we began a BLU-U(R) marketing effort to allow prospective customers to evaluate a BLU-U for a short period of time prior to making a purchase decision. BLU-U(R) commercial light sources placed in physicians' offices pursuant to the Company's BLU-U(R) evaluation program are classified as inventory in the accompanying Consolidated Balance Sheets. The Company amortizes the cost of the evaluation units during the evaluation period to cost of goods sold using an estimated useful life for the equipment of 3 years.

Net revenues generated by the products acquired as part of our merger with Sirius totaled \$898,000 for the period March 10, 2006 through March 31, 2006. The substantial majority of these revenues were from sales of Nicomide(R).

We have continued our efforts to penetrate the market by expanding our sales coverage in key geographic locations. We are encouraged with the year-over-year increase in sales, as well as the positive feedback we continue to receive from physicians across the country that believe Levulan(R) PDT should become a routine part of standard dermatological practice. We are currently exploring opportunities to develop, market, and distribute our Levulan(R) PDT platform in Europe and/or other countries outside of the United States, Canada and Latin America following our recently completed agreement with Stiefel Laboratories, Inc. We also market and sell the products acquired as part of our merger with Sirius in the United States.

We cannot predict when product sales may offset the costs associated with our efforts to penetrate the PDT market but we expect that following integration of Sirius' operations we will approach positive cash flow from operations more quickly than we otherwise would have. We are aware that physicians have been using Levulan(R) with the BLU-U(R) using short incubation, and with light devices manufactured by other companies, and for uses other than our FDA-approved use. While we are not permitted to market our products for so-called 'off-label' uses, we believe that these activities are positively affecting the sales of our products.

We believe that some compounding pharmacies are exceeding the legal limits for their activities, including manufacturing and/or selling quantities of ALA in circumstances which may be inducing purchasers to infringe our intellectual property. We believe that these activities are negatively impacting our sales growth. Therefore in December 2004 and in January 2005, we filed lawsuits against two compounding pharmacies and several physicians. Most of these lawsuits have been settled favorably to us and we will continue to vigilantly protect our intellectual property, as we become aware of other infringers. See section entitled "Part II. Other Information, Item 1. Legal Proceedings".



In connection with our merger with Sirius, we have assumed a number of key agreements relating to the manufacture and supply of the Sirius current and potential products, and relating to the development of certain product candidates. We intend to continue to use third-party manufacturers for such products. The Sirius products are distributed through several major wholesalers in the United States pursuant to customary industry arrangements. The foregoing key agreements are discussed herein under the caption "Contractual Obligations and Other Commercial Commitments."

Certain of the Sirius products acquired in connection with the merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications. FDA regulates such products under its compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, 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. We believe that so long as we comply with applicable manufacturing and labeling standards we will be consistent with FDA's current enforcement policy. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual products. If the FDA were to do so, we may be required to seek FDA approval for these products, market these products as over-the-counter products or as dietary supplements under applicable legislation, or withdraw such products from the market. As a result of our due diligence efforts, including inspection of the third-party manufacturers, we are working with the supplier of the AVAR(R) line of products to address certain manufacturing concerns that were identified. There is a risk that inventory of some of these products could become in short supply while such concerns are being addressed.

We are also continuing to seek to acquire and/or license additional dermatology products that complement our current product portfolio that would provide our sales force with additional complementary products to sell in the near to medium term.

On March 28, 2006, a lawsuit was filed by River's Edge Pharmaceuticals, LLC against us alleging, among other things, that, prior to the merger, Sirius Laboratories, Inc. agreed to authorize River's Edge to market a generic version of Nicomide(R), and that the United States patent covering Nicomide(R) issued to Sirius in December, 2005 is invalid. Nicomide is one of the key products DUSA acquired in the merger with Sirius. The declaratory judgment suit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division. River's Edge has also filed an application with the U.S. Patent and Trademark Office requesting reexamination of the Nicomide patent. On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that a River's Edge niacinamide product infringes U.S. patent 6,979,468 and on April 26, 2006 we filed a Motion to Dismiss the Georgia action. In response to a motion put forward with the filing by us, the New Jersey court granted an expedited hearing date of May 5, 2006 in order to hear arguments on a motion for preliminary injunction to enjoin River's Edge from selling its alternative product to Nicomide(R). The court has not yet ruled on this motion.

We continue to believe that issues related to reimbursement have negatively impacted the economic competitiveness of our therapy with other AK therapies and have hindered its adoption. We support efforts to improve reimbursement levels to physicians. Such efforts included working with the Centers for Medicare and Medicaid Services, or CMS, and the

American Academy of Dermatology, or AAD, on matters related to the PDT procedure fee and the separate drug reimbursement fee. Doctors can also bill for any applicable visit fees. Effective January 1, 2006, the CMS average national reimbursement for the use of Levulan(R) PDT for AK's Ambulatory Patient Classifications code ("APC code") was increased. The APC code is used by many hospitals. The CMS Current Procedural Terminology code ("CPT code"), which is used by private physician clinics using Levulan(R) PDT for treating AKs was not increased for 2006 (i.e. it will be unchanged from 2005 levels). We had expected reimbursement under the CPT code to increase on January 1, 2006; however, we now believe that an increase will not be effective until at least January 1, 2007. We are aware that some physicians believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices. We continue to support ongoing efforts that might lead to further increases in reimbursement in the future; and intend to continue supporting efforts to seek reimbursement for our FDA-cleared use of the BLU-U(R) alone in the treatment of mild to moderate inflammatory acne of the face.

Most major private insurers have approved coverage for our AK therapy. We believe that due to these efforts, plus future improvements, along with our education and marketing programs, a more widespread adoption of our therapy should occur over time.

As of March 31, 2006, we had a staff of 80 full-time employees and 2 part-time employees, as compared to 64 full-time employees and 2 part-time employees at the end of 2005, including marketing and sales, production, maintenance, customer support, and financial operations personnel, as well as those who support research and development programs for dermatology and internal indications. During the first quarter of 2006, with the closing of the Sirius merger, we expanded our sales capacity to 33 from 26 at the end of 2005. Also, as previously reported in April 2006, William F. O'Dell joined the Company as our Executive Vice President of Sales and Marketing. We may add and/or replace employees during 2006 as business circumstances deem necessary.

#### CRITICAL ACCOUNTING POLICIES

Our accounting policies are disclosed in Note 2 to the Notes to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2005. 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. We consider the following policies and estimates to be critical to our financial statements.

#### Revenue Recognition

PDT Drug and Device Products. Revenues on the Kerastick (R) and BLU-U(R) product sales are recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and collection is probable. Product sales made through distributors, historically, have been recorded as deferred revenue until the product was sold by

the distributors to the end users because we did not have sufficient history with our distributor to be able to reliably estimate returns. Beginning in the first quarter of 2006, we began recognizing revenue as product is sold to

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

distributors because we now believe have sufficient history to reliably estimate returns from distributors. Certain device units are held by physicians for a trial period. No revenue is recognized on these units until the physician elects to purchase the equipment and all other revenue recognition criteria are met.

**Non-PDT Drug Products.** We recognize revenue for these products in accordance with SAB No. 101, Revenue Recognition in Financial Statements, as amended by SAB No. 104, Revenue Recognition. Our accounting policy for revenue recognition has a substantial impact on our reported results and relies on certain estimates that require difficult, subjective and complex judgments on the part of management. We recognize revenue for sales when substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment to wholesale customers, with the exceptions described below. Revenue is recognized net of revenue reserves, which consists of allowances for discounts, returns, rebates chargebacks and fees paid to wholesalers under distribution service agreements.

In the case of sales made to wholesalers as a result of incentives and that are in excess of the wholesaler's ordinary course of business inventory level, substantially all the risks and rewards of ownership do not transfer upon shipment and, accordingly, such sales are recorded as deferred revenue and the related costs as deferred cost of revenue until the product is sold through to the wholesalers' customers on a FIFO basis.

