

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

DUSA PHARMACEUTICALS INC  
Form 10-Q  
November 09, 2007

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended: September 30, 2007

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

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

Commission file number: 001-31533

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

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

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

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

01887  
(Zip Code)

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

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

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

Yes  No

Indicate by check mark whether the registrant 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  NON-ACCELERATED FILER

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

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 November 8, 2007, the registrant had 24,076,110 shares of Common Stock, no par value per share, outstanding.

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

	Page Number -----
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	
- Condensed Consolidated Balance Sheets at September 30, 2007 and December 31, 2006 (Unaudited)	3
- Condensed Consolidated Statements of Operations for the three and nine-month periods ended September 30, 2007 and 2006 (Unaudited)	4
- Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2007 and 2006 (Unaudited)	5
- Notes to the Condensed Consolidated Financial Statements (Unaudited)	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	23
Item 3. Quantitative and Qualitative Disclosures About Market Risk	41
Item 4. Controls and Procedures	41
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	43
Item 1A. Risk Factors	44
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	58
Item 3. Defaults Upon Senior Securities	58
Item 4. Submission of Matters to a Vote of Security Holders	58
Item 5. Other Information	58
Item 6. Exhibits	59
SIGNATURES	
Exhibit Index	

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

EX-10(a) Amendment to the Marketing, Distribution and Supply Agreement dated September 26, 2007, between the Company and Stiefel Laboratories, Inc.  
 EX-31.1 SECTION 302 CERTIFICATION OF THE C.E.O.  
 EX-31.2 SECTION 302 CERTIFICATION OF THE C.F.O.  
 EX-32.1 SECTION 906 CERTIFICATION OF THE C.E.O.  
 EX-32.2 SECTION 906 CERTIFICATION OF THE C.F.O.  
 EX-99.1 Press Release

2

### PART I.

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

	SEPTEMBER 30, 2007	DECEMBER 31, 2006
	-----	-----
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 1,004,387	\$ 3,267,071
Marketable securities available-for-sale	10,219,201	14,943,196
Accrued interest receivable	82,762	158,374
Accounts receivable, net	1,717,076	2,060,565
Inventory	3,430,296	2,343,472
Prepays and other current assets	965,743	1,535,819
	-----	-----
TOTAL CURRENT ASSETS	17,419,465	24,308,497
Restricted cash	166,813	162,805
Property, plant and equipment, net	2,278,264	2,567,286
Goodwill	6,272,505	5,772,505
Deferred charges and other assets	1,019,338	944,720
	-----	-----
TOTAL ASSETS	\$ 27,156,385	\$ 33,755,813
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 721,387	\$ 649,523
Accrued compensation	599,112	1,674,470
Other accrued expenses	2,975,167	3,841,891
Deferred revenue	468,741	57,270
	-----	-----
TOTAL CURRENT LIABILITIES	4,764,407	6,223,154
Other liabilities	2,240,847	1,199,086
	-----	-----
TOTAL LIABILITIES	\$ 7,005,254	\$ 7,422,240
	=====	=====
COMMITMENTS AND CONTINGENCIES (NOTE 16)		
SHAREHOLDERS' EQUITY		
Capital Stock		
Authorized: 100,000,000 shares; 40,000,000		
shares designated		
As common stock, no par, and 60,000,000		
shares issuable in series or classes;		
and 40,000 junior Series A preferred		
shares.		

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

Issued and outstanding: 19,495,067 and 19,480,067 shares of common stock, no par, at September 30, 2007 and December 31, 2006

	143,250,537	142,959,298
Additional paid-in capital	5,466,745	4,320,625
Accumulated deficit	(128,613,094)	(120,886,977)
Accumulated other comprehensive gain (loss)	46,943	(59,373)
	-----	-----
TOTAL SHAREHOLDERS' EQUITY	20,151,131	26,333,573
	-----	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 27,156,385	\$ 33,755,813
	=====	=====

See the accompanying notes to the Condensed Consolidated Financial Statements

3

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2007	2006	2007	2006
	-----	-----	-----	-----
Product Revenues	\$ 5,784,194	\$ 6,062,720	\$19,323,232	\$ 17,432,
Cost of Product Revenues	1,573,897	2,849,485	5,506,540	7,635,
	-----	-----	-----	-----
GROSS MARGIN	4,210,297	3,213,235	13,816,692	9,796,
Operating Costs				
Research and Development	1,225,462	1,343,880	4,328,475	4,382,
In-process Research and Development	--	--	--	1,600,
Marketing and Sales	2,887,370	3,246,886	9,727,660	9,114,
General and Administrative	2,110,766	2,603,237	7,966,791	8,427,
	-----	-----	-----	-----
TOTAL OPERATING COSTS	6,223,598	7,194,003	22,022,926	23,523,
	-----	-----	-----	-----
LOSS FROM OPERATIONS	(2,013,301)	(3,980,768)	(8,206,234)	(13,726,
OTHER INCOME				
Other income, net	135,519	194,129	480,117	645,
	-----	-----	-----	-----
NET LOSS	\$ (1,877,782)	\$ (3,786,639)	\$ (7,726,117)	\$ (13,080,
	=====	=====	=====	=====
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (0.10)	\$ (0.19)	\$ (0.40)	\$ (0
	=====	=====	=====	=====
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED	19,495,067	19,449,442	19,487,594	17,041,
	=====	=====	=====	=====

See the accompanying notes to the Condensed Consolidated Financial Statements

4

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

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2007	2006
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (7,726,117)	\$ (13,080,901)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of premiums and accretion of discounts on marketable securities available-for-sale	(157,401)	38,766
Realized loss (gain) on sale of marketable securities, available-for-sale	2,533	(14,015)
Depreciation and amortization	512,471	3,302,624
Deferred revenue recognized	(481,051)	--
In-process research and development charge	--	1,600,000
Stock-based compensation	1,146,120	1,413,116
Changes in other assets and liabilities impacting cash flows from operations (net of impact of acquisition):		
Accrued interest receivable	343,489	241,497
Accounts receivable	75,612	259,100
Inventory	(1,086,824)	(79,271)
Prepaid and other current assets	570,076	(730,129)
Deferred charges and other assets	(74,618)	(793,082)
Accounts payable	71,864	(1,310,300)
Accrued compensation and other accrued expenses	(1,691,490)	(143,590)
Deferred revenue	1,839,088	971,443
Other liabilities	95,195	323
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(6,561,053)</b>	<b>(8,324,419)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Cash paid for acquisition, net of cash received	(500,000)	(7,767,006)
Purchases of marketable securities	(12,560,937)	(4,008,844)
Proceeds from maturities and sales of marketable securities	17,546,115	21,176,393
Restricted cash	(4,008)	(16,295)
Purchases of property, plant and equipment	(223,451)	(172,277)
<b>NET CASH PROVIDED BY INVESTING ACTIVITIES</b>	<b>4,257,719</b>	<b>9,211,971</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from exercise of options	40,650	40,956
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(2,262,684)</b>	<b>928,508</b>
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,267,071	4,210,675
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 1,004,387	\$ 5,139,183

See the accompanying notes to the Condensed Consolidated Financial Statements

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

1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of September 30, 2007, and the Condensed Consolidated Statements of Operations for the three and nine-month periods ended September 30, 2007 and 2006, and Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2007 and 2006 of DUSA Pharmaceuticals, Inc. (the "Company" or "DUSA") have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and in accordance with accounting principles generally accepted in the United States of America ("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 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, 2006 filed with the SEC.

The Company has an accumulated deficit of \$128,613,000 as of September 30, 2007. The Company has funded its operations primarily through public offerings, private placements of equity securities and payments received under our collaboration agreements. The Company expects to incur significant additional research and development and other costs including costs related to clinical trials. The Company's costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any of our existing or future products to be marketed by us or our collaborators currently exceed and may continue to exceed revenues in the future, which may result in continued losses from operations. The Company's net cash used in operations for the nine-month period ended September 30, 2007 was \$6,561,000, versus \$8,324,000 used in the comparable 2006 period. At September 30, 2007, the Company had approximately \$11,224,000 of total liquid assets, comprised of \$1,005,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$10,219,000. The Company estimates that existing cash and cash equivalents and marketable securities, milestone payments associated with its international marketing and distribution agreements, the settlement payment from River's Edge, and the approximately \$10.3 million of net proceeds raised subsequent to September 30, 2007 in the private placement, see Note 17 Subsequent Events, will be sufficient to meet our cash requirements for at least the next two years.

2) SIGNIFICANT ACCOUNTING POLICIES

REVENUE RECOGNITION AND PROVISIONS FOR ESTIMATED REDUCTIONS TO GROSS REVENUES

The Company recognizes revenues in accordance with Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition in Financial Statements, as amended by SAB No. 104, Revenue Recognition. Accounting for revenue transactions relies on certain estimates that require difficult, subjective and complex judgments on the part of management.

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

For revenues associated with contractual agreements with multiple deliverables, the Company uses revenue recognition criteria outlined in Securities and Exchange Commission ("SEC") Staff Accounting Bulletin Topic 13, Revenue Recognition ("SAB Topic 13") and Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. Accordingly, revenues from contractual agreements are recognized based on the performance requirements of those agreements. As

6

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

prescribed by EITF 00-21, the Company analyzes each contract in order to separate each deliverable into separate units of accounting and then recognizes revenue for those separated units at their fair values as earned in accordance with the SAB Topic 13 or other applicable revenue recognition guidance.

PHOTODYNAMIC THERAPY (PDT) DRUG AND DEVICE PRODUCTS. Revenues on the Kerastick(R) and BLU-U(R) product sales in the U.S. and Canada 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 the Company did not have sufficient history with its distributors to be able to reliably estimate returns. Beginning in the first quarter of 2006, the Company began recognizing revenue as product is sold to distributors because it believes it has sufficient history to reliably estimate returns from distributors beginning January 1, 2006. This change in estimate was not material to the Company's revenues or results of operations. We offer programs that allow physicians access to our BLU-U(R) device 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.

In January 2006, as amended in September 2007, the Company entered into an exclusive marketing, distribution and supply agreement (the "Agreement") with Stiefel Laboratories, Inc. ("Stiefel") for Levulan(R) PDT in Latin America (see Note 12). Under the Agreement, Stiefel is required to purchase Levulan(R) from the Company and make up front, milestone and royalty payments. Stiefel may cancel the Agreement if there is a breach of contract, if either party files for bankruptcy, if its sales during any year are less than its minimum purchase obligations, or, as to Brazil only, if acceptable pricing approval, as defined in the Agreement, is not obtained. No upfront or milestone payments are refundable in any instance. Product shipments are subject to return and refund only if the product does not comply with technical specifications. The Company is obligated under the Agreement to provide multiple deliverables; the primary deliverables being license/product distribution rights and commercial product supply. Under EITF No. 00-21 the deliverables under the Agreement are treated as a single unit of accounting, as the Company does not have evidence to support that the consideration for the undelivered item, Levulan(R) units to be shipped, is at fair value. Except during the launch phase when revenues are recognized based on end-user demand, revenues from unit sales of Levulan(R) are recognized upon product shipment. The Agreement establishes a fixed supply price per unit, as well as a royalty based on a percentage of the net sales price to end-users. Royalty revenues are recorded each quarter based on Stiefel's reported net sales for that quarter. Royalties are included in product revenues.

The non-refundable up-front payments will be recognized into revenues on a straight-line basis commencing upon the first product shipments in a country

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

(see Note 12) over the remaining initial contractual term of the Agreement, which is 10 years. The initial contractual term coincides with management's best estimate of the product life cycle. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining initial contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of September 30, 2007, in accordance with the Company's policy of deferring revenues on new product launches, the Company has deferred revenues of \$110,000 related to product shipments of Levulan(R) Kerastick(R) into Mexico and Argentina that have not yet been sold through to the end user customers.