### Sales Return Accrual

We account for sales returns in accordance with SFAS No, 48 by establishing an accrual in an amount equal to our estimate of sales recorded for which the related products are expected to be returned. We determine the estimate of the sales return accrual primarily based on historical experience regarding sales returns, but also by considering other factors that could impact sales returns. These factors include levels of inventory in the distribution channel, estimated shelf life, product recalls, product discontinuances, price changes of competitive products, introductions of generic products and introductions of competitive new products. It is our policy to accept returns of Non-PDT Drug products when product is within six months of expiration. We consider all of these factors and adjust the accrual periodically to reflect actual experience.

### Inventory

Inventories are stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Inventories are continually reviewed for slow moving, obsolete and excess items. Inventory items identified as slow-moving are evaluated to determine if an adjustment is required. Additionally, our industry is characterized by regular technological developments that could result in obsolete inventory. Although we make every effort to assure the reasonableness of our estimates, any significant unanticipated changes in demand, technological development, or significant changes to our business model could have a significant impact on the value of our inventory and our results of operations. We use sales projections to estimate the appropriate level of inventory reserves, if any, that are necessary at each balance sheet date.

### Valuation of Long-Lived and Intangible Assets

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

We review our long-lived and intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of a long-lived or intangible asset may not be recoverable or that the useful lives of these assets are no longer appropriate. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. When it is determined that the carrying value of a long-lived asset is not recoverable, the asset is written down to its estimated fair value on a discounted cash flow basis.

Goodwill is deemed to have an indefinite life and is no longer amortized, but is reviewed at least annually for impairment, utilizing the "fair value" methodology. The Company has adopted December 1st as the date of the annual impairment test for goodwill.

### Stock-Based Compensation

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123(R), "Share-Based Payment," a revision of SFAS Statement No. 123. We adopted SFAS 123(R) effective January 1, 2006, using the modified prospective application method, and beginning with the first quarter of 2006, we measure all employee share-based compensation awards using a fair value based method and record share-based compensation expense in our financial statements if the requisite service to earn the award is provided. The pro forma results and assumptions used in fiscal years 2005, 2004 and 2003 were based solely on historical volatility of our common stock over the most recent period commensurate with the estimated expected life of our stock options. The adoption of SFAS No. 123(R) will not affect our net cash flow, but it will have a material negative impact on our results of operations. In accordance with SFAS 123R, we will recognize the expense attributable to stock awards that are granted or vest in periods ending subsequent to December 31, 2005 in the accompanying condensed consolidated statements of operations.

In connection with our adoption of SFAS 123R, we refined our valuation assumptions and the methodologies used to derive those assumptions; however, we elected to continue using the Black-Scholes option valuation model. Concurrent with our adoption of SFAS 123R, we determined that a combination of historical and implied volatility for traded options on DUSA's stock would be a better measure of market conditions and expected volatility than historical volatility of our common stock alone. Previously, we used historical stock price volatility as it was the most reliable source of volatility data. We estimate the weighted-average expected life of our stock-option awards based on historical cancellation and exercise data related to our stock-based awards as well as the contractual term and vesting terms of the awards. In calculating the expected life of the options for 2006, we classified our grantee population into two groups, directors and officers and non-officer employees. Prior to the first quarter of 2006, we had used a company-wide weighted average expected life of five years for grants in 2005, 2004 and 2003 and seven years for grants in 2002. Stock-based compensation expense related to stock options is recognized net of estimated forfeitures. We estimated forfeitures based on our historical experience. In the first quarter of 2006, departure rates, defined as the annual percentage of options forfeited or exercised early due to departure, were estimated to be approximately 2.96% for officers and directors and 10.53% for non-officer employees.

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

REVENUES -- Total revenues for the three month period ended March 31, 2006 were \$4,751,000 as compared to \$3,369,000 in 2005, and were comprised of the following:

	THREE MONTHS ENDED MARCH 31, (UNAUDITED)		
	2006	2005	INCREASE/ (DECREASE)
PDT DRUG & DEVICE PRODUCT REVENUES			
KERASTICK(R) PRODUCT REVENUES			
United States	\$ 2,810,000	\$ 2,249,000	\$ 561,000
Canada	343,000	261,000	82,000
Subtotal Kerastick(R) product revenues	3,153,000	2,510,000	643,000
BLU-U(R) PRODUCT REVENUES			
United States	669,000	686,000	(17,000)
Canada	31,000	173,000	(142,000)
Subtotal BLU-U(R) product revenues	700,000	859,000	(159,000)
TOTAL PDT DRUG & DEVICE PRODUCT REVENUES	\$ 3,853,000	\$ 3,369,000	\$ 484,000
TOTAL NON-PDT DRUG PRODUCT REVENUES	\$ 898,000	--	\$ 898,000
TOTAL PRODUCT REVENUES	\$ 4,751,000	\$ 3,369,000	\$ 1,382,000

For the three month period ended March 31, 2006 total PDT Drug and Device Product Revenues were \$3,853,000. This represents an increase of \$484,000 or 14% over the comparable 2005 total of \$3,369,000. The incremental revenue was driven by increased Kerastick(R) revenues which were partially offset by decreased BLU-U(R) revenues.

For the three month period ended March 31, 2006, Kerastick(R) revenues were \$3,153,000 representing a \$643,000 or 26% increase over the comparable 2005 total of \$2,510,000. Overall Kerastick(R) unit sales for the period were 32,934, including 28,080 sold in the United States and 4,854 sold to Coherent-AMT, our Canadian marketing and distribution partner. This represents an increase from 28,704 Kerastick(R) units sold in the three months ended March 31, 2005, including 24,900 sold in the United States and 3,804 sold in Canada by Coherent-AMT. Our average net selling price for the Kerastick(R) increased to \$95.73 in the first quarter of 2006 from

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

\$87.44 in the first quarter of 2005. Our average net selling price for the Kerastick(R) includes sales made directly to our end-user customers, as well as sales made to our distributors, both in the United States and Canada. The increase in 2006 Kerastick(R) revenues was driven mainly by increased sales volumes, an increase in our average unit selling price, a reduction in our overall sales volume discount programs, and increased levels of direct distribution to customers. Effective January 1, 2006, DUSA became the sole US distributor of the Kerastick(R).

For the three month period ended March 31, 2006, BLU-U(R) revenues were \$700,000 representing a \$159,000 or 19% decrease over the comparable 2005 total of \$859,000. The decrease in 2006 BLU-U(R) revenue was driven by lower overall sales volumes which were partially offset by an increase in our average selling price. There were 92 units sold for the three months ended March 31, 2006 versus 143 units sold in the comparable 2005 period. The 2006 total consists of 86 units sold in the United States and 6 sold in Canada to Coherent-AMT. The 2005 total consists of 112 units sold in the United States and 31 sold in Canada by Coherent-AMT. Our average selling price increased to \$7,496 for the three months ended March 31, 2006 from \$5,977 in the comparable 2005 period. During the fourth quarter of 2005, we introduced a BLU-U(R) evaluation program, which, for a limited number of BLU-U(R) units, allows customers to take delivery of a unit for a period of up to 4 months for private practitioners and up to one year for hospital clinics, before a purchase decision is required. At March 31, 2006, there were approximately 85 units in the field pursuant to this evaluation program. 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 3 years.

Non-PDT Drug Product Revenues reflect the revenues generated by the products acquired as part of our March 10, 2006 merger with Sirius Laboratories. Total revenues for the period March 10, 2006 through March 31, 2006 were \$898,000. The substantial majority of the Non-PDT product revenues were from sales of Nicomide(R).

The increase in our total revenues results from the acquisition of new products, as well as, the efforts of our sales force and related marketing and sales activities. With respect to United States sales, we increased our average selling prices, increased our direct selling efforts, became the sole US distributor of the Kerastick(R), and reduced our overall sales volume discount programs, all of which have had a positive impact on our average selling prices during 2006. 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 products by our existing customers, as well as the addition of new customers. However, should one or more generic niacinamide products remain on the market for any significant length of time, our revenues of Nicomide(R) could be significantly eroded, and our achievement of profitability would be delayed.

29

COST OF PRODUCT SALES AND ROYALTIES -- Cost of product sales and royalties for the three months ended March 31, 2006 were \$1,791,000 as compared to \$2,004,000 in 2005. A summary of the components of cost of product sales and royalties is provided below:

THREE MONTHS ENDED MA  
(UNAUDITED)

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

KERASTICK(R) COST OF PRODUCT REVENUES AND ROYALTIES	2006	2005
Direct Kerastick(R) Product Costs	\$455,000	\$580,000
Other Kerastick(R) Product costs including internal costs assigned to support products	312,000	272,000
Royalty and supply fees (1)	160,000	128,000
Subtotal Kerastick(R) Cost of Product Revenues and Royalties	\$927,000	\$980,000
BLU-U(R) COST OF PRODUCT REVENUES		
Direct BLU-U(R) Product costs	\$313,000	\$476,000
Other BLU-U(R) Product costs including internal costs assigned to support products; as well as costs incurred to ship, install and service the BLU-U(R) in physicians offices	268,000	548,000
Total Device cost of product revenues	\$581,000	\$1,024,000
TOTAL PDT DRUG & DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	\$1,508,000	\$2,004,000
TOTAL NON-PDT DRUG COST OF PRODUCT REVENUES AND ROYALTIES (2)	\$283,000	-
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$1,791,000	\$2,004,000

- 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(R) Kerastick(R) in Canada.
- 2) Non-PDT Drug Cost of Product Revenues and Royalties reflect the costs associated with the products acquired as part of our March 10, 2006 merger with Sirius.

30

MARGINS -- Total product margins for the three month period ended March 31, 2006 were \$2,960,000 as compared to \$1,365,000 for the comparable 2005 period, as shown below:

THREE MONTHS ENDED MARCH 31, (UNAUDITED)		
2006	2005	INCRE (DECR

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Kerastick(R) Gross Margin	\$2,226,000	71%	\$1,530,000	61%	\$
BLU-U(R) Gross Margin	119,000	17%	(165,000)	(19%)	
Total PDT Drug & Device Gross Margin	\$2,345,000	61%	\$1,365,000	41%	\$
Total Non-PDT Drug Gross Margin	\$615,000	69%	-	-	\$
TOTAL GROSS MARGIN	\$2,960,000	62%	\$1,365,000	41%	\$1,

For the three month period ended March 31, 2006 total PDT Drug and Device Product Margins were 61% versus 41% for the comparable 2005 period. The incremental margin was driven by positive margin gains on both the Kerastick(R) and BLU-U(R).

Kerastick(R) gross margins for the three month period ended March 31, 2006 were 71% versus 61% for the comparable 2005 period. Similar to the increase in revenues, the increase in margin is mainly attributable to an increase in our average unit selling price, increased levels of direct distribution to customers eliminating the cost of distributors; as well as a reduction in our overall sales volume discount programs. Our long-term goal is to achieve higher gross margins on Kerastick(R) sales which will be significantly dependent on increased volume.

BLU-U(R) margins for the three month period ended March 31, 2006 were 17% versus (19%) for the comparable 2005 period. The increase in margin is a result of an increase in the average selling price per unit; as well as, lower overall costs incurred to support the product line. Our short-term strategy is to at a minimum breakeven on device sales in an effort to drive Kerastick(R) sales volumes.

Non-PDT Drug Product Margins reflect the margin generated by the products acquired as part of our March 10, 2006 merger with Sirius Laboratories. Total margin for the period March 10, 2006 through March 31, 2006 was 69%. Non-PDT Drug Product Margins were negatively impacted by fair value accounting for the inventory acquired as part of the merger. We expect the purchase accounting adjustment will continue to effect gross margins for the next two quarters, and beyond that we expect gross margins on Non-PDT Drug Products to be in the 80% to 90% range.

RESEARCH AND DEVELOPMENT COSTS -- Research and development costs for the three month period ended March 31, 2006 were \$3,111,000 including \$1.6 million related to in-process research and development acquired as part of the acquisition of Sirius, as compared to \$1,596,000 in 2005. The increase was caused primarily by the recording of the acquired in-process research and development. During the fourth quarter of 2004, we initiated a DUSA-sponsored Phase II study of Levulan(R) PDT for the treatment of acne, the results of which were announced in February 2006. This 72 patient, investigator blinded study was designed to examine the effects of varying Levulan/vehicle incubation times prior to light treatment, namely 15, 60 and 120 minutes. Patients were all pre-treated with an acetone wash, and 18 subjects in each group received Levulan(R) plus the BLU-U(R) and six received BLU-U(R) alone. There were no formal placebo arms in this study. Up to four PDT treatments were given at 2-week intervals. The results of the study, determined at 4 weeks post-treatment, indicate that both Levulan(R) plus BLU-U(R) and BLU-U(R) alone



## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

appear to effectively reduce the number of both inflammatory and non-inflammatory acne lesions. There was a higher than anticipated 'BLU-U alone' response rate using this protocol, but the study was not sized to discern differences between the two types of treatment. At the Week 8 time point, the median percent decrease in total lesion count, for Levulan BLU-U and BLU-U alone was 61% and 80%, respectively. In the overall Acne Severity Assessment at the Week 8 time point, the Levulan plus BLU-U group showed 7/18 (39%) of subjects had at least 2 grades of improvement in their acne, compared with 4/6 (67%) in the BLU-U alone group.

In the subset of 28 patients with the most severe (Grade 4) acne, in general, the total lesion count at Week 8 decreased in the Levulan BLU-U group, whereas total lesion count at Week 8 increased in the BLU-U alone group. Treatment was well tolerated in both arms of the study with no unanticipated adverse events being reported. Side effects were minimal. We believe that the results of this study suggest that for future development of Levulan(R) PDT for acne, those patients with the most severe form(s) of acne should receive the greatest benefit. During September 2005, the FDA issued new draft guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. As a result of the issuance of this guidance, in combination with the results of our Phase II study, we believe that additional Phase II work will be required before we commence Phase III acne trials.

In February 2006, we reported the interim analysis results from our 80 patient, multi-center Phase II split-face clinical study of PDT in the treatment of photodamaged skin using the Company's Levulan(R) (aminolevulinic acid HCl, ALA) Kerastick(R) in combination with either our BLU-U(R), an Intense Pulsed Light, or IPL, or a Long Pulsed Dye Laser, or LPDL. The goal of the study was to guide selection of light source(s) for future PDT development in the treatment of photodamaged skin. Each patient served as his or her own control, using a 'split-face' design. Following skin cleansing with an acetone solution, and approximately 60 minutes of drug and/or vehicle incubation, light treatment with a fixed dose was given using one of the three light sources. Up to 3 treatments were given, 3 weeks apart. Interim results were assessed at Weeks 9 and 12. The protocol includes additional follow-up visits scheduled for Weeks 26 and 52.

At Week 12, Levulan PDT with BLU-U light demonstrated material improvement in photodamaged skin, in comparison to BLU-U and vehicle. Statistical significance in net changes from baseline scores was achieved in 2 parameters of photodamage, namely mottled pigmentation ( $p=0.0348$ ) and tactile roughness ( $p=0.0455$ ). In addition, the trend toward

32

improvement in a number of parameters was notably greater at Week 12 than Week 9, without any additional treatments with Levulan, which suggests that other parameters may also reach statistical significance over time. Specifically, Levulan with BLU-U showed greater improvements in mottled pigmentation, tactile roughness, fine wrinkling, sallowness and Global Photodamage Score (i.e. all the parameters that were measured except for telangiectasia (small blood vessels in the skin)), compared with areas treated with BLU-U and vehicle. BLU-U by itself is not known to have any effects on photodamaged skin.