On January 4, 2007, we entered into an exclusive marketing, distribution and supply agreement with Daewoong Pharmaceutical Co., Ltd., or Daewoong, and Daewoong's wholly owned subsidiary, DNC Daewoong Derma & Plastic Surgery Network Company, and collectively with Daewoong referred to as D&D, covering current and future uses of the Levulan(R) Kerastick(R) for PDT in dermatology. The agreement grants D&D exclusive rights to distribute, promote and sell the Levulan(R) Kerastick(R) in Korea, Taiwan, China, including without limitation Hong Kong, India, Indonesia, Malaysia, Philippines,

7

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

Singapore, Thailand and Vietnam. We will manufacture and supply the product to D&D from our facility in Wilmington, MA. The agreement has an initial term of ten years (subject to earlier termination and extension provisions). Under the terms of the agreement, D&D will make up to \$3.5 million in milestone payments to DUSA, \$1.0 million of which was paid upon contract execution during the first quarter of 2007 and another \$1.0 million was paid subsequent to September 30, 2007 upon achieving regulatory approval in Korea. See Note 17 Subsequent Events. The remaining milestones are based upon achievement of pre-determined cumulative sales targets in the territory subject to certain terms and conditions. In order to maintain its exclusive rights, D&D is obligated to purchase a minimum number of units of the product and meet regulatory timelines. We will also receive a minimum transfer price per unit plus a percentage of D&D's end-user price above a certain level. The \$1.0 million received during the first quarter of 2007 has been deferred in its entirety and is included in other long term liabilities in the accompanying condensed consolidated financial statements. We expect to launch our product in Korea during the fourth quarter of 2007.

NON-PDT DRUG PRODUCTS. The Company recognizes revenue for sales of Non-PDT Drug Products 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 consist 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 first in, first out basis.

The Company evaluates inventory levels at its wholesaler customers, which



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

account for the vast majority of its sales in the Non-PDT Drug Products segment, through an analysis that considers, among other things, wholesaler purchases, wholesaler shipments to retailers, available end-user prescription data obtained from third parties and on-hand inventory data received directly from our three largest wholesaler customers. The Company believes that this evaluation of wholesaler inventory levels, allows it to make reasonable estimates for its applicable revenue related reserves. Additionally, the Company's products are sold to wholesalers with a product shelf life that allows sufficient time for its wholesaler customers to sell its products in their inventory through to retailers and, ultimately, to end-user consumers prior to product expiration.

For new product launches where the Company does not have the ability to reliably estimate returns, revenue is recognized based on end-user demand, which is typically based on dispensed subscription data. When inventories have been reduced to targeted stocking levels at wholesalers, and the Company has sufficient data to determine product acceptance in the marketplace which allows the Company to estimate product returns, the Company recognizes revenue upon shipment to wholesalers, net of discounts and allowances. As of September 30, 2007, the Company deferred \$303,000 in revenue related to the launch of ClindaReach(TM), which occurred in March 2007.

RETURNS AND ALLOWANCES - The Company's provision for returns and allowances consists of its estimates of future sales returns, rebates and chargebacks.

SALES RETURNS - The Company accounts for sales returns in accordance with Statements of Financial Accounting Standards (SFAS) No. 48, Revenue Recognition When Right of Return Exists, by establishing an accrual in an amount equal to its estimate of sales recorded for which the related products are expected to be returned. The Company determines the estimate of the sales return accrual primarily based on historical experience regarding sales returns, but also by considering other factors that could

8

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

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 the Company's policy to accept returns of Non-PDT Drug products when product is within nine months of expiration. The Company considers all of these factors and adjusts the accrual periodically to reflect actual experience.

CHARGEBACKS AND REBATES - Chargebacks typically occur when suppliers enter into contractual pricing arrangements with end-user customers, including certain federally mandated programs, who then purchase from wholesalers at prices below what the supplier charges the wholesaler. Since the Company only offers "preferred pricing" to end-user customers under federally mandated programs, chargebacks have not been significant to the Company. The Company's rebate programs can generally be categorized into the following two types: Medicaid rebates and consumer rebates. Medicaid rebates are amounts owed based on legal requirements with public sector benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant. Consumer rebates are amounts owed as a result of mail-in coupons that are distributed by health care providers to consumers at the time a prescription is written.

The Company offers its wholesaler customers a 2% prompt pay discount. The

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

Company evaluates the amount accrued for prompt pay discounts by analyzing the unpaid invoices in its accounts receivable aging subject to a prompt pay discount. Prompt pay discounts are known within 15 to 30 days of sale, and therefore can be reliably estimated based on actual and expected activity at each reporting date. The Company records these discounts at the time of sale and they are accounted for as a reduction of revenues. A summary of activity in the Company's valuation accounts are as follows:

FOR THE THREE MONTH PERIOD ENDED SEPTEMBER 30, 2007:

	BALANCE AT JULY 1, 2007	PROVISION RELATED TO SALES MADE IN THE CURRENT PERIOD	PROVISION FOR SALES MADE IN PRIOR PERIODS	ACTUAL RETURNS OR CREDITS IN THE CURRENT PERIOD	BALANCE SEPTEMBER 30, 2007
	-----	-----	-----	-----	-----
Accrued Expenses:					
Returns and allowances	\$705,000	\$ (16,000)	\$--	\$ (189,000)	\$500,000
Accounts receivable:					
Prompt payment discounts	\$ 17,000	\$ 53,000	\$--	\$ (57,000)	\$13,000

9

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

FOR THE NINE MONTH PERIOD ENDED SEPTEMBER 30, 2007:

	BALANCE AT JANUARY 1, 2007	PROVISION RELATED TO SALES MADE IN THE CURRENT PERIOD	PROVISION FOR SALES MADE IN PRIOR PERIODS	ACTUAL RETURNS OR CREDITS IN THE CURRENT PERIOD	BALANCE SEPTEMBER 30, 2007
	-----	-----	-----	-----	-----
Accrued Expenses:					
Returns and allowances	\$632,000	\$484,000	\$--	\$ (616,000)	\$500,000
Accounts receivable:					
Prompt payment discounts	\$ 23,000	\$181,000	\$--	\$ (191,000)	\$13,000

### WARRANTIES

The Company routinely accrues for estimated future warranty costs on its medical device product sales at the time of sale. Our products are subject to rigorous regulation and quality standards. Warranty costs were \$25,000 and \$77,000 for the three and nine month periods ended September 30, 2007 compared to \$10,000 and \$31,000, respectively, in the comparable 2006 periods, and were included in cost of product revenues.

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

### GOODWILL AND OTHER INTANGIBLE ASSETS

Goodwill and intangible assets with indefinite lives are not 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 are amortized over their useful lives. The Company has adopted December 1st as the date of the annual impairment test for goodwill.

### SHARE-BASED COMPENSATION

The Company adopted SFAS No. 123(R), Share-Based Payment, effective January 1, 2006, using the modified prospective application method, and beginning with the first quarter of 2006, the Company measures all employee share-based compensation awards using a fair value based method and records share-based compensation expense in its financial statements if the requisite service to earn the award is provided. In accordance with SFAS No. 123(R), the Company recognizes the expense attributable to stock awards that are expected to vest in the accompanying condensed consolidated statements of operations.

### RECENTLY ISSUED ACCOUNTING STANDARDS

In February 2007 the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities. SFAS No. 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. This statement is effective for fiscal years beginning after November 15, 2007. The Company will not early adopt the provisions of SFAS No. 159 and is in the process of evaluating whether it will choose to measure any eligible financial assets and liabilities at fair value.

In September 2006 the FASB issued SFAS No. 157, Fair Market Measurements. SFAS No. 157

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

establishes a framework for measuring fair value and expands disclosures about the use of fair value measurements and liabilities in interim and annual reporting periods subsequent to initial recognition. Prior to SFAS 157, which emphasizes that fair value is a market-based measurement and not an entity-specific measurement, there were different definitions of fair value and limited definitions for applying those definitions in GAAP. SFAS 157 is effective for the Company on a prospective basis for the reporting period beginning January 1, 2008. The effect of adoption on the Company's financial position and results of operations have not been determined.

In September 2006, Emerging Issues Task Force Issue No. 06-4, Accounting for Deferred Compensation and Postretirement Benefit Aspects of Endorsement Split-Dollar Life Insurance Arrangements (EITF 06-4) was issued. EITF 06-4 requires the recognition of a liability for an agreement with an employee to provide future postretirement benefits, as this obligation is not effectively settled upon entering into an insurance arrangement. The provisions of this standard are effective for years beginning after December 15, 2007. The Company is currently evaluating what effect the adoption of EITF 06-4 will have on its consolidated financial statements.

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

### 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 five 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 merger with Sirius has enabled DUSA to expand its product portfolio, capitalize on cross-selling and marketing opportunities, increase its sales force size; as well as, develop 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 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.

11

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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 (but see below for the amendment to this provision). The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments earned are, as follows:

CUMULATIVE SALES MILESTONE: (in millions)	PAYMENT EARNED: (in millions)
-----	-----
\$25.0	\$1.5
35.0	1.0
45.0	1.0
	----
Total:	\$3.5
	====

In addition, the merger agreement provides for the payment of three

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

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, if the milestones are achieved. During the first quarter of 2007, the Company paid the first of these milestones in the amount of \$500,000 to the former shareholders of Sirius related to the March 2007 launch of ClindaReach(TM). This payment has increased goodwill in the accompanying Condensed Consolidated Balance Sheet. The Company will not accrue contingent consideration obligations prior to the attainment of the objectives. The maximum remaining potential future consideration pursuant to such arrangements, to be resolved over the potential milestone period from the date of close, is \$4.5 million. If attained, the new product or launch portion of the contingent consideration is payable in cash and the sales milestone 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 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 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.

In connection with the license agreement between the Company and River's Edge Pharmaceuticals, LLC, ("River's Edge") as described in Note 17 Subsequent Events, the Company granted a perpetual, exclusive license to River's Edge to manufacture and sell four products acquired from Sirius in connection with the settlement of litigation with River's Edge. As part of the consideration for the settlement, the Company will receive a royalty on net sales of those products, including a guaranteed minimum royalty of \$300,000, payable in equal annual installments of \$100,000 for three years. In connection with the license, DUSA requested and received a waiver to certain obligations to promote these products from the Sirius shareholder representatives acting on behalf of all of the former shareholders of Sirius. As consideration for the waiver, the Company and the Sirius shareholder representatives agreed to amend the merger agreement to extend the milestone termination date provided in the merger agreement by eight (8) additional months and agreed that for the balance of the 50 month period prior to the milestone termination date (as amended), DUSA will credit the cumulative net sales milestone amounts under the merger agreement with a monthly amount equal to the average of the last

12

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

12-months of net sales by DUSA of the four products licensed to River' Edge.

#### 4) GOODWILL AND INTANGIBLE ASSETS

Under SFAS No. 142, Goodwill and Other Intangible Assets ("SFAS No. 142"), goodwill and certain intangible assets are deemed to have indefinite lives and are not amortized, but are reviewed at least annually for impairment. Other identifiable intangible assets are amortized over their estimated useful lives.

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

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.

At September 30, 2007, goodwill was \$6.3 million and was all attributable to the Non-PDT Drug Products operating segment (see Note 13). Amortization expense related to intangible assets was \$437,000 and \$977,000 for the three and nine-month periods ended September 30, 2006 and \$0 for both periods in 2007. Amortization expense is included in cost of product revenues in the accompanying Condensed Consolidated Statements of Operations. Shortly after the closing of the merger, the Company became engaged in patent litigation with River's Edge Pharmaceuticals, LLC ("River's Edge"), a company that launched its niacinamide-based product which is being substituted for our product, Nicomide. River's Edge also requested that the United States Patent and Trademark Office, or USPTO, reexamine the Nicomide(R) patent claiming that it is invalid. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. Although the court issued a preliminary injunction against sales of River's Edge's product in May 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. River's Edge reentered the market with its product in competition with Nicomide(R). As a result, in 2006 the identifiable intangible assets resulting from the Sirius acquisition were determined to be impaired based on an analysis of the carrying value and projected future cash flows of the assets. The impairment analysis resulted in a write down of approximately \$15.7 million in 2006, the then remaining net book value of the intangible assets.

Subsequent to September 30, 2007, the Company and River's Edge entered into a settlement agreement related to the litigation involving Nicomide(R) (the "Settlement Agreement"). The Settlement Agreement is further described in Note 17 Subsequent Events.