We believe that these results support the conclusions of a prior independent study by Touma et al (2004), using Levulan with BLU-U versus BLU-U alone, that achieved statistical significance with the addition of Levulan in all photodamage parameters measured, other than deep wrinkles. In that study, the investigators treated more severely sun-damaged patients than were treated in our Phase II study, each with a minimum of 4 actinic keratoses. They also used twice the dose of blue light compared to the current study (10 vs. 5

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Joules/cm<sup>2</sup>), and drug incubation times ranging from 1-3 hours.

It is well known that IPL, by itself, improves photodamage, predominantly by targeting brown discoloration and red blood vessels. As we expected, at Week 12 in our study, the results show significant improvement in photodamage with IPL and vehicle, especially with respect to mottled pigmentation and telangiectasia. With the addition of Levulan, there was a trend toward greater improvement in all parameters of photodamage except for mottled pigmentation, although these trends did not achieve statistical significance at Week 12. However, the trend toward improvement was notably greater at Week 12 than Week 9 without any additional treatments with Levulan, and additional follow up is scheduled at weeks 26 and 52.

With LPDL, as would be expected, there was significant improvement in photodamaged skin with LPDL and vehicle, especially with respect to telangiectasia, the primary target of this device. However, with LPDL, the addition of Levulan for the treatment of photodamage did not lead to any discernable differences in photodamage parameters between the two groups, as suggested by the results of an earlier study (Smith et al, 2004).

In general, safety was excellent in all groups, but treatment using Levulan(R) with BLU-U was better tolerated than treatment with IPL or LPDL (with or without Levulan(R) i.e. the frequency and severity of stinging and burning during treatment was greater with IPL and LPDL (with or without Levulan(R)) compared to Levulan(R) with BLU-U(R), and for BLU-U(R) with vehicle. Levulan(R) with BLU-U(R) was also easy to use and less operator dependent. We are continuing to evaluate data prior to deciding appropriate next steps.

As our Phase II clinical trials proceed for acne and photodamage, and especially at such time as we may commence Phase III trials in these indications, research and development expenses are expected to increase significantly.

On September 27, 2004, DUSA signed a clinical trial agreement with the National Cancer Institute, Division of Cancer Prevention, or NCI DCP, for the clinical development of Levulan(R) PDT for the treatment of high-grade dysplasia within Barrett's Esophagus. In addition, to further our objectives concerning treatment of internal indications using Levulan(R) PDT, on November 4, 2004, we signed an additional clinical trial agreement with the NCI DCP for the treatment of oral cavity dysplasia. DUSA and the NCI DCP are working together to prepare

33

overall clinical development plans for Levulan(R) PDT in these indications, starting with Phase I/II trials, and continuing through Phase III studies, if appropriate. DUSA and the NCI DCP have prepared protocols for the initial Phase I/II clinical studies in both indications. The NCI DCP is currently working with DUSA and investigators to finalize the clinical trial designs. The NCI DCP will use its resources to file its own Investigational New Drug applications with the FDA. Our costs related to these studies will be limited to providing Levulan(R), laser devices and our proprietary light device sheath and the necessary training for the investigators involved. All other costs of these studies will be the responsibility of the NCI DCP. We have options on new intellectual property and, subject to successful clinical trial results, intend to seek FDA approvals in due course. In preparation for new Phase II clinical trials for the treatment of high-grade dysplasia associated with Barrett's esophagus, our small single-center pilot Phase II clinical trial using our proprietary endoscopic light delivery device is continuing.

We have entered into a series of agreements for our research projects

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

and clinical studies. We expect research and development costs to increase in 2006 as compared to 2005 as we continue to invest in our clinical programs. We have retained the services of a regulatory consultant to assist us with seeking foreign marketing approvals for our products, which will also cause research and development expenses to increase.

**MARKETING AND SALES COSTS** -- Marketing and sales costs for the three months ended March 31, 2006 were \$2,691,000 as compared to \$2,785,000 for 2005. These costs consist 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 \$1,596,000 for the three month period ended March 31, 2006, compared to \$1,837,000 in 2005. The decrease in this category is due to a lower average headcount in 2006 in comparison to 2005. The remaining expenses consist of tradeshows, miscellaneous marketing and outside consultants totaling \$1,097,000, including \$102,000 related to amortization of developed/core technology resulting from the acquisition of Sirius, for the three month period ended March 31, 2006, compared to \$948,000 in 2005. We expect that our overhead expenses will remain elevated reflecting the expansion of our sales capacity and the addition of executive sales management in the second quarter of 2006; however, these expenses should be somewhat offset by lower tradeshow spending for the remainder of the year, as the major conferences took place during the first quarter of 2006. The expected amortization expense related to the core/developed technology for the remainder of 2006 is \$1.3 million. We anticipate that the level of marketing and sales expenses and related support functions will continue to increase in 2006 as we integrate the members of the Sirius sales force and seek to expand our sales coverage as a result of the initial success of our sales initiatives.

**GENERAL AND ADMINISTRATIVE COSTS** -- General and administrative costs for the three months ended March 31, 2006 increased to \$2,070,000 as compared to \$1,682,000 for 2005. This increase is mainly attributable to \$149,000 resulting from the adoption of FAS 123R, and incremental costs associated with the acquisition of Sirius, and increased professional fees.

34

General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period.

**OTHER INCOME, NET** -- Other income for the three months ended March 31, 2006 decreased to \$272,000 as compared to \$367,000 during the same period in 2005. This decrease is primarily attributable to a decrease in of the balance of marketable securities as we use these resources to fund operations.

**NET LOSSES** - We incurred a net loss of \$4,640,000, or \$0.26 per share, for the three months ended March 31, 2006, as compared to a net loss of \$4,332,000 or \$0.26 per share for the comparable period in 2005. Net losses are expected to continue until end-user sales offset the cost of launching our sales force and marketing initiatives, and the costs for other business support functions.

### LIQUIDITY AND CAPITAL RESOURCES

We believe that we have sufficient cash to continue to fund Levulan(R) PDT sales and marketing expenses at current levels, planned research and development activities for our Levulan(R) PDT/PD platform, and to fund operations and capital expenditures for the foreseeable future. However, should one or more generic niacinamide products remain on the market for any significant length of time our liquidity could be significantly impacted. We have invested our funds in liquid investments, so that we will have ready access

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis.

At March 31, 2006, we had approximately \$23,406,000 of total cash resources, comprised of \$4,283,000 of cash and cash equivalents, marketable securities available for sale totaling \$18,977,000, and restricted cash of \$146,000. As of March 31, 2006, these securities had yields ranging from 2.35% to 7.43% and maturity dates ranging from April 1, 2006 to June 15, 2008.

As of March 31, 2006, working capital (total current assets minus total current liabilities) was \$24,915,000, as compared to \$34,889,000 as of December 31, 2005. Total current assets decreased by \$8.7 million during the three months ended March 31, 2006, due primarily to a decrease in our marketable securities, and total current liabilities increased by \$1.3 million during the same period due primarily to an increase in accrued expenses resulting from the acquisition of Sirius.