### 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 September 30, 2007, current yields range from 2.5% to 6.2% and maturity dates range from October 2007 to October 2011. The estimated fair value and cost of marketable securities at September 30, 2007 and December 31, 2006 are as follows:

	September 30, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government securities	\$ 8,610,638	\$74,284	\$(27,674)	\$ 8,657,
Corporate securities	1,561,620	2,664	(2,331)	1,561,
Total marketable securities available-for-sale	\$10,172,258	\$76,948	\$(30,005)	\$10,219,

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

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

	December 31, 2006			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government securities	\$11,673,884	\$112	\$(51,687)	\$11,622,
Corporate securities	3,328,685	295	(8,093)	3,320,
<b>Total marketable securities available-for-sale</b>	<b>\$15,002,569</b>	<b>\$407</b>	<b>\$(59,780)</b>	<b>\$14,943,</b>

The change in net unrealized gains and losses on such securities for the three and nine-month periods ended September 30, 2007 was (\$94,000) and (\$106,000), respectively, as compared to (\$57,000) and \$(27,000) for the three and nine-month periods ended September 30, 2006, and have been recorded in accumulated other comprehensive income, which is reported as part of shareholders' equity in the Condensed Consolidated Balance Sheets. Realized gains (losses) on sales of marketable securities were (\$10,000) and (\$3,000) for the three and nine-month periods ended September 30, 2007, respectively, as compared to \$0 and \$14,000 for the three and nine-month periods ended September 30, 2006.

### 6) CONCENTRATIONS

The Company invests cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. The Company manages the credit risk associated with its investments in marketable securities by investing in U.S. government securities and investment grade corporate bonds. In addition, the Company is dependent upon sole source suppliers for a number of its products.

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 in the Company's total revenues for the three and nine-month periods ended September 30, 2007 and 2006, and accounts receivable as of September 30, 2007 and December 31, 2006 are as follows:

	% OF REVENUE THREE MONTHS ENDED		% OF REVENUE NINE MONTHS ENDED		% OF ACC RECEIVABL
	SEPTEMBER 30, 2007	SEPTEMBER 30, 2006	SEPTEMBER 30, 2007	SEPTEMBER 30, 2006	SEPTEMBER 30, 2007
Customer A	2%	4%	5%	6%	4%
Customer B	14%	14%	12%	11%	15%
Customer C	16%	27%	17%	19%	19%
Customer D	7%	7%	6%	6%	8%
Other customers	61%	48%	60%	58%	54%

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

	---	---	---	---	---
Total	100%	100%	100%	100%	100%
	===	===	===	===	===

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

14

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

7) INVENTORY

Inventory consisted of the following:

	September 30, 2007	December 31, 2006
	-----	-----
Finished goods	\$2,456,967	\$1,425,131
BLU-U(R) evaluation units	126,845	166,812
Work in process	305,369	257,358
Raw materials	541,115	494,171
	-----	-----
	\$3,430,296	\$2,343,472
	=====	=====

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. We amortize the cost of the evaluation units during the valuation period to cost of product revenues to approximate their net realizable value.

8) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

	September 30, 2007	December 31, 2006
	-----	-----
Research and development costs	\$ 358,074	\$ 458,792
Marketing and sales costs	158,765	314,770
Product related costs	1,256,700	1,739,424
Legal and other professional fees	834,796	634,655
Employee benefits	358,584	294,673
Other accrued expenses	8,248	399,577
	-----	-----



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

\$2,975,167	\$3,841,891
=====	=====

### 9) INCOME TAXES

On July 13, 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109 ("FIN 48"). FIN 48 prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the amount of tax benefits recognized must be the largest amount of tax benefit that has a greater than 50% likelihood of being sustained upon audit by the relevant taxing authority. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, and accounting for interim periods and requires expanded disclosure with respect to the uncertainty in income taxes. FIN 48 is effective for fiscal years beginning after December 15, 2006. The cumulative effect, if any, of adopting FIN 48 is to be reported as an adjustment to the opening balance of retained earnings in the year of adoption.

The Company adopted the provisions of FIN 48 on January 1, 2007. As of the date of adoption, the total amount of unrecognized tax benefits is \$1,800,000, all of which, if recognized, would affect the effective tax rate prior to the adjustment for the Company's valuation allowance. As a result of the implementation of FIN 48, the Company did not recognize an increase in tax liability for the unrecognized tax benefits because the Company has recorded a tax net operating loss carryforward that

15

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

would offset this liability.

The Company recognizes interest and penalties related to unrecognized tax benefits in operating expenses. Since a full valuation allowance was recorded against the Company's net deferred tax assets and the unrecognized tax benefits determined under FIN 48 would not result in a tax liability, the Company has not accrued for any interest and penalties relating to these unrecognized tax benefits.

Tax years ended December 31, 2003, 2004, 2005 and 2006 remain subject to examination by major tax jurisdictions, which are Federal and the Commonwealth of Massachusetts. However, since the Company has net operating loss and tax credit carryforwards which may be utilized in future years to offset taxable income, those years may also be subject to review by relevant taxing authorities if utilized.

The Company has performed an analysis of its changes in ownership under Internal Revenue Code Section 382 and has determined that approximately \$5,400,000 of state NOL's are limited and unavailable to offset future taxable income, resulting in a reduction of the related deferred tax asset and valuation allowance of approximately \$280,000.

### 10) SHARE-BASED COMPENSATION

Total share-based compensation expense, related to all of the Company's share-based awards, recognized for the three and nine-month periods ended September 30, 2007 and 2006 included the following line items:

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

	Three-months ended		Nine-months ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Cost of Product Revenues	\$ 25,000	\$ 24,000	\$ 75,000	\$ 61,000
Research and Development	94,000	101,000	280,000	263,000
Marketing and Sales	115,000	123,000	134,000	270,000
General and Administrative	194,000	195,000	657,000	819,000
Total share-based compensation expense	\$428,000	\$443,000	\$1,146,000	\$1,413,000

The weighted-average estimated fair value of employee stock options granted during the nine month periods ended September 30, 2007 and 2006 was \$1.99 and \$4.58 per share, respectively, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	Three-months ended September 30		Nine-months ended September 30	
	2007	2006	2007	2006
Volatility	62.2%	63.7%	62.2%	63.7%
Risk-free interest rate	4.7%	5.1%	4.5%	5.1%
Expected dividend yield	0%	0%	0%	0%
Expected life-directors and officers	5.9 years	8.0 years	5.9 years	8.0 years
Expected life-non-officer employees	5.5 years	6.3 years	5.5 years	6.3 years

Under the Company's 2006 Equity Compensation Plan (the "2006 Plan"), the Company may grant share-based awards in amounts not to 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

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

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 individual during any calendar year is 300,000.

The 2006 Plan is administered by the Compensation Committee of the Board of Directors (the "Committee"). The 2006 Plan provides for the grant of incentive stock options ("ISO"), nonqualified stock options ("NSO"), stock awards, and stock appreciation rights to (i) employees, consultants, and advisors; (ii) the

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

employees, consultants, and advisors of the Company's parents, subsidiaries, and affiliates; and (iii) the Company's non-employee directors.

**Non-Qualified Stock Options** - All of the non-qualified stock options, or NSOs, granted under the 2006 Plan have an expiration period not exceeding seven years and are issued at a price not less than the market value of the common stock on the grant date. The Committee may establish such vesting and other conditions with respect to options as it deems appropriate. In addition, the Company initially grants each individual who agrees to become a non-management director 15,000 NSOs to purchase common stock of the Company. Thereafter, each non-management director reelected at an Annual Meeting of Shareholders will automatically receive an additional 10,000 NSOs on June 30 of each year. Grants to directors immediately vest on the date of the grant.

**Incentive Stock Options** - All of the incentive stock options, or ISOs, granted under the 2006 Plan have an expiration period not exceeding seven 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. The Committee may establish such vesting and other conditions with respect to options as it deems appropriate.

A summary of stock option activity for the nine month period ended September 30, 2007 is as follows:

	NUMBER OF SHARES (IN THOUSANDS)	WEIGHTED AVERAGE EXERCISE PRICE
	-----	-----
Outstanding at January 1, 2006	2,730,875	\$11.58
Options granted	414,000	3.30
Options forfeited	(24,499)	7.48
Options expired	(91,251)	6.70
Options exercised	(15,000)	2.71
	-----	-----
Outstanding at September 30, 2007	3,014,125	\$10.66
	=====	=====
Exercisable at September 30, 2007	2,139,442	\$12.33
	=====	=====

The weighted average remaining contractual term was approximately 5.11 years for stock options outstanding and approximately 4.24 years for stock options exercisable as of September 30, 2007.

The total intrinsic value (the excess of the market price over the exercise price) was approximately \$55,000 for stock options outstanding and \$53,000 for stock options exercisable as of September 30, 2007. The total intrinsic value for stock options exercised in 2007 was \$31,000.

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

Basic net loss per common share is based on the weighted-average number of shares outstanding

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

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

during each period. For the periods ended September 30, 2007, and 2006, stock options, warrants and rights totaling approximately 3,264,000 and 3,110,000 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 a liability escrow account, are included in the weighted-average number of shares outstanding from the date of issuance, March 10, 2006.

### 12) STIEFEL AGREEMENT

In January 2006, DUSA licensed to Stiefel Laboratories, Inc. ("Stiefel") the exclusive Latin American rights to market Levulan(R) PDT. The agreement was amended in September, 2007. The amendment reduced the milestone payments by Stiefel from up to \$3.0 million to up to \$2.25 million. DUSA also manufactures and supplies finished product for Stiefel, which the Company began shipping in September 2007. In consideration for the transaction Stiefel agreed to pay DUSA as follows: (i) \$375,000 upon launch of the product in either Mexico or Argentina; (ii) \$375,000 upon receipt of acceptable pricing approval in Brazil; (iii) two installments of \$375,000 each for cumulative end-user sales in Brazil totaling 150,000 units and 300,000 units, and (iv) two installments of \$375,000 each for cumulative sales in countries excluding Brazil totaling 150,000 units and 300,000 units. Stiefel launched the product in October 2007 in Mexico and Argentina. DUSA is currently deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2016, which is DUSA's best estimate of the end of the useful economic life of the product, which also coincides with the contractual term of the Stiefel Agreement. During the third quarter of 2007, DUSA's product sales of Levulan(R) to Stiefel was \$110,000, which has been deferred in its entirety at September 30, 2007 in accordance with the Company's policy of deferring revenues during a product's launch phase and recognizing revenues based on end-user demand.

### 13) SEGMENT REPORTING

Beginning in the first quarter of 2006 with the acquisition of Sirius, 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.

18

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

THREE MONTHS ENDED		NINE MONTHS ENDED	
-----		-----	
SEPTEMBER 30,	SEPTEMBER 30,	SEPTEMBER 30,	SEPTEMBER 30,

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

	2007	2006	2007	2006
REVENUES				
PDT Drug & Device Product Revenues	\$3,488,759	\$3,234,919	\$12,107,246	\$10,900,000
Non-PDT Drug Product Revenues	2,295,435	2,827,801	7,215,986	6,500,000
Total Revenues	5,784,194	6,062,720	19,323,232	17,400,000
COSTS OF REVENUES				
PDT Drug & Device Cost of Product Revenues and Royalties	1,154,644	1,242,860	3,608,233	3,900,000
Non-PDT Drug Cost of Product Revenues and Royalties	419,253	1,606,625	1,898,307	3,600,000
Total Costs of Product Revenues and Royalties	1,573,897	2,849,485	5,506,540	7,500,000
GROSS MARGIN				
PDT Drug and Device Product Gross Margin	2,334,115	1,992,059	8,499,015	6,900,000
Non-PDT Drug Product Gross Margin	1,876,182	1,221,176	5,317,677	2,800,000
Total Gross Margin	\$4,210,297	\$3,213,235	\$13,816,692	\$9,700,000

During the three and nine-month periods ended September 30, 2007 and 2006, the Company derived revenues from the following geographies (as a percentage of product revenues):

	THREE MONTHS ENDED SEPTEMBER 30		NINE MONTHS ENDED SEPTEMBER 30	
	2007	2006	2007	2006
United States	98%	96%	97%	94%
Canada	2%	4%	3%	6%
Total	100%	100%	100%	100%

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

14) COMPREHENSIVE LOSS

For the three and nine-month periods ended September 30, 2007 and 2006, comprehensive loss consisted of the following:

	THREE MONTHS ENDED SEPTEMBER 30		NINE MONTHS ENDED SEPTEMBER 30	
	2007	2006	2007	2006
NET LOSS	\$ (1,877,782)	\$ (3,786,639)	\$ (7,726,117)	\$ (13,080,901)
Change in net unrealized gains				

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

and losses on marketable securities available for sale	94,312	(56,756)	106,316	(27,313)
	-----	-----	-----	-----
COMPREHENSIVE LOSS	\$(1,783,470)	\$(3,843,395)	\$(7,619,801)	\$(13,108,214)
	=====	=====	=====	=====

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.