As stated above, we acquired all of the outstanding common stock of Sirius in March 2006 in exchange for 2,396,245 shares of DUSA common stock and cash. At closing, we paid \$8.0 million less certain expenses, in cash, and 1,973,353 unregistered shares of DUSA's common stock, no par value per share (the "Common Stock") to the shareholders of Sirius and issued an additional 422,892 unregistered shares to an escrow agent to be held for up to two

35

years subject to certain indemnification provisions of the Merger Agreement. We have an obligation to file a registration statement covering these shares. See Note 3 to the Notes to the Condensed Consolidated Financial Statements for the effect of purchase method accounting on the value of the acquisition. We have agreed to pay additional consideration in future periods, based upon the attainment of defined operating objectives, including new product approvals or launches and the achievement 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 earned are, as follows:

CUMULATIVE SALES MILESTONE:	PAYMENT EARNED:
\$25.0 million	\$1.5 million
35.0 million	\$1.0 million
45.0 million	\$1.0 million
Total	\$3.5 million
	=====

In addition, there are three milestones related to new product approvals and/or launches each in the amount of \$500,000 per milestone, or \$1.5 million in the aggregate, that will be paid if the milestones are achieved.

We are still actively seeking to further expand or enhance our business by using our resources to acquire by license, purchase or other arrangements, additional businesses, new technologies, or products in the field of dermatology. For 2006, we are focusing primarily on increasing the sales of the Levulan(R) Kerastick(R) and the BLU-U(R), as well as the Non Photodynamic Therapy Drug Products, advancing our Phase II studies for use of Levulan(R) PDT in photodamaged skin and acne, and continuing to pursue our product development pipeline .

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

DUSA has no off-balance sheet financing arrangements.

### CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

Altana, Inc.

In June 2005, Sirius entered into a development and product license agreement with Altana, Inc. relating to a reformulated dermatology product. According to the agreement, Sirius pays for all development costs. The agreement was assigned to us by virtue of the Sirius merger. Should development efforts be successful, Altana will manufacture the product for us and we will be obligated to pay royalties, including certain minimum royalties on net sales of the product. The agreement expires six years after the first commercial sale of the product.

36

Amide Pharmaceuticals, Inc.

Under an agreement dated May 18, 2001, and amended on February 8, 2006, Sirius entered into an arrangement for the supply of Nicomide(R) with Amide Pharmaceuticals, Inc. Currently, Amide supplies all of our requirements; however, we have the right to use a second source for a significant portion of our needs if we choose to do so. The agreement expires on February 8, 2009. The agreement was assigned to us as part of the Sirius merger.

Harmony Labs, Inc.

Under an agreement dated September 18, 2001, and amended on February 16, 2006 and March 10, 2006, Sirius entered into an arrangement for the manufacturing and supply of the AVAR(R) line of products and Nicomide-T(R) with Harmony Labs, Inc. The agreement was assigned to us as part of the Sirius merger. Currently, Harmony supplies all of our requirements; however, we have the right to use a second source for a significant portion of its needs if we choose to do so. The agreement expires on February 16, 2009.

L. Perrigo Company

On October 25, 2005, Sirius entered into a supply agreement with L. Perrigo Company for the exclusive manufacture and supply of a proprietary device/drug kit designed by Sirius pursuant to an approved ANDA owned by Perrigo. The agreement was assigned to us as part of the Sirius merger. Sirius is responsible for all development costs and for obtaining all necessary regulatory approvals. Perrigo is entitled to royalties on net sales of the product, including certain minimum royalties commencing May 1, 2006. The initial term of the agreement expires in July, 2011 and may be renewed based on certain minimum purchase levels and other terms and conditions. Minimum royalties to Perrigo are \$250,000 per year.

Winston Laboratories, Inc.

On or about January 30, 2006 Winston Laboratories, Inc. and Sirius entered into a license agreement relating to a Sirius product, Psoriatec(R) (known by Winston as Micanol) revising a former agreement. Winston Laboratories, Inc. is controlled by Dr. Joel Bernstein, a principal shareholder of Sirius. The 2006 agreement grants to Sirius 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. Royalties are paid on net

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

sales of the product by Sirius, and certain minimum royalties are due each year to maintain the license. Sirius has an option to purchase the product from Winston at certain times during the two-year term of the agreement. The agreement is due to expire on January 31, 2008, subject to rights to extend or

37

terminate the agreement earlier. This agreement was assigned to us as part of the Sirius Merger. Minimum royalties to Winston Laboratories are \$300,000 per year ending January 31, 2008.

Our contractual obligations and other commercial commitments to make future payments under contracts, including lease agreements, research and development contracts, manufacturing contracts, or other related agreements, are as follows at March 31, 2006:

	TOTAL -----	1 YEAR OR LESS -----	2-3 YEARS -----	4-5 YEARS -----
Operating lease obligations	\$ 3,170,000	\$ 683,758	\$ 992,466	\$ 887,800
Purchase obligations (1, 2)	\$ 1,966,660	1,966,660	-	
Minimum royalty obligations	\$ 2,486,000	\$ 615,167	\$ 922,000	\$ 672,000

-----

1) Research and development projects include various commitments including obligations for our Phase II clinical studies for photodamaged skin and moderate to severe acne.

2) In addition to the obligations disclosed above, we have contracted with Therapeutics, Inc., a clinical research organization, to manage the clinical development of our products in the field of dermatology. This organization has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from \$250,000 to \$1,250,000, depending on the regulatory phase of development of products under Therapeutics' management.

### 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, the overall net effect of inflation on our operations is expected 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.

As of March 31, 2006, the weighted average rate of return on our investments was 4.48%. If market interest rates were to increase immediately and

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

uniformly by 100 basis points from levels as of March 31, 2006, the fair market value of the portfolio would decline by \$122,000. Declines in interest rates could, over time, reduce our interest income.

38

### 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 Exchange Act Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2006.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2006 that have materially affected, or are reasonably likely to materially affect, DUSA's internal control over financial reporting.

### FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including the Management's Discussion and Analysis, and certain written and oral statements incorporated herein by reference of DUSA Pharmaceuticals, Inc. (referred to as "DUSA," "we," and "us") contain forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended. Such forward-looking statements are based on current expectations, estimates, beliefs and projections about future events, including, without limitation statements regarding our use of estimates and assumptions in the preparation of our financial statements and policies, including certain pro forma financial statements and the impact on us of the adoption of certain accounting standards, our obligation to make certain milestone payments to third parties, our beliefs and intent regarding the manufacture of our products and the availability of inventory of our products, the outcome and costs of litigation to which we are a party, the terms and conditions of our equity compensation plans, our beliefs regarding our recent merger with Sirius Laboratories, Inc. and the benefits, effects, impact and risks thereof, our goal of achieving profitability, our beliefs regarding our sales and marketing efforts, competition with other companies, the adoption of our products, and the outcome of such efforts, our beliefs regarding the use of our products and technologies by third parties, our beliefs regarding our compliance with applicable laws, rules and regulations, our beliefs regarding available reimbursement for our products and changes to applicable CPT codes, our expectation regarding the margins on our products, our beliefs regarding the current and future clinical development and testing of our potential products and technologies and the costs thereof, our expectations and beliefs regarding our future expenses and losses, the sufficiency of our capital resources and our needs for additional capital, our plans for obtaining financing in the future and for pursuing certain goals and objectives, and the possibility of the holders of options and warrants to purchase our common stock exercising these securities. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," or variations of such words and similar expressions, are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and

39

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

assumptions that are difficult to predict particularly in the highly regulated pharmaceutical industry in which we operate. Therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include changing market, regulatory and marketplace conditions, actual clinical results of our trials, our ability to sell, market and develop our products and product candidates, the potential need to hire additional personnel or retain existing personnel, the impact of competitive products and pricing, the timely development, FDA approval, and market acceptance of our products, the maintenance of our patent portfolio, changes in our long and short term goals, financial and operational risks associated with our recent merger with Sirius Laboratories, Inc., the litigation process, the ability to obtain competitive levels of reimbursement by third-party payors, and other risks noted herein and in our other SEC filings from time to time and those set forth herein under "Risk Factors" on pages 42 through 57, as well as those noted in the documents incorporated herein by reference. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. However, readers should carefully review the statements set forth in other reports or documents we file from time to time with the Securities and Exchange Commission, particularly our Quarterly Reports on Form 10-Q and any Current Reports on Form 8-K.

### PART II - OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS.

##### Photocure ASA

In April 2002, we received a copy of a notice issued by PhotoCure ASA to Queen's University at Kingston, Ontario, alleging that Australian Patent No. 624985 was invalid. Australian Patent No. 624985 is one of the patents covered by our agreement with PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University, relating to 5-aminolevulinic acid technology. PhotoCure instituted this proceeding on April 12, 2002 in the Federal Court of Australia, Victoria District Registry. As a consequence of this action, Queen's University assigned the Australian patent to us so that we could participate directly in this litigation. On April 6, 2005, the Federal Court of Australia ruled that the patent is valid and remains in full force and effect. However, the Court also ruled that PhotoCure's product does not infringe the claims in the Australian patent. Since these claims are unique to the Australian patent and Australian law differs from patent law in other jurisdictions, we do not expect that this decision is determinative of the validity of any other patents licensed by us from Queen's University or of whether PhotoCure's product infringes claims in such other patents, including the United States patent. None of the parties appealed the decision. The parties, including PhotoCure's marketing partner, Galderma S.A., signed a Mediation Agreement in August 2004 to attempt to settle their disputes. We are making progress in the negotiations.

##### NECC

In December 2004, we filed a lawsuit against New England Compounding Center of Framingham, Massachusetts alleging violations of U.S. patent law in the U.S. District Court in

Boston, Massachusetts. On March 17, 2005, New England Compounding Pharmacy filed



## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

an answer against us, including a defense that our patents are invalid and several counterclaims against us, and we filed our response on April 5, 2005. On April 10, 2006, we announced that we and NECC had settled our respective claims against each other. Under the terms of the settlement agreement, NECC does not admit any wrongdoing but has agreed that it will not infringe or induce others to infringe the two patents that were the subject of the lawsuit, and all claims against us were released.

### Levulan(R) Suits

In November, 2005 and January, 2006 we filed lawsuits against physicians in several states to prevent their continued use of versions of our Levulan (R) brand of aminolevulinic acid HCl (ALA) produced, by third-parties for use in our patented photodynamic therapy (PDT) treatment for actinic keratosis, basal cell carcinoma, acne and other dermatological conditions. The suits allege that ALA obtained from sources other than DUSA is being used by these physicians for patient treatments that are covered under patents exclusively licensed by DUSA, resulting in direct infringement of these patent(s). Additionally, some doctors are also being sued for misuse of DUSA's trademarks and for violations of the Lanham Act for using the Levulan (R) brand name on their web sites and promotional materials, but performing patient treatments with ALA obtained from other sources. Most of the physicians have entered Consent Judgments in which they admit the infringement and provide DUSA with the right to review their books and records. Two lawsuits are currently on-going.

### River's Edge

On March 28, 2006, a lawsuit was filed by River's Edge Pharmaceuticals, LLC against us alleging, among other things, that, prior to the merger, Sirius Laboratories, Inc. agreed to authorize River's Edge to market a generic version of Nicomide(R), and that the United States patent covering Nicomide(R) issued to Sirius in December, 2005 is invalid. Nicomide(R) is one of the key products DUSA acquired from Sirius in our merger. The declaratory judgment suit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division. River's Edge has also filed an application with the U.S. Patent and Trademark Office requesting reexamination of the Nicomide patent. On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that a River's Edge niacinamide product infringes U.S. patent 6,979,468, and on April 26, 2006 we filed a Motion to Dismiss the Georgia action. In response to a motion put forward with the filing by us, the New Jersey court granted an expedited hearing date of May 5, 2006 in order to hear arguments on a motion for preliminary injunction to enjoin River's Edge from selling its alternative product to Nicomide(R). The court has not yet ruled on this motion.

41

### 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 1.A. of our 2005 Annual Report on Form 10-K for the year ended December 31, 2005.

You should carefully consider and evaluate all of the information in, or incorporated by reference in, this Current Report on Form 10-Q. The following

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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 value of the securities being offered by this report.

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" and "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 risks 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.

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

If we are unable to successfully market and sell sufficient quantities of our products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. We are responsible for marketing our dermatology products in the United States and the rest of the world, except Canada, and Mexico and Central and South America, 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. Acquiring and retaining marketing and sales force capabilities involves significant expense, and current sales levels are not offsetting the expenses related to these efforts. In addition, our sales personnel have only recently begun to sell and market the Sirius products. If our sales and marketing efforts fail, then sales of the Kerastick(R), the BLU-U(R) and the Sirius Products -- Nicomide(R), Nicomide-T(R), the AVAR(R) line of products, METED(R), Psoriacap(R) and Psoriatec(R) will be adversely affected.

42

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(R) Kerastick(R) 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, adoption of our therapy and sales of our products could be negatively impacted. Although 2005 reimbursement changes related to AK were made, some physicians still believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices.

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

If insurance companies do not cover, or stop covering products which are currently covered, our sales could be dramatically reduced.

Since We Now Operate The Only FDA Approved Manufacturing Facility For The Kerastick(R) And Continue To Rely Heavily On Sole Suppliers For The Manufacture Of Levulan(R), The BLU-U(R) and the Sirius Products -- Nicomide(R), Nicomide-T(R), the AVAR(R) line of products, METED(R), Psoriacap(R) and Psoriatec(R), Any Supply Or Manufacturing Problems Could Negatively Impact Our Sales.

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

We are working with the supplier of the AVAR(R) line of products to address certain manufacturing concerns. There is a risk that inventory of some of these products could become in short supply while such concerns are being addressed and negatively affect revenues from these products.

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

- o product yields,
- o quality control,
- o component and service availability,
- o compliance with FDA regulations, and
- o the need for further FDA approval if manufacturers make material changes to

43

manufacturing processes and/or facilities.

We cannot guarantee that problems will not arise with production yields, costs or quality as we and our suppliers seek to increase production. 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 any 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.

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

The manufacture and marketing of our products, the Levulan(R) Kerastick(R) with the BLU-U(R) for AKs, the BLU-U(R) without Levulan(R) to treat

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

moderate inflammatory acne and the Sirius Products -- Nicomide(R), Nicomide-T(R), the AVAR(R) line of products, METED(R), Psoriacap(R) and Psoriatec(R)., 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:

- o approval of manufacturing facilities, including adherence to good manufacturing and laboratory practices during production and storage,
- o controlled research and testing of some of these products even after approval, and
- o 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:

- o send us warning letters,
- o impose fines and other civil penalties on us,
- o seize our products,
- o suspend our regulatory approvals,
- o refuse to approve pending applications or supplements to approved applications filed by us,
- o refuse to permit exports of our products from the United States,

44

- o require us to recall products,
- o require us to notify physicians of labeling changes and/or product related problems,
- o impose restrictions on our operations, and/or
- o criminally prosecute us.

We and our manufacturers must continue to comply with the FDA's Good Manufacturing Practice, commonly known as 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.

As part of our FDA approval for the Levulan(R) Kerastick(R) 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 could request additional information and/or studies. Additionally, if previously unknown problems with the product, a manufacturer or its facility are discovered in the future, changes in product

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

labeling restrictions or withdrawal of the product from the market may occur.

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(R) facility, will continue to meet all applicable FDA regulations. If we, or any of our manufacturers, including without limitation, the manufacture of the AVAR(R) products, 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 an adverse effect on our financial condition and operations.

Certain of the Sirius products acquired in connection with the merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications. FDA regulates such products under its compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, 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. We believe that so long as we comply with applicable manufacturing and labeling standards we will be consistent with FDA's current enforcement policy. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual products. If the FDA were to do so, we may be required to seek FDA approval for these products, market these products as over-the-counter products or as dietary supplements under applicable legislation, or withdraw such products from the market.