19

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

### 15) DEFERRED COMPENSATION PLAN

In October 2006, the Company adopted the DUSA Pharmaceuticals, Inc. Non-Qualified Deferred Compensation Plan (the "Plan"), a non-qualified supplemental retirement plan maintained primarily for the purpose of providing deferred compensation for a select group of management or highly compensated employees and members of the Board of Directors of DUSA (the "Participants"). Participants may defer up to 80% of their compensation. A Participant will be 100% vested in all of the amounts he or she defers as well as in the earnings attributable to a Participant's deferred account. A Participant may elect to receive distributions from the deferred account at various times, either in a lump sum or in up to ten annual installments. Included in other liabilities is \$105,000 at September 30, 2007, representing the Company's obligation under the Plan. DUSA's obligation to pay the Participant an amount from his or her deferred account is an unsecured promise and benefits shall be paid out of the general assets of the Company. The Company has purchased corporate owned life insurance to serve as the funding vehicle for the Plan. The cash surrender value of the life insurance policy is recorded in deferred charges and other assets and totaled \$103,000 at September 30, 2007.

### 16) 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 with DUSA, Sirius 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 but has been dismissed. Nicomide(R) 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(R) patent. On April 20, 2006, the Company filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that the River's Edge niacinamide product infringes U.S. Patent No. 6,979,468. The Company posted \$750,000 with the court in an interest bearing account. Although the court issued a preliminary injunction against sales of River's Edge's product in May 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. On June 14, 2007, the court granted DUSA's request to amend its

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

complaint to assert claims against River's Edge for violations of the Lanham Act and infringement of its copyright. Also, the court dismissed the various state law claims that River's Edge had alleged against the Company. The court also ordered that the parties participate in a non-binding mediation which took place on August 9, 2007. Following the lifting of the preliminary injunction, River's Edge reentered the market with its niacinamide-based product in competition with Nicomide(R). Following the end of this quarter, DUSA and River's Edge settled this litigation. See Note 17 Subsequent Events.

### 17) SUBSEQUENT EVENTS

#### SETTLEMENT OF RIVER'S EDGE LITIGATION INVOLVING NICOMIDE(R)

On October 28, 2007, the Company entered into a Settlement and Mutual Release Agreement (the "Settlement Agreement") to dismiss the lawsuit brought by DUSA against River's Edge Pharmaceuticals, LLC ("River's Edge") asserting a number of claims arising out of River's Edge's alleged infringement of U.S. Patent No. 6,979,468 under which DUSA has marketed, distributed and sold Nicomide(R). Under the terms of the Settlement Agreement, River's Edge unconditionally acknowledged the validity and

20

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

enforceability of the Nicomide(R) patent, made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages and will pay to DUSA a per unit amount for every bottle of NIC 750 above a certain number of units that is substituted for Nicomide(R) after September 30, 2007. River's Edge shall be responsible for all returns of NIC 750 from the distribution chain and/or order its destruction and will immediately cease the manufacture, distribution and sale of NIC 750. River's Edge is obligated to withdraw and cease participating in the re-examination of the Company's Nicomide(R) patent and has consented to the return to the Company of the \$750,000 bond that is currently being held by the courts with all accrued interest.

As part of the settlement, DUSA and River's Edge have also entered into a license agreement, dated October 28, 2007 (the "License Agreement") whereby DUSA granted a perpetual, exclusive license to River's Edge to manufacture and sell four of products from the AVAR(R) line, including AVAR cleanser, AVAR gel, AVAR E-emollient cream and AVAR E-green in exchange for a royalty on net sales of these products, including a guaranteed minimum royalty of \$300,000, payable in equal annual installments of \$100,000 for three years. DUSA provided its on-hand inventory of these products to River's Edge for no cost. The Company will participate in returns of split lots based on the two company's respective pro-rata sales of these lots.

DUSA acquired the AVAR products from Sirius Laboratories, Inc., the Illinois corporation, as a result of the merger which closed on March 10, 2006. In connection with the License Agreement, DUSA requested and received a waiver to certain obligations to promote the AVAR products being licensed to River's Edge from the Sirius shareholder representatives acting on behalf of all of the former shareholders of Sirius Laboratories, Inc.

As consideration for the waiver, the Company and the Sirius shareholder representatives agreed to amend the merger agreement to extend the milestone termination date provided in the merger agreement by eight (8) additional months and agreed that for the balance of the 50 month period prior to the milestone

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

termination date (as amended), DUSA will credit the cumulative net sales milestone amounts under the merger agreement with a monthly amount equal to the average of the last 12-months of net sales by DUSA of the four products licensed to River' Edge.

### KOREA FDA APPROVAL

In October 2007, Daewoong Pharmaceutical Co., Ltd. and its affiliate DNC Daewoong Derma & Plastic Surgery Network Company received approval from the Korea Food and Drug Administration for the use of Levulan(R) Kerastick(R) for Photodynamic Therapy (PDT) for the treatment of actinic keratosis (AKs). Pursuant to the terms of the agreement with Daewoong, the Company received a payment of \$1.0 million upon receipt of such approval.

### LAUNCH OF LEVULAN KERASTICK IN LATIN AMERICA

In October 2007 the Company achieved the first milestone under the Stiefel Agreement upon the launch of the Levulan(R) Kerastick(R) in Mexico and Argentina. Subsequent to quarter end, the Company received a payment of \$375,000 from Stiefel related to the achievement of this milestone.

### \$11 MILLION PRIVATE PLACEMENT OF COMMON STOCK AND WARRANTS TO INSTITUTIONAL INVESTORS

On October 29, 2007, the Company entered into a securities purchase agreement, common stock purchase warrants, and a registration rights agreement (the "Definitive Agreements") with certain accredited investors for the private placement of 4,581,043 shares of its common stock (the "Shares") at a purchase price of \$2.40 per share which resulted in gross proceeds to DUSA of \$11,000,000, and warrants to purchase an additional 1,145,259 shares of common stock (the "Warrants"). The Warrants become

21

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

exercisable on April 30, 2008, have a term of 5 years from the initial exercise date, and have an exercise price of \$2.85 per share. The Company has committed to register the Shares and the shares underlying the Warrants with the Securities and Exchange Commission on a Form S-3 registration statement. If the registration statement does not become effective within a stated period of time, then the investors are entitled to receive a cash payment of 1% of the aggregate purchase price they paid for their respective Shares for each month that the registration statement is delayed beyond the time periods stated in the Definitive Agreements, up to a maximum of 12% of such aggregate purchase price. The Company has paid the placement agent its fee, including expenses, of \$695,000 for its services in connection with the transaction.

22

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

### OVERVIEW



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

DUSA is a vertically integrated dermatology company that is developing and marketing Levulan(R) PDT and other products for common skin conditions. Our currently marketed products include among others Levulan(R) Kerastick(R) 20% Topical Solution with PDT, the BLU-U(R) brand light source, and the products acquired in the March 10, 2006 merger with Sirius Laboratories, Inc., including, Nicomide(R), Nicomide-T(R) and the newly launched product, ClindaReach(TM).

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

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

Sirius Laboratories, Inc., or Sirius, a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Nicomide(R), an oral prescription vitamin supplement and Nicomide-T(R), a topical cosmetic product, two of the important Sirius products, target the acne and acne rosacea markets. The merger has allowed 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 potential new products, including ClindaReach(TM) which was launched in March 2007.

Acne is a common skin condition caused, in part, by the blockage and/or inflammation of sebaceous (oil) glands. We are currently conducting a Phase II study examining the use of Levulan(R) PDT for the treatment of moderate to severe acne. We currently expect results from this study by the end of the third quarter of 2008 depending upon how quickly we complete enrollment of patients. We have received comments on our acne development program from the FDA statistical reviewer assigned to our investigational new drug application, or IND. In this letter, the reviewer stated concern about whether we will have sufficient data to select an appropriate dosing regimen for Phase III trials. We believe that we have the data to indicate that sufficient drug dose ranging has been done; however, if the FDA does not accept our rationale, additional clinical trials and/or formulation development work may be required for the acne development program, which may extend the expected development time lines for such program.

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.

We are responsible for manufacturing of our Levulan(R) Kerastick(R) and for the regulatory, sales, marketing, and customer service of our Levulan(R) Kerastick(R), and other related product activities for all of our products. Our current objectives include increasing the sales of our products in the United States and Canada, launching Levulan(R) with our distributors in Brazil and other Latin American countries and Asia, continuing our efforts of exploring partnership opportunities for Levulan(R) PDT for dermatology in Europe, continuing our Levulan(R) PDT clinical development program for the moderate to severe acne indication and development of our pipeline product programs.

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. We have been actively working with Stiefel to obtain acceptable final pricing from the Brazilian regulatory authorities. During the quarter ended September 30, 2007, in light of the unexpected delay in receiving acceptable final pricing in Brazil, we amended certain terms of the original Stiefel agreement to reflect our plans to launch in other Latin American countries prior to Brazil. During the quarter ended September 30, 2007 our first shipments were released to Argentina and Mexico. Pursuant to the Amendment, Stiefel will make aggregate milestone payments to DUSA of up to \$2,250,000, rather than up to \$3,000,000 under the Agreement as follows: (i) \$375,000 upon launch of the product in either Mexico or Argentina; (ii) \$375,000 upon receipt of acceptable pricing approval in Brazil; (iii) two installments of \$375,000 each for cumulative end-user sales in Brazil totaling 150,000 units and 300,000 units, and (iv) two installments of \$375,000 each for cumulative sales in countries excluding Brazil totaling 150,000 units and 300,000 units. In addition, the transfer price for the product was amended to set a fixed price plus a royalty on net sales, rather than a revenue-sharing arrangement as under the Agreement. DUSA believes that the amended transfer price reduces some of the risk related to currency and market price fluctuations during the ten-year term of the Agreement. Subsequent to September 30, 2007, we achieved the first milestone under the Stiefel Agreement upon the launch of the Levulan(R) Kerastick(R) in Mexico and Argentina and received a payment of \$375,000. In addition, on November 9, 2007, we became aware that the Brazilian authorities had accepted the appeal of the initial pricing decision and that Stiefel would receive the final outcome shortly.

Similarly, we entered into a marketing and distribution agreement with Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Company, or collectively, Daewoong, granting Daewoong exclusive rights to distribute the Levulan(R) Kerastick(R) in certain Asian countries. Subsequent to September 30, 2007 the Korean Food and Drug Administration, or KFDA, approved Levulan(R) Kerastick(R) for PDT for the treatment of actinic keratosis. Pursuant to the terms of the agreement with Daewoong, we received a payment of \$1.0 million upon receiving such approval. We expect to launch our product during the first quarter of 2008.

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 our drug and related processes and improvements. In the United States, DUSA(R), DUSA Pharmaceuticals, Inc.(R), Levulan(R), Kerastick(R), BLU-U(R) Nicomide(R), Nicomide-T(R), Meted(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.

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

As of September 30, 2007, we had an accumulated deficit of approximately \$128,613,000. We expect to continue to incur operating losses through 2007 and until sales of our products increase. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our therapy by the medical and consumer constituencies in the United States, international expansion of the Levulan(R) franchise, and our ability to develop and/or acquire new profitable 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

24

manufacturing and sales and marketing capabilities than we do. On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby in settlement of patent disputes we granted a non-exclusive license to PhotoCure under the patents we license from PARTEQ for esters of aminolevulinic acid, or ALA. Furthermore, we granted a non-exclusive license to PhotoCure for its existing formulations of its Hexvix(R) and Metvix(R) (known in the United States as Metvixia(R)) products for any relevant patents that may issue to DUSA or that we may license in the future. PhotoCure received FDA approval to market Metvixia(R) for treatment of actinic keratosis in July 2004 and it would be directly competitive with our Levulan(R) Kerastick(R) product should PhotoCure with its marketing partner, Galderma S.A., decide to begin marketing this product in the United States which could happen at any time. While we are entitled to royalties from PhotoCure on its net sales of Metvixia in certain territories, this product may adversely affect our ability to maintain or increase our Levulan(R) market.

We are dependent upon sole-source suppliers for a number of our raw materials and products including Nicomide(R), Levulan(R) and the BLU-U(R). There can be no assurance that these suppliers will be able to meet our 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 our operating results in any given period.