45

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 might be required to seek additional funding. There is no guarantee that adequate funding sources could be found to continue the development of all 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.

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

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

of factors, including:

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

We Have Significant Losses And Anticipate Continued Losses For The Foreseeable Future.

We have a history of operating losses. We expect to have continued losses through at least 2006 as we attempt to increase sales of our approved products in the marketplace and

46

continue research and development of potential new products. We incurred net losses of \$14,998,709 for the year ended December 31, 2005 and \$15,628,980 for the year ended December 31, 2004. We have continued to experience net losses during the quarter ended March 31, 2006. As of March 31, 2006, our accumulated deficit was approximately \$94,178,000. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable.

If We Are Unable To Protect Our Proprietary Technology, Trade Secrets Or Know-How, We May Not Be Able To Operate Our Business Profitably.

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(R) 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:

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

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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 are developing therapies may not be covered by the claims in any of our existing patents. Even with the issuance of additional patents to DUSA, other parties are free to develop other uses of ALA, including medical uses, and to market ALA for such uses, assuming that they have obtained appropriate regulatory marketing approvals. ALA in the chemical form has been commercially supplied for decades, and is not itself subject to patent protection. There are reports of third-parties conducting clinical studies with ALA in countries outside the United States where PARTEQ 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(R) products even though they are marketed for different uses.

47

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:

- o these persons or entities might breach the agreements,
- o we might not have adequate remedies for a breach, and/or
- o our competitors will independently develop or otherwise discover our trade secrets.

Nicomide is covered by a U.S. patent which issued in December 2005. River's Edge Pharmaceuticals LLC has filed an application with the U.S. Patent and Trademark Office for the reexamination of the patent. If the USPTO finds that the patent is invalid, River's Edge and other generics will be able to compete with Nicomide.

Patent 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-party competitors may infringe one or more of our patents, and we could be required to spend significant resources to enforce our patent rights. Also, if we were to sue a third-party for infringement of our patents in the United States, that third-party could challenge the validity of our patent(s). We cannot guarantee that a third-party will not claim, with or without merit, that we have infringed their patent(s) or misappropriated their proprietary material. Defending this type of legal action involves considerable expense and could negatively affect our financial results.

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

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

participate in interference proceedings in the United States Patent and Trademark Office 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.

On March 28, 2006, a lawsuit was filed by River's Edge Pharmaceuticals, LLC against us alleging, among other things, that, prior to the merger, Sirius Laboratories, Inc. agreed to authorize River's Edge to market a generic version of Nicomide(R), and that the United States patent covering Nicomide(R) issued to Sirius in December, 2005 is invalid. The declaratory judgment suit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division. Nicomide is one of the key products DUSA acquired from Sirius in its Merger. On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that a River's Edge niacinamide product infringes U.S.

48

patent 6,979,468. In response to a motion put forward with the filing by us, the Court granted an expedited hearing date of May 5, 2006 in order to hear arguments on a motion for preliminary injunction to enjoin River's Edge from selling its alternative product to Nicomide(R). If we do not prevail in our lawsuit, or the Nicomide(R) patent is found to be invalid, our revenues from sales of Nicomide(R) could decrease significantly. The court has not yet ruled on this motion.

During 2005 and into 2006, we filed several lawsuits against compounding pharmacies and physicians alleging violations of patent law. While we have been successful in obtaining a default judgment against one compounding pharmacy, settled another suit, and have obtained consent judgments from several physicians, we do not know whether these lawsuits will prevent others from infringing our patents or whether we will be successful in stopping these activities which we believe are negatively affecting our revenues.

We Have Only 2 Therapies That Have Received Regulatory Approval Or Clearance And We Cannot Predict Whether We Will Ever Develop Or Commercialize Any Other Products.

Except For The Levulan(R) Kerastick(R) With The BLU-U(R) To Treat AKs, The Use Of The BLU-U(R) Alone To Treat Moderate Inflammatory Acne, and the Sirius Products -- Nicomide(R), Nicomide-T(R), the AVAR(R) line of products, METED(R), Psoriacap(R) and Psoriatec(R), All Of Our Potential Products Are In Early Stages Of Development And May Never Result In Any Commercially Successful Products.

We do not know if the Levulan(R) Kerastick(R), the BLU-U(R) products will ever be commercially successful. To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products. Except for DUSA's 2 approved therapies, all of our other potential Levulan(R), BLU-U(R) products, and other potential product candidates which we acquired in our merger with Sirius, are at an early stage of development and subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

- o delays in product development, clinical testing or manufacturing,



## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

- o unplanned expenditures in product development, clinical testing or manufacturing,
- o failure in clinical trials or failure to receive regulatory approvals,
- o emergence of superior or equivalent products,
- o inability to market products due to third-party proprietary rights, and
- o 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(R) drug technology.

49

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(R) 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 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 1 to 3 years or more. The FDA may require additional animal studies and/or human clinical trials before granting approval. Our Levulan(R) PDT products are based on relatively new technology. To the best of our knowledge, the FDA has approved only 3 drugs for use in photodynamic therapy, including Levulan(R). 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(R) PDT or photodetection, known as PD, is safe and effective for any new use we are studying. 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. During September 2005, the FDA issued guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. As a result, it is likely that the costs and time to approval associated with seeking regulatory approval of this indication will be increased. The FDA may issue additional guidance in the future, which may result on additional costs and delays. We must also obtain foreign regulatory clearances before we can market any potential products in foreign markets. The foreign regulatory approval process includes all of the risks associated with obtaining FDA marketing approval and may impose substantial additional costs.

Certain of the Sirius products acquired in connection with the Merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications. FDA regulates such products under its compliance policy guide

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, 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. We believe that so long as we comply with applicable manufacturing and labeling standards we will be consistent with FDA's current enforcement policy. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual products. If the FDA were to do so, we may be required to seek FDA approval for these products, market these products as over-the-counter products or as dietary supplements under applicable legislation, or withdraw such products from the market.

50

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.

Since our current sales goals for our products may not be met in the future, we may need substantial additional funds to fully develop, manufacture, market and sell our other potential products. We may obtain funds through other public or private financings, including equity financing, and/or through collaborative arrangements. We cannot predict whether any financing will be available at all or on acceptable terms.

Dependent 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.

We Are Exposed To Risks Associated With Acquisitions.

On March 10, 2006, we acquired Sirius Laboratories, Inc. We may in the future make other acquisitions of, or significant investments in, businesses with complementary products, services and/or technologies. Acquisitions involve numerous risks, including, but not limited to:

- o difficulties and increased costs in connection with integration of the personnel, operations, technologies and products of acquired companies;
- o diversion of management's attention from other operational matters;
- o the potential loss of key employees;
- o the potential loss of key collaborators;
- o lack of synergy, or the inability to realize expected synergies, resulting from the acquisition;
- o acquired intangible assets becoming impaired as a result of technological advancements or worse-than-expected performance of the acquired company;
- o the potential for unexpected liabilities; and
- o use of cash which could be difficult to replace on reasonable terms.

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Mergers and acquisitions are inherently risky, and the inability to effectively manage these risks could materially and adversely affect our business, financial condition and results of operations. In addition, there may be liabilities that we fail, or are unable, to discover in the course of performing due diligence investigations on any company that we may acquire, or have recently acquired. Also, there may be additional costs relating to acquisitions including, but not limited to, possible purchase price adjustments. Any of our rights to indemnification from sellers to us, even if obtained, may not be enforceable, collectible or sufficient in amount, scope or

51

duration to fully offset the possible liabilities associated with the business or property acquired. Any such liabilities, individually or in the aggregate, could have a material adverse effect on our business.