Marketing and sales activities since the launch of our sales force in 2003 have resulted in significant additional revenues as well as expenses. Levulan(R) Kerastick(R) unit sales to end-users were 30,108 and 104,364 for the three and nine-month periods ended September 30, 2007, respectively, including 1,890 and 7,098, respectively, sold in Canada. This represents an increase from 27,480 and 95,358 units sold in the three and nine-month periods ended September 30, 2006, respectively, including 2,400 and 12,990, respectively, sold in Canada

The net number of BLU-U(R) units placed in physicians' offices during the nine months ended September 30, 2007 and 2006 was 178 and 211, respectively, including 16 and 25 placed in Canada in 2007 and 2006, respectively. As of September 30, 2007 and December 31, 2006 there were 1,815 and 1,637 units in physicians' offices, respectively. During the quarter ended September 30, 2007 we implemented a "one-time" sales promotion in which we sold earlier generation devices at a discounted price. During 2005 we began a BLU-U(R) marketing effort to allow prospective customers to evaluate a BLU-U(R) for a short period of time prior to making a purchase decision. BLU-U(R) commercial light sources placed in

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

physicians' offices pursuant to the Company's BLU-U(R) evaluation program are classified as inventory in the accompanying consolidated balance sheets. We amortize the cost of the evaluation units during the evaluation period to cost of product revenues to approximate its net realizable value.

Net revenues generated by the products acquired as part of our merger with Sirius totaled \$2,295,000 and \$7,216,000 for the three and nine-month periods ended September 30, 2007, respectively, compared to \$2,828,000 and \$6,503,000 for the three month period ended September 30, 2006 and the period March 10, 2006 (date of acquisition) through September 30, 2006, respectively. The substantial majority of these revenues were from sales of Nicomide(R). We believe that our Non-PDT Drug Products revenues were materially adversely impacted during 2007 as a result of the dissolution of a preliminary injunction by the United States District Court in Trenton, New Jersey on March 7, 2007, which allowed River's Edge to reenter the market and sell its niacinamide-based product, which was being substituted for Nicomide(R). See section entitled "Part II. Other Information-Legal Proceedings-River's Edge."

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide(R). FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to

25

obtain marketing approval and we have begun discussions with FDA to begin that process. The FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and the FDA may bring an action against a drug or a firm when the FDA concludes that such other violations exist. The contract manufacturer of Nicomide(R) has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide(R) could not be marketed as a dietary supplement with its current labeling. There can be no assurance that the FDA will continue this policy or not take a contrary position with Nicomide(R). If the FDA were to take further action, we may be required to make certain labeling changes and market Nicomide(R) as an over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA would have a material impact on our Non-PDT Drug Product revenues. Label changes eliminating claims of certain medicinal benefits could make it more difficult to market Nicomide(R) and could therefore, negatively affect our revenues and profits.

Shortly after the closing of the merger with Sirius, we became engaged in patent litigation with River's Edge Pharmaceuticals LLC, or River's Edge, a company that launched a niacinamide-based product. River's Edge also requested that the United States Patent and Trademark Office, or USPTO, reexamine the Nicomide(R) patent claiming that it is invalid. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. Although the court issued a preliminary

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

injunction against sales of River's Edge's product in May, 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process by the USPTO presented sufficient changed circumstances to warrant the dissolution of the injunction. On October 28, 2007, we entered into a settlement and mutual release agreement, or Settlement Agreement, and a license agreement with River's Edge ending the litigation. See section entitled "Part II. Other Information-Legal Proceedings-River's Edge." Nicomide(R) sales were adversely impacted throughout the litigation process and had a material negative impact on our revenues, results of operations and liquidity. We expect that sales of Nicomide should begin to return to pre-litigation levels in the coming months.

We have recently been advised that the sole manufacturer of our product, Psoriatec(R), may have produced batches that are not meeting stability specifications. We are currently conducting testing of these batches and may have to recall the product that is in the distribution channel which will impact our sales of this product. We do not expect the costs of the potential recall, if any, to be material. The license agreement for Psoriatec(R) expires January 31, 2008 and we do not intend to renew the license.

We are continuing to explore opportunities to develop, market, and distribute our Levulan(R) PDT platform in Europe and expect that our distribution partners, Stiefel for Latin America and Daewoong for Asia will give the product increased visibility in the market and thereby advance our international strategy. 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 term.

We believe that issues related to reimbursement negatively impacted the economic competitiveness of our therapy with other AK therapies and hindered its adoption in the past. We have continued to 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 Association, or AADA, on matters related to PDT-related procedures fee and the separate drug reimbursement. In addition, in many cases, physicians can also bill for any applicable office visit reimbursements. 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. The currently proposed reimbursement amount for our PDT-related procedure fee would increase by approximately 18% effective January, 2008 if adopted as proposed.

26

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

We recognize that we have to continue to demonstrate the clinical value of our unique therapy, and the related product benefits as compared to other well-established conventional therapies, in order for the medical community to accept our products on a large scale. Since we cannot predict when product sales may offset the costs associated with these efforts, we expect that we will continue to generate operating losses through 2007. We are aware that physicians have been using Levulan(R) with the BLU-U(R) using short incubation times, and with light devices manufactured by other companies, and for uses other than our

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

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 have exceeded the legal limits for their activities, including manufacturing and/or selling quantities of ALA in circumstances which may have induced purchasers to infringe our intellectual property. We believe that these activities have negatively impacted our Levulan(R) sales growth. Therefore during the last two years we have filed lawsuits against compounding pharmacies, chemical companies, a distributor and sales representative, as well as against a number of physicians. Many of these lawsuits have already settled favorably to us. See section entitled "Part II. Other Information-Legal Proceedings - Levulan(R) Lawsuits."

After the close of the quarter, we entered into a securities purchase agreement, common stock purchase warrants, and a registration rights agreement with certain accredited investors for the private placement of 4,581,043 shares of our common stock at a purchase price of \$2.40 per share which resulted in gross proceeds to us of \$11,000,000. We also issued warrants to purchase an additional 1,145,259 shares of common stock. The warrants become exercisable on April 30, 2008, have a term of 5 years from the initial exercise date, and have an exercise price of \$2.85 per share. We have committed to register the shares that were issued and the shares underlying the warrants with the Securities and Exchange Commission on a Form S-3 registration statement. If the registration statement does not become effective within a stated period of time, then the investors are entitled to receive a cash payment of 1% of the aggregate purchase price they paid for their respective shares for each month that the registration statement is delayed beyond the time periods stated in the agreements, up to a maximum of 12% of such aggregate purchase price. We paid the placement agent its fee, including expenses, of \$695,000 for its services in connection with the transaction. We will use the proceeds from the sale of the securities to further advance our Levulan(R) PDT clinical development programs and activities associated with expanding our market presence in the U.S.

As of September 30, 2007, we had a staff of 86 employees, including 4 part-time employees, as compared to 85 full-time employees, including 2 part-time employees at the end of 2006, who worked across all operating functions at DUSA.

### 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, 2006. 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 AND PROVISIONS FOR ESTIMATED REDUCTIONS TO GROSS REVENUES

We recognize revenues in accordance with Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition in Financial Statements, as amended by SAB No. 104, Revenue Recognition. This accounting policy for revenue recognition has a substantial impact on our reported results and relies on

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

certain estimates that require difficult, subjective and complex judgments on the part of management.

PHOTODYNAMIC THERAPY (PDT) DRUG AND DEVICE PRODUCTS. Revenues on the Kerastick(R) and BLU-U(R) product sales in the U.S. and Canada 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 beginning January 1, 2006. This change in estimate was not material to our revenues or results of operations. We offer programs that allow physicians access to our BLU-U(R) device 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.

In January 2006, as amended in September 2007, we entered into an exclusive marketing, distribution and supply agreement with Stiefel Laboratories, Inc. for Levulan(R) PDT in Latin America (see Note 12). Under the agreement, Stiefel is required to purchase Levulan(R) from us and make up front, milestone and royalty payments. Stiefel may cancel the agreement if there is a breach of contract, if either party files for bankruptcy, if its sales during any year are less than its minimum purchase obligations, or, as to Brazil only, if acceptable pricing approval, as defined in the agreement, is not obtained. No upfront or milestone payments are refundable in any instance. Product shipments are subject to return and refund only if the product does not comply with technical specifications. We are obligated under the agreement to provide multiple deliverables; the primary deliverables being license/product distribution rights and commercial product supply. Under EITF No. 00-21 the deliverables under the agreement are treated as a single unit of accounting, as we do not have evidence to support that the consideration for the undelivered item, Levulan(R) units to be shipped, is at fair value. Except during the launch phase when revenues are recognized based on end-user demand, revenues from unit sales of Levulan(R) are recognized upon product shipment. The agreement establishes a fixed supply price per unit, as well as a royalty based on a percentage of the net sales price to end-users. Royalty revenues are recorded each quarter based on Stiefel's reported net sales for that quarter. Royalties are included in product revenues.

The non-refundable up-front payments will be recognized into revenues on a straight-line basis commencing upon the first product shipments in a country (see Note 12) over the remaining initial contractual term of the agreement, which is 10 years. The initial contractual term coincides with management's best estimate of the product life cycle. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining initial contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of September 30, 2007, in accordance with our policy of deferring revenues on new product launches, we have deferred revenues of \$110,000 related to product shipments of Levulan(R) Kerastick(R) into Mexico and Argentina that have not yet been sold through to the end user customers.

On January 4, 2007, we entered into an exclusive marketing, distribution and supply agreement with Daewoong Pharmaceutical Co., Ltd., or Daewoong, and Daewoong's wholly owned subsidiary, DNC Daewoong Derma & Plastic Surgery Network Company, and collectively with Daewoong referred to as D&D, covering current and future uses of the Levulan(R) Kerastick(R) for PDT in dermatology. The agreement grants D&D exclusive rights to distribute, promote and sell the Levulan(R) Kerastick(R) in Korea, Taiwan, China, including without limitation Hong Kong, India, Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam. We

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

will manufacture and supply the product to D&D from our facility in Wilmington, MA. The agreement has an initial term of ten years (subject to earlier termination and extension provisions). Under the terms of the agreement, D&D will make up to \$3.5 million in milestone payments to DUSA, \$1.0 million of which was paid upon contract execution during the first quarter of 2007 and another \$1.0 million was paid subsequent to September 30, 2007 upon achieving regulatory approval in Korea. See Note 17 Subsequent Events. The remaining milestones are based upon

28

achievement of pre-determined cumulative sales targets in the territory subject to certain terms and conditions. In order to maintain its exclusive rights, D&D is obligated to purchase a minimum number of units of the product and meet regulatory timelines. We will also receive a minimum transfer price per unit plus a percentage of D&D's end-user price above a certain level. The \$1.0 million received during the first quarter of 2007 has been deferred in its entirety and is included in other long term liabilities in the accompanying condensed consolidated financial statements. We expect to launch our product in Korea during the fourth quarter of 2007.

**NON-PDT DRUG PRODUCTS.** We recognize revenue for sales of Non-PDT Drug Products 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 consist 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 a 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 wholesaler's customers on a FIFO basis.

We evaluate inventory levels at our wholesaler customers, which account for the vast majority of our sales in the Non-PDT Drug Products segment, through an analysis that considers, among other things, wholesaler purchases, wholesaler shipments to retailers, available end-user prescription data obtained from third parties and on-hand inventory data received directly from our three largest wholesaler customers. We believe that our evaluation of wholesaler inventory levels allows us to make reasonable estimates for our applicable revenue related reserves. Additionally, our products are sold to wholesalers with a product shelf life that allows sufficient time for our wholesaler customers to sell its products in their inventory through to the retailers and, ultimately, to the end-user consumer prior to product expiration.

For new product launches where we do not have the ability to reliably estimate returns, we recognize revenues based on end-user demand, which is typically based on dispensed subscription data. When inventories have been reduced to targeted stocking levels at wholesalers, and we have sufficient data to determine product acceptance in the marketplace which allows us to estimate product returns, we recognize revenue upon shipment to wholesalers, net of discounts and allowances. As of September 30, 2007, the Company deferred \$303,000 in revenue related to the launch of ClindaReach(TM) that has not been sold through to the end user customers.

**RETURNS AND ALLOWANCES** - Our provision for returns and allowances consists



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

of our estimates of future sales returns, rebates and chargebacks.

**SALES RETURNS** - We account for sales returns in accordance with Statements of Financial Accounting Standards (SFAS) No. 48, Revenue Recognition When Right of Return Exists, 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 our actual experience.