The merger between DUSA and Sirius Laboratories may be more difficult, costly or time consuming than expected, and we may not be able to successfully integrate our business with Sirius' business.

Upon completion of our merger with Sirius, we began to integrate our operations with those of Sirius. Although we have not experienced significant difficulties to date, as the integration process continues, it is possible that we may face difficulties which may result in, among other things, disruptions in our ongoing operations. For example, we may experience differences in the two companies' business procedures, controls or personnel policies, and there could be problems that affect our ongoing relationships with our customers or that affect our ability to realize all anticipated benefits of the merger. Some of these difficulties include, without limitation, the loss of key employees and customers, the disruption of ongoing business relationships, and possible inconsistencies in standards, controls, procedures and policies. The success of our merger with Sirius depends on our ability to successfully merge corporate cultures and operational and financial systems, integrate and retain the customer base of the acquired business, realize cost reduction synergies; and as necessary, retain key management members and technical personnel of acquired companies. If we fail to integrate Sirius' business and operations successfully, that failure could have a material adverse effect on our business.

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 80 employees, including 2 part-time employees as of March 31, 2006. We are highly dependent on several key officer/employees with specialized scientific and technical skills without whom our business, financial condition and results of operations would suffer. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very few people with their expertise could be hired. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain other qualified personnel in our specialty drug and light device areas

Our 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

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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.

52

### 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 exposes 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(R), 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. 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, rosacea,

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

photodamaged skin and Barrett's esophagus. 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.

53

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:

- o price reductions,
- o lower levels of third-party reimbursements,
- o failure to achieve market acceptance, and
- o 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.

Our Products May Lose Market Share If New Manufacturers Begin Producing Competing Products That Are Able To Penetrate Our Market.

We Have Learned That 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(R) product. On January 31, 2005, we filed a lawsuit in the United States District Court for the District of Arizona against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement and of United States patent law. A motion for default judgment was granted on July 25, 2005 in our favor for failure of The Cosmetic Pharmacy of Tucson to appear, together with injunctive relief and attorney fees and costs in the amount of approximately \$20,700. Also, on December 27, 2004, we filed a lawsuit in United States District Court for the District of Massachusetts against New England Compounding Pharmacy, Inc. of Framingham, Massachusetts alleging violations of United States patent law which has now settled. While we believe that certain actions of compounding pharmacies go 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 lawsuits will be successful in curbing the practices of these pharmacies or that regulatory authorities will intervene to stop their activities. In addition, there may be other compounding pharmacies which are

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

following FDA guidelines, or others conducting illegal activities of which we are not aware, which may be negatively impacting our sales revenues.

54

We have learned that River's Edge is marketing an alternative niacinamide Product.

If generic manufacturers launch products to compete with Nicomide in spite of our patent position, they may erode our market and negatively impact our sales revenues, liquidity and operations.

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

We anticipate that we will face increased competition as the scientific development of PDT/PD and the Non-PDT Drug Products advance and new companies enter our markets. Several companies are developing PDT agents other than Levulan(R). These include: QLT Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); and Pharmacyclics, Inc. (U.S.). We are also aware of several companies commercializing and/or conducting research with ALA or ALA-related compounds, including: medac GmbH and photonamic GmbH & Co. KG (Germany); 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. 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. In July 2004, PhotoCure received FDA approval in the United States for its AK therapy. If PhotoCure enters into the marketplace based on receiving this approval, its product will represent direct competition for our products.

Axcan Pharma Inc. has received FDA approval for the use of its product, PHOTOFRIN(R), 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, which we are also pursuing.

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

- o the ease of administration of our method of PDT,
- o the degree of generalized skin sensitivity to light,
- o the number of required doses,
- o the selectivity of our drug for the target lesion or tissue of interest, and
- o the type and cost of our light systems.

Our primary competition in the acne and rosacea markets include 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.

55

#### 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 March 31, 2006 there were outstanding options and warrants to purchase 3,079,875 shares of common stock, with exercise prices ranging from U.S. \$1.60 to \$31.00 per share, and of CDN \$6.79 per share, respectively. 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.

Results Of Our 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, 2005 to March 31, 2006, the price of our stock has ranged from a low of \$6.57 to a high of \$16.30. Factors that contributed to the volatility of our stock during the last 15 months included:

- o quarterly levels of product sales;
- o clinical trial results;
- o general market conditions;
- o increased marketing activities; and
- o 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 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.

56

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

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 (or 20% or more in the case of certain parties) 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 20% of the outstanding common stock in the case of a shareholder or group who beneficially held in excess of 15% at the record date), 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 20% or more, as the case may be, of DUSA, or until such later date as may be determined by the our board of directors.

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

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

Information relating to our issuance of unregistered securities in connection with our merger with Sirius Laboratories, Inc. was included in our Current Report on Form 8-K filed with the Commission on March 14, 2006.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES.



## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

None.

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

None.

### ITEM 5. OTHER INFORMATION.

None.

### ITEM 6. EXHIBITS

- 10(a) Supply Agreement by and between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated May 18, 2001, filed herewith, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(b) Amendment and Extension of the Supply Agreement by and between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated February 8, 2006, filed herewith, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(c) Supply and Development Agreement by and between Sirius Laboratories, Inc. and Harmony Laboratories dated September 18, 2001, filed herewith, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(d) Amendment and Extension of the Supply and Development Agreement by and between Sirius Laboratories, Inc. and Harmony Laboratories dated February 16, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(e) Second Amendment of the Supply and Development Agreement by and between Sirius Laboratories, Inc. and Harmony Laboratories dated March 10, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(f) Supply Agreement by and between Sirius Laboratories, Inc. and L. Perrigo Company dated October 21, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

58

- 10(g) 2006 Micanol License Agreement by and between Sirius Laboratories, Inc. and Winston Laboratories, Inc. effective as of January 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference; and
- 10(h) Development, License and Supply Agreement by and between Sirius

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Laboratories, Inc. and Altana Inc. dated June 13, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference.

- 31(a) Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer.
- 31(b) Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
- 32(a) Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and
- 32(b) Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99(a) Press Release of the Company dated May 10, 2006.

59

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.

Date: May 10, 2006

By: /s/ D. Geoffrey Shulman

-----  
D. Geoffrey Shulman  
Director, Chairman and Chief Executive Officer  
(principal executive officer)

Date: May 10, 2006

By: /s/ Richard C. Christopher

-----  
Richard C. Christopher  
Vice President, Finance and Chief Financial  
Officer (principal financial officer)

EXHIBIT INDEX

- 10(a) Supply Agreement by and between Sirius Laboratories, Inc. and Amide

## Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Pharmaceuticals, Inc. dated May 18, 2001, filed herewith, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

- 10(b) Amendment and Extension of the Supply Agreement by and between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated February 8, 2006, filed herewith, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(c) Supply and Development Agreement by and between Sirius Laboratories, Inc. and Harmony Laboratories dated September 18, 2001, filed herewith, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(d) Amendment and Extension of the Supply and Development Agreement by and between Sirius Laboratories, Inc. and Harmony Laboratories dated February 16, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(e) Second Amendment of the Supply and Development Agreement by and between Sirius Laboratories, Inc. and Harmony Laboratories dated March 10, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(f) Supply Agreement by and between Sirius Laboratories, Inc. and L. Perrigo Company dated October 21, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(g) 2006 Micanol License Agreement by and between Sirius Laboratories, Inc. and Winston Laboratories, Inc. effective as of January 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference; and
- 10(h) Development, License and Supply Agreement by and between Sirius Laboratories, Inc. and Altana Inc. dated June 13, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference.
- 31(a) Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer.
- 31(b) Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
- 32(a) Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and
- 32(b) Certification of the Chief Financial Officer pursuant to 18 U.S.C.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

99(a) Press Release of the Company dated May 10, 2006.