**CHARGEBACKS AND REBATES** - Chargebacks typically occur when suppliers enter into contractual pricing arrangements with end-user customers, including certain federally mandated programs, who then purchase from wholesalers at prices below what the supplier charges the wholesaler. Since we only offer

29

"preferred pricing" to end-user customers under federally mandated programs, chargebacks have not been significant to us. Our rebate programs can generally be categorized into the following two types: Medicaid rebates and consumer rebates. Medicaid rebates are amounts owed based on legal requirements with public sector benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant. Consumer rebates are amounts owed as a result of mail-in coupons that are distributed by health care providers to consumers at the time a prescription is written. Since only a small percentage of our prescriptions are reimbursed under Medicaid and the quantity of consumer coupon redemptions have not been substantial, rebates have not been significant.

We offer many of our customers a 2% prompt pay discount. We evaluate the amount accrued for prompt pay discounts by analyzing the unpaid invoices in our accounts receivable aging subject to a prompt pay discount. Prompt pay discounts are known within 15 to 30 days of sale, and therefore we can reliably estimate them based on actual and expected activity at each reporting date. We record these discounts at the time of sale and they are accounted for as a reduction of revenues.

### WARRANTIES

The Company routinely accrues for estimated future warranty costs on its product sales at the time of sale. Our products are subject to rigorous regulation and quality standards. Warranty costs are included in cost of product revenues within the consolidated statements of operations.

### VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS

We review long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Factors considered important which could trigger an impairment review include significant changes relative to: (i) projected future operating results; (ii) the use of the assets or the strategy for the overall business; (iii) business collaborations; and (iv) industry, business, or economic trends and developments. Each impairment test is based on a comparison of the

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

undiscounted cash flow to the recorded value of the asset. If it is determined that the carrying value of long-lived or intangible assets may not be recoverable, the asset is written down to its estimated fair value on a discounted cash flow basis. At September 30, 2007 and December 31, 2006, respectively, total property, plant and equipment had a net carrying value of \$2,278,000 and \$2,567,000, including \$1,517,000 and \$1,639,000 at September 30, 2007 and December 31, 2006 associated with our manufacturing facility. As of September 30, 2007 and December 31, 2006, respectively, we had intangible assets totaling \$66,000 and \$102,000 recorded in deferred charges and other assets relating to the unamortized balance of payments made in 2004 to a light source supplier related to an amendment to our agreement and to a licensor related to the reacquisition of our product rights in Canada. We reviewed the valuation of our intangible assets and goodwill associated with Nicomide(R) for impairment as a result of a decision by the U.S. federal district court in the River's Edge litigation to dissolve a preliminary injunction, which had enjoined River's Edge from manufacturing and selling its niacinamide-based product, which was being substituted for Nicomide(R). As a result of this review, we recorded a write down in 2006 of \$15.7 million representing the then remaining net asset value of the intangible assets.

Goodwill is deemed to have an indefinite life and is not 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.

### SHARE-BASED COMPENSATION

We adopted SFAS 123R 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 adoption of SFAS No. 123R did not affect our net cash flow, but it did have a material negative impact on our results of operations. In

30

accordance with SFAS 123R, we 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.

### RESULTS OF OPERATIONS -THREE AND NINE MONTHS ENDING SEPTEMBER 30, 2007 VERSUS SEPTEMBER 30, 2006

REVENUES - Total revenues for the three and nine-month periods ended September 30, 2007 were \$5,784,000 and \$19,323,000, respectively, as compared to \$6,619,000 and \$11,370,000 in 2006, and were comprised of the following:

Three-months ended September 30,		Increase/ (Decrease)	Nine-months e September 3
2007	2006		2007

PDT DRUG & DEVICE PRODUCT REVENUES

KERASTICK(R) PRODUCT REVENUES

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

United States	\$2,923,000	\$2,490,000	\$ 433,000	\$10,108,000	\$ 8
Canada	143,000	176,000	(33,000)	536,000	
	-----	-----	-----	-----	-----
Subtotal Kerastick(R) product revenues	3,066,000	2,666,000	400,000	10,644,000	9
	-----	-----	-----	-----	-----
BLU-U(R) PRODUCT REVENUES					
United States	423,000	516,000	(93,000)	1,369,000	1
Canada	--	53,000	(53,000)	94,000	
	-----	-----	-----	-----	-----
Subtotal BLU-U(R) product revenues	423,000	569,000	(146,000)	1,463,000	1
TOTAL PDT DRUG & DEVICE PRODUCT REVENUES	3,489,000	3,235,000	254,000	12,107,000	10
	-----	-----	-----	-----	-----
TOTAL NON-PDT DRUG PRODUCT REVENUES	2,295,000	2,828,000	(533,000)	7,216,000	6
	-----	-----	-----	-----	-----
TOTAL PRODUCT REVENUES	\$5,784,000	\$6,063,000	\$(279,000)	\$19,323,000	\$17
	=====	=====	=====	=====	=====

For the three and nine-month periods ended September 30, 2007 total PDT Drug and Device Product Revenues were \$3,489,000 and \$12,107,000, respectively. This represents an increase of \$254,000 or 8%, and \$1,178,000 or 11%, over the comparable 2006 totals of \$3,235,000 and \$10,929,000, respectively. The incremental revenue on a year-to-date basis was driven by increased Kerastick(R) revenues which were partially offset by decreased BLU-U(R) revenues.

For the three and nine-month periods ended September 30, 2007, Kerastick(R) revenues were \$3,066,000 and \$10,644,000, respectively, representing a \$400,000 or 15%, and \$1,493,000 or 16%, increase over the comparable 2006 totals of \$2,666,000 and \$9,151,000, respectively. Kerastick(R) unit sales to end-users were 30,108 and 104,364 for the three and nine-month periods ended September 30, 2007, respectively, including 1,890 and 7,098, respectively, sold in Canada. This represents an increase from 27,480 and 95,358 Kerastick(R) units sold in the three and nine-month periods ended September 30, 2006, respectively, including 2,400 and 12,990, respectively, sold in Canada. Our average net selling price for the Kerastick(R) increased to \$101.89 for the first nine months of 2007 from \$95.96 for the first nine months of 2006. Our average net selling price for the Kerastick(R) includes sales made directly to our end-user customers in the United States, as well as sales made to our distributor in Canada. The increase in 2007 Kerastick(R) revenue was driven mainly by increased sales volumes and an increase in our average unit selling price.

For the three and nine-month periods ended September 30, 2007, BLU-U(R) revenues were \$423,000 and \$1,463,000, respectively, representing a \$146,000, or 26%, and \$315,000, or 18%, decrease over the comparable 2006 totals of \$569,000 and \$1,778,000, respectively. The decrease in year-to-date 2007 BLU-U(R) revenue versus

the comparable 2006 period was driven by a decrease in our overall sales volumes, partially offset by an increase in our average selling price to \$7,596 for the nine-month period ended September 30, 2007 from \$7,392 for the nine-month period ended September 30, 2006. In the three and nine-month periods ended September 30, 2007, there were 60 and 181 units sold, respectively, versus 77 and 235 units, respectively, in the comparable 2006 periods. The 2007 total consists of 165 units sold in the United States and 16 sold in Canada by Coherent-AMT. The 2006 total consists of 210 sold in the United States and 25 sold in Canada. During the fourth quarter of 2005, we introduced a BLU-U(R)

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

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 four months for private practitioners and up to one year for hospital clinics, before a purchase decision is required. At September 30, 2007, there were 31 units in the field pursuant to this evaluation program. 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. We amortize the cost of the evaluation units during the evaluation period to cost of product revenues to approximate their net realizable value.

Non-PDT Drug Product Revenues reflect the revenues generated by the products acquired as part of our March 10, 2006 acquisition of Sirius. Total revenues for the three and nine-month periods ended September 30, 2007 were \$2,295,000 and \$7,216,000, respectively, compared to \$2,828,000 and \$6,503,000, respectively for the three month period ended September 30, 2006 and the period March 10, 2006 through September 30, 2006. The substantial majority of the Non-PDT product revenues were from sales of Nicomide(R). The products acquired from Sirius all belong to the same therapeutic category, "non-photodynamic therapy dermatological treatment of acne and rosacea." The decrease in Non-PDT product revenues for the three-month period ended September 30, 2007 compared to the prior year is due primarily to the dissolution of the preliminary injunction on March 7, 2007, which had previously enjoined River's Edge from selling its niacinamide-based product. On October 28, 2007 we entered into a settlement agreement with River's Edge. See section entitled "Part II. Other Information-Legal Proceedings-River's Edge. We expect that sales of Nicomide should begin to return to pre-litigation levels in the coming months.

The increase in our total revenues results from the Sirius acquisition, as well as from the efforts of our sales force and related marketing and sales activities. With respect to PDT segment United States sales, we increased both our volumes through increased sales activities and our average selling prices during 2007. However, we must increase sales significantly from these levels in order for us to become profitable. We remain confident that PDT Drug Product sales should continue to increase through increased consumption of our PDT segment products by our existing customers, as well as through the addition of new customers.

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide(R). The FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with FDA to begin that process. The FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and the FDA may bring an action against a drug or a firm when the FDA concludes that such other violations exist. The contract manufacturer of Nicomide(R) has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide(R) could not be marketed as a dietary supplement with its current labeling. There can be no assurance that the FDA will continue this policy or not take a contrary position with Nicomide(R). If the FDA were to take further action, we may be required to make certain labeling changes and market Nicomide(R) as an over-the-counter products or as a dietary supplements under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenue. Label changes eliminating claims of certain medicinal benefits could make it more difficult to market Nicomide(R) and could therefore, negatively affect our revenues and profits. Also see section entitled "Risk Factors - Any Failure to Comply with Government Regulations in the United States and Elsewhere Will Limit Our Ability

32

to Market Our Products."

COST OF PRODUCT REVENUES - Cost of product revenues for the three and nine-month periods ended September 30, 2007 were \$1,574,000 and \$5,507,000, respectively, as compared to \$2,849,000 and \$7,635,000 in the comparable periods in 2006. A summary of the components of cost of product revenues and royalties is provided below:

	THREE MONTHS ENDED SEPTEMBER 30,		INCREASE/ (DECREASE)
	2007	2006	
LEVULAN(R) KERASTICK(R) COST OF PRODUCT REVENUES			
Direct Levulan(R) Kerastick(R) Product Costs	\$ 433,000	\$ 380,000	\$ 53,000
Other Levulan(R) Kerastick(R) Product costs including internal costs assigned to support products	231,000	224,000	7,000
Royalty and supply fees (1)	138,000	126,000	12,000
Subtotal Levulan(R) Kerastick(R) Cost of Product Revenues	\$ 802,000	\$ 730,000	\$ 72,000
BLU-U(R) COST OF PRODUCT REVENUES			
Direct BLU-U(R) Product costs	\$ 133,000	\$ 263,000	\$ (130,000)
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	219,000	250,000	(31,000)
Total Device cost of product revenues	\$ 352,000	\$ 513,000	\$ (161,000)
TOTAL PDT DRUG & DEVICE COST OF PRODUCT REVENUES	\$1,154,000	\$1,243,000	\$ (89,000)
TOTAL NON-PDT DRUG COST OF PRODUCT REVENUES	\$ 420,000	\$1,606,000	\$ (1,186,000)
TOTAL COST OF PRODUCT REVENUES	\$1,574,000	\$2,849,000	\$ (1,275,000)

	NINE MONTHS ENDED SEPTEMBER 30,		INCREASE/ (DECREASE)
	2007	2006	

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

LEVULAN(R) KERASTICK(R) COST OF PRODUCT REVENUES			
Direct Levulan(R) Kerastick(R) Product Costs	\$1,508,000	\$1,318,000	\$ 190,000
Other Levulan(R) Kerastick(R) Product costs including internal costs assigned to support products	386,000	636,000	(250,000)
Royalty and supply fees (1)	486,000	461,000	25,000
Subtotal Levulan(R) Kerastick(R) Cost of Product Revenues	\$2,380,000	\$2,415,000	\$ (35,000)
BLU-U(R) COST OF PRODUCT REVENUES			
Direct BLU-U(R) Product costs	\$ 555,000	\$ 802,000	\$ (247,000)
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	673,000	754,000	(81,000)
Total Device cost of product revenues	\$1,228,000	\$1,556,000	\$ (328,000)
TOTAL PDT DRUG & DEVICE COST OF PRODUCT REVENUES	\$3,608,000	\$3,971,000	\$ (363,000)
TOTAL NON-PDT DRUG COST OF PRODUCT REVENUES	\$1,899,000	\$3,664,000	\$ (1,765,000)
TOTAL COST OF PRODUCT REVENUES	\$5,507,000	\$7,635,000	\$ (2,128,000)

33

1) Royalties 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 reflect the costs associated with the products acquired as part of our March 10, 2006 merger with Sirius.

MARGINS - Total product margins for the three and nine month periods ended September 30, 2007 were \$4,210,000 and \$13,817,000, respectively, as compared to \$3,213,000 and \$9,796,000 for the comparable 2006 periods, as shown below:

	THREE MONTHS ENDED SEPTEMBER 30,				
	2007		2006		INCREASE/ (DECREASE)
Levulan(R) Kerastick(R) Gross Margin	\$2,263,000	74%	\$1,935,000	73%	\$328,000
BLU-U(R) Gross Margin	71,000	17%	57,000	10%	14,000
Total PDT Drug & Device Gross Margin	\$2,334,000	67%	\$1,992,000	62%	\$342,000
Total Non-PDT Drug Gross Margin	1,876,000	82%	1,222,000	43%	\$654,000
TOTAL GROSS MARGIN	\$4,210,000	73%	\$3,214,000	53%	\$996,000

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

	NINE MONTHS ENDED SEPTEMBER 30,				INCREASE/ (DECREASE)
	2007		2006		
Levulan(R) Kerastick(R) Gross Margin	\$ 8,264,000	78%	\$6,736,000	74%	\$1,528,000
BLU-U(R) Gross Margin	235,000	16%	222,000	13%	13,000
Total PDT Drug & Device Gross Margin	\$ 8,499,000	70%	\$6,958,000	64%	\$1,541,000
Total Non-PDT Drug Gross Margin	5,318,000	74%	2,839,000	44%	\$2,479,000
TOTAL GROSS MARGIN	\$13,817,000	72%	\$9,797,000	56%	\$4,020,000

For the three and nine-month periods ended September 30, 2007 total PDT Drug and Device Product Margins were 67% and 70%, respectively, versus 62% and 64% for the comparable 2006 periods. The incremental margin was driven by positive margin gains on both the Levulan(R) Kerastick(R) and BLU-U(R).

Levulan(R) Kerastick(R) gross margins for the three and nine month periods ended September 30, 2007 were 74% and 78%, respectively, versus 73% and 74% for the comparable 2006 periods. Similar to the increase in revenues, the increase in margin is mainly attributable to an increase in our average unit selling price. 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 and nine month periods ended September 30, 2007 were 17% and 16%, respectively, versus 10% and 13% for the comparable 2006 periods. 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 gross margin generated by the products acquired as part of our acquisition of Sirius. Gross margins for the three and nine-month periods ended September 30, 2007 were 82% and 74%, respectively, compared to 43% and 44% for the three month period ended September 30, 2006 and the period March 10, 2006 (date of acquisition) through September 30, 2006, respectively. During the three and nine-month periods ended September 30, 2006, Non-PDT Drug Product margins were negatively impacted by the recording of intangible asset amortization and the fair

value adjustment to inventory recorded as part of the Sirius acquisition, which is partially offset by an increase in both the number and dollar amount of rebate redemptions on sales of Nicomide(R) in 2007. We expect Non-PDT Drug Product gross margins to be in the 70-80% range during the remainder of 2007.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs for the three and nine month periods ended September 30, 2007 were \$1,225,000 and \$4,328,000, respectively, as compared to \$1,344,000 and \$5,982,000, respectively, in the comparable 2006 periods, which for the nine-month period ended September 30, 2006 included \$1,600,000 related to in-process research and

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

development acquired as part of the acquisition of Sirius. Increased spending on our Phase IIb clinical trial on acne was offset by reduced spending in the areas of photodamaged skin and Barrett's Esophagus.

Research and development expenses reflect the costs of our Phase IIb clinical trial for acne, which commenced in March 2007. We expect our research and development costs to increase to an even greater extent at such time as we may commence Phase III trials, or potentially a larger Phase II trial. The current Phase II trial is being conducted at thirteen (13) sites and will accrue approximately 260 patients, when fully enrolled. To date, approximately 150 patients have been accrued to this study. We had entered into a clinical trial agreement in September 2004 with the National Cancer Institute, Division of Cancer Prevention, or NCI DCP, to study the use of ALA to treat high grade dysplasia within Barrett's Esophagus. However, the NCI DCP notified us that it will not be pursuing this study at this time. Therefore, at this time, we will not be incurring expenses for the laser devices, fiber optics and units of our proprietary sheath device that we were obligated to provide under the agreement. In March 2007, the U.S. Food and Drug Administration granted orphan drug status for Levulan(R) PDT for treatment of esophageal dysplasia. In November 2004, we also signed a clinical trial agreement with the NCI DCP for the treatment of oral cavity dysplasia. DUSA and the NCI DCP are working together to prepare the overall clinical development plan for Levulan(R) PDT in this indication, starting with Phase I/II trials. A Phase I/II protocol has been finalized. The NCI DCP used its resources to file its own investigational new drug application with the FDA, and approval to initiate the study was received. Our costs related to this study will be limited to providing Levulan(R), leasing lasers and the necessary training for the investigators involved. All other costs of this study are the responsibility of the NCI DCP. Although we expect the clinical trial on oral cavity dysplasia to commence in 2007, the actual timing of the initiation is within the total control of NCI so we cannot be certain of the initiation date. We have options on any new intellectual property.

We have entered into a series of agreements for our research projects and clinical studies. As of September 30, 2007, future payments to be made pursuant to these agreements, under certain terms and conditions, total approximately \$2,777,000 for the remainder of 2007.

**MARKETING AND SALES COSTS** - Marketing and sales costs for the three and nine-month periods ended September 30, 2007 were \$2,887,000 and \$9,728,000, respectively, as compared to \$3,246,000 and \$9,114,000 for the comparable 2006 periods. 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 \$2,010,000 and \$6,275,000 for the three and nine-month periods ended September 30, 2007, compared to \$2,515,000 and \$6,514,000 in the comparable periods in 2006. The decrease in this category on year-to-date basis is due to decreased commissions and bonuses, which is partially offset by increased salaries resulting from higher average headcount in 2007 in comparison to 2006, primarily as the result of the Sirius acquisition. The remaining expenses consist of tradeshows, miscellaneous marketing and outside consultants totaling \$877,000 and \$3,453,000 for the three and nine month periods ended September 30, 2007, respectively, compared to \$731,000 and \$2,600,000 for the comparable 2006 periods. We expect marketing and sales costs to increase in 2007, compared with 2006, reflecting a full year of the expanded sales force, as well as expenses associated with the launch of our new product, ClindaReach(TM), but to decrease as a percentage of revenues.

**GENERAL AND ADMINISTRATIVE COSTS** - General and administrative costs for the three and nine-month periods ended September 30, 2007 were \$2,111,000 and \$7,967,000, respectively, as compared to \$2,603,000 and \$8,427,000 for the comparable 2006 periods. The decrease on a year-to-date basis is



mainly attributable to a decrease in accrued compensation during the third quarter of 2007 reflecting a reduced estimate of our expected bonus payouts for 2007. General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period particularly in light of our litigation strategy to protect our intellectual property.

OTHER INCOME, NET - Other income for the three and nine-month periods ended September 30, 2007 decreased to \$136,000 and \$480,000, respectively, from \$194,000 and \$646,000 during the comparable 2006 periods. This decrease is primarily attributable to a decrease in our average investable cash balances during 2007 as we used cash to purchase Sirius, as well as to support our operating activities. We expect other income will increase in the future from current levels due to the closing of a private placement subsequent to September 30, 2007. See Note 17 to the Notes to the Condensed Consolidated Financial Statements.

NET LOSSES - For the three and nine-month periods ended September 30, 2007, we incurred net losses of \$1,878,000, or \$0.10 per share, and \$7,726,000, or \$0.40 per share, respectively, as compared to net losses of \$3,787,000, or \$0.19 per share, and \$13,081,000, or \$0.77 per share, for the comparable periods in 2006. Net losses are expected to continue until end-user sales offset the cost of our sales force and marketing initiatives, and the costs for other business support functions.

#### LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2007, we had approximately \$11,224,000 of total liquid assets, comprised of \$1,005,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$10,219,000. We estimate that existing cash and cash equivalents and marketable securities, milestone payments associated with our international marketing and distribution agreements, the settlement payment from River's Edge, and the approximately \$10.3 million of net proceeds raised subsequent to September 30, 2007 in the private placement, will be sufficient to meet our cash requirements for at least the next two years. Our net cash used in operations for the nine-month period ended September 30, 2007 was \$6,561,000, versus \$8,324,000 used in the comparable 2006 period. The year-over-year decrease is directly attributable to the growth in our PDT products segment, as well as the addition of the Non-PDT Drug Products acquired in the Sirius merger, and the receipt of a milestone payment in the amount of \$1.0 million from Daewoong, our distribution partner for certain Asian countries. During the first quarter of 2007, we made a milestone payment of \$500,000 to the former shareholders of Sirius related to the launch of ClindaReach(TM). We expect that a second payment of \$500,000 could become due in 2008 when we expect the next product from the Sirius pipeline to be approved. An abbreviated new drug application is currently pending.

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

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

As of September 30, 2007, working capital (total current assets minus total current liabilities) was \$12,655,000, as compared to \$18,085,000 as of December 31, 2006. Total current assets decreased by \$6.9 million during the nine-month period ended September 30, 2007, due primarily to a decrease in our marketable securities, which was used primarily to fund our loss from operations. Total current liabilities decreased by \$1.5 million during the same period due primarily to a decrease in accrued compensation and accrued expenses, partially offset by an increase in accounts payable.

In consummating the merger with Sirius in 2006, we acquired all of the outstanding common stock of Sirius in exchange for 2,396,245 shares of our common stock and cash. At closing, we paid \$8.0

36

million less certain expenses, in cash, and 1,973,353 shares of our common stock, no par value per share to the shareholders of Sirius and issued an additional 422,892 shares to an escrow agent to be held for up to two years subject to certain indemnification provisions of the merger agreement. We 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 are as follows:

CUMULATIVE SALES MILESTONE: (in millions)	PAYMENT EARNED: (in millions)
-----	-----
\$25.0	\$1.5
35.0	1.0
45.0	1.0
	----
Total:	\$3.5
	====

During the first quarter of 2007, we paid \$500,000 to the former shareholders of Sirius related to the March 2007 launch of ClindaReach(TM). This payment has increased goodwill in the accompanying condensed consolidated balance sheet. The maximum remaining potential future consideration pursuant to such arrangements, to be resolved over the period ending 50 months from the date of close, is \$4.5 million. If attained, the product launch portion of the contingent consideration is payable in cash and the cumulative sales milestone portion is payable in either common stock or cash, at our sole discretion. We expect that any such payments will result in increases in goodwill at time of payment.

We are 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 2007, we are focusing primarily on increasing the sales of the Levulan(R) Kerastick(R) and the BLU- U(R), as well as the Non-PDT Drug Products, advancing our Phase II study for use of Levulan(R) PDT in acne, and continuing to pursue our product development pipeline.

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

After the close of the quarter, we entered into a securities purchase agreement, common stock purchase warrants, and a registration rights agreement with certain accredited investors for the private placement of 4,581,043 shares of its common stock at a purchase price of \$2.40 per share which resulted in gross proceeds to DUSA of \$11,000,000. We also issued warrants to purchase an additional 1,145,259 shares of common stock. The warrants become exercisable on April 30, 2008, have a term of 5 years from the initial exercise date, and have an exercise price of \$2.85 per share. We have committed to register the shares that were issued and the shares underlying the warrants with the Securities and Exchange Commission on a Form S-3 registration statement. If the registration statement does not become effective within a stated period of time, then the investors are entitled to receive a cash payment of 1% of the aggregate purchase price they paid for their respective shares for each month that the registration statement is delayed beyond the time periods stated in the agreements, up to a maximum of 12% of such aggregate purchase price. We paid the placement agent its fee, including expenses, of \$695,000 for its services in connection with the transaction. We will use the proceeds from the sale of the securities to further advance our Levulan(R) PDT clinical development programs and activities associated with expanding our market presence in the U.S.

In October 2007, Daewoong Pharmaceutical Co., Ltd. and its affiliate DNC Daewoong Derma & Plastic Surgery Network Company received approval from the Korea Food and Drug Administration for the use of Levulan(R) Kerastick(R) for PDT for the treatment of actinic keratosis. Pursuant to the terms of the agreement with Daewoong, we received a payment of \$1.0 million upon receipt of the approval.

In October 2007 we achieved the first milestone under the amended Stiefel Agreement that being the launch of the Levulan(R) Kerastick(R) in Mexico and Argentina. Subsequent to the end of the quarter, we received a payment of \$375,000 from Stiefel related to the achievement of this milestone.

37

On October 28, 2007, we entered into a settlement agreement with River's Edge dismissing the lawsuit we brought against River's Edge. Under the terms of the agreement, River's Edge made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages, among other consideration. River's Edge has also consented to the return to the Company of the \$750,000 bond with all accrued interest that is currently being held by the court.

DUSA has no off-balance sheet financing arrangements.

### CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

#### ALTANA, INC.

In September 2005, Sirius entered into a development and product license agreement with Altana, Inc. relating to a reformulated dermatology product. The agreement was assigned to us by virtue of the Sirius merger. According to the agreement, we will pay for all development costs. 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.

#### ACTAVIS TOTOWA, LLC

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

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., now known as Actavis Totowa, LLC. The agreement was assigned to us as part of the Sirius merger. Actavis Totowa 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. Actavis Totowa has received several warning letters from the FDA regarding certain regulatory observations. To our knowledge, the primary cGMP observations noted in the warning letters were not related to Nicomide(R). However, with respect to Nicomide(R) and certain other products manufactured by Actavis Totowa that may be covered under the FDA's compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs", the FDA requested that the manufacturer provide a copy of the labeling and information providing its position regarding the regulatory status of these products and has notified Actavis Totowa that the FDA believes Nicomide(R) is not properly labeled as a vitamin supplement. The FDA may take further action against Actavis Totowa, or DUSA, and we are evaluating our options in order to maintain supply of Nicomide(R).

### L. PERRIGO COMPANY

On October 25, 2005, Sirius entered into a supply agreement with L. Perrigo Company, or Perrigo, for the exclusive manufacture and supply of a proprietary device/drug kit designed by Sirius pursuant to an approved ANDA owned by Perrigo. The agreement was assigned to us as part of the Sirius merger. We have now launched this product, called ClindaReach(TM). Perrigo is entitled to royalties on net sales of ClindaReach(TM), including certain minimum annual royalties, which commenced May 1, 2006, in the amount of \$250,000. The initial term of the agreement expires in July, 2011 and may be renewed based on certain minimum purchase levels and other terms and conditions.

### WINSTON LABORATORIES, INC.

On or about January 30, 2006 Winston Laboratories, Inc., or Winston, 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 the former Sirius. This agreement was assigned to us as part of the Sirius merger. The 2006 agreement grants 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. We pay royalties on net sales of the product,

38

and certain minimum royalties are due each year to maintain the license. We have an option to purchase the product from Winston at certain times prior to the expiration of the agreement on January 31, 2008, which we have decided not to exercise. Minimum royalties to Winston are \$300,000 per year ending January 31, 2008. We do not intend to renew this agreement.

### PARTEQ AGREEMENT

We license certain patents underlying its Levulan(R) PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations, or PARTEQ, the licensing arm of Queen's University, Kingston, Ontario. Under the agreement, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ patent rights, to make, have made, use and sell certain products,

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

including ALA. The agreement covers certain use patent rights. When we are selling our products directly, we agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where we have a sublicensee, we will pay 6% and 4% when patent rights do and do not exist, respectively, on its net selling price less the cost of goods for products sold to the sublicensee, and 6% of payments we receive on sales of products by the sublicensee.

Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$101,000) as of September 30, 2007.

We are also obligated to pay to PARTEQ 5% of any lump sum sublicense fees we receive with respect to Levulan(R), such as milestone payments, excluding amounts designated by a sublicensee for future research and development efforts.

### LICENSE AND SUPPLY AGREEMENTS

On August 7, 2007, we terminated our former License and Development Agreement with photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a German pharmaceutical company, and a supply agreement with medac. These agreements provided for the licensing to DUSA of photonamic's proprietary technology related to ALA for systemic dosing in the field of brain cancer. Since we did not believe that the results from medac's European Phase III clinical study would be acceptable to the FDA and we do not intend to conduct additional clinical trials in the brain cancer field, we mutually terminated these agreements, without penalty, relinquishing our rights to the technology for fluorescent-guided resection of brain cancer. However, certain provisions of these agreements survive the termination. We entered a new License and Supply Agreement as of August 7, 2007 among photonamic, medac and us confirming our rights to use certain pre-clinical data and licensed technology on a non-exclusive basis outside of this field, in the U.S., and other territories and providing for a supply of medac's oral and intravenous formulation of ALA on terms to be mutually agreed upon. The term of the agreement is five (5) years, subject to rights to earlier termination and automatic renewals. No additional royalties or payments for the license is due to photonamic.

### AMENDED AND RESTATED PURCHASE AND SUPPLY AGREEMENT

On June 21, 2004, we signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation ("NBC"), the manufacturer of our BLU-U(R) light source. This agreement provides for the elimination of certain exclusivity clauses, permits us to order on a purchase order basis without minimums, and includes other modifications of the original agreement providing both parties greater flexibility related to the development and manufacture of light sources and the associated technology within the field of PDT. We paid \$110,000 to NBC upon execution of the agreement which is being amortized over the remaining term of the agreement, expiring November 5, 2008.

### DRAXIS TERMINATION AND TRANSFER AGREEMENT

On February 24, 2004, we reacquired the rights to the aminolevulinic acid (Levulan(R)) technology for Canada held by Draxis Health Inc. ("Draxis"). These rights were initially assigned to

Draxis in 1991. We mutually agreed to terminate the assignment and we agreed to pay to Draxis an upfront fee of \$150,000 CDN (\$114,000 USD at February 24, 2004) and a 10% royalty on sales of the Levulan(R) Kerastick(R) in Canada over a five

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

year term commencing in June 2004 based on the first Kerastick(R) sale in Canada by Coherent, our Canadian marketing and distribution partner.

### LEASE AGREEMENTS

We have entered into lease commitments for office space in Wilmington, Massachusetts, Valhalla, New York, and Toronto, Ontario. These leases generally have five or ten year terms. The minimum lease payments disclosed below include the non-cancelable terms of the leases.

### RESEARCH AGREEMENTS

We have entered into various agreements for research projects and clinical studies. As of September 30, 2007, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$2,777,000. Included in this future payment is a master services agreement, effective June 15, 2001, with Therapeutics, Inc. for an initial term of two years, with annual renewal periods thereafter, to engage Therapeutics to manage the clinical development of our products in the field of dermatology. The agreement was renewed on June 15, 2007 for a one year period. Therapeutics is entitled to receive a bonus of between \$50,000 and \$200,000, in cash or stock at our discretion, upon each anniversary of the effective date. Therapeutics has the opportunity for additional bonuses for each product indication ranging from \$250,000 to \$1,250,000 depending on the regulatory phase of development of products during Therapeutics' management.

Our contractual obligations and other commercial commitments to make future payments under contracts, including lease agreements, research and development contracts, manufacturing contracts, or other related agreements, are as follows at September 30, 2007:

	Total	1 Yr or less	2-3 Years	4-5 Years	After 5
	-----	-----	-----	-----	-----
Operating lease obligations	\$2,223,000	\$ 445,000	\$ 923,000	\$ 788,000	\$ 67,000
Purchase obligations (1,2)	3,912,000	3,053,000	859,000	--	--
Minimum royalty obligations(3)	1,512,000	450,000	700,000	263,000	99,000
	-----	-----	-----	-----	-----
Total obligations	\$7,647,000	\$3,948,000	\$2,482,000	\$1,051,000	\$166,000
	=====	=====	=====	=====	=====

- 1) Research and development projects include various commitments including obligations for our Phase IIb clinical study for 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 bonuses for each product indication ranging from \$250,000 to \$1,250,000 depending on the regulatory phase of development of products under Therapeutics' management.
- 3) Minimum royalty obligations relate to our agreements with PARTEQ, Winston and Perrigo described above.

### INFLATION

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

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

overall net effect of inflation on our operations to be minimal.

40

### 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 September 30, 2007, the weighted average rate of return on our investments was 3.46%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of September 30, 2007, the fair market value of the portfolio would decline by \$153,000. Declines in interest rates could, over time, reduce our interest income.

### ITEM 4. CONTROLS AND PROCEDURES

We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2007.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2007 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, but not limited to beliefs concerning the impact of compounding pharmacies, beliefs regarding estimates, our expectations regarding our merger with Sirius Laboratories, Inc. and matters relating thereto, our expectations concerning the introduction of niacinamide-based product, which is being substituted for Nicomide(R) and such products' impact on sales of Nicomide(R), beliefs concerning the focus on ClindaReach(TM) and its impact on other products and revenues, management's beliefs regarding the unique nature of Levulan(R) and its use and potential use, expectations regarding the timing of results of clinical trials, future development of Levulan(R) and our other products and other potential indications, intention to pursue licensing, marketing, co-promotion, collaboration or acquisition opportunities, status of clinical programs for all other indications and beliefs regarding potential efficacy and marketing, our intention to develop combination drug and light device systems, our expectations regarding new proprietary endoscopic light delivery systems and the potential use of other light devices, our beliefs

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

regarding the safety, simplicity, reliability and cost-effectiveness of certain light sources, our expectations regarding other product launches in Brazil, Mexico, Korea and other territories, hope that our products will be an AK therapy of choice and barriers to achieving that status, our beliefs regarding growth, revenues and market opportunities from approved and potential products, our plans to eliminate certain expenses for the coming year and reallocate others, beliefs regarding the clinical benefit of Levulan(R) PDT for acne and other indications, beliefs regarding the suitability of clinical data, expectations regarding the confidentiality of our proprietary information, intentions to seek additional U.S. and foreign regulatory approvals, and to market and increase sales outside the U.S., beliefs regarding regulatory classifications, filings, timelines, off-label use and environmental compliance, beliefs concerning patent disputes and litigation, the impact of a third-party's

41

regulatory compliance and fulfillment of contractual obligations, and our anticipation that third parties will launch products upon receipt of regulatory approval, expectations of increases in cost of product sales, expectations regarding margins on Kerastick(R) and other products, expected use of cash resources, requirements of cash resources for our future liquidity, beliefs regarding investments and economic conditions, beliefs regarding accounting policies and practices, expectations regarding outstanding options and warrants and our dividend policy, anticipation of increases or decreases in personnel, effect of reimbursement policies on revenues and acceptance of our therapies, expectations for future strategic opportunities and research and development programs and expenses, expectations for continuing operating losses and competition including from Metvixia, expectations regarding the adequacy and availability of insurance, expectations regarding general and administrative costs, expectations regarding increased sales and marketing costs and research and development costs, levels of interest income and our capital resource needs, intention to raise additional funds to meet capital requirements and the potential dilution and impact on our business, other income will increase in the future from current levels due to the closing of a private placement, potential for additional inspection and testing of our manufacturing facilities or additional FDA actions, beliefs regarding the adequacy of our inventory of Kerastick(R) and BLU-U(R) units, our manufacturing capabilities and the impact of inventories on revenues, belief regarding interest rate risks to our investments and effects of inflation and new and existing accounting standards and policies, beliefs regarding the impact of any current or future legal proceedings, dependence on key personnel, and beliefs concerning product liability insurance. 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 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 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



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

"Risk Factors" on pages 44 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.

42

### PART II - OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS.

##### LEVULAN(R) LAWSUITS

In December 2004, we began a litigation strategy to protect our intellectual property. We began to file lawsuits against physicians to prevent their unlicensed use of versions of our Levulan(R) brand of ALA produced by third-parties for use in our patented PDT treatment for actinic keratosis, basal cell carcinoma, or acne. We have also sued compounding pharmacies which we believed were inducing physicians to infringe our patents on the photodynamic treatment of acne or actinic keratosis. The lawsuits against physicians and compounding pharmacies have settled favorably to us and we have the right to review their books and records to verify ongoing compliance. We expect to maintain this strategy as long as we believe physicians and compounding pharmacies are infringing our intellectual property.

We are in litigation with a chemical supplier in United States District Court for the District of District of Utah, alleging that the defendant induced physicians to infringe patents licensed to us, among other things. In its answer and counterclaim, as expected, the defendant alleges that our patents are invalid. This case is still at an early stage.

While we believe that certain actions of compounding pharmacies and others may have gone beyond the activities which are permitted under the Food, Drug and Cosmetic Act and we 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 companies or that regulatory authorities will intervene to stop their activities. In addition, there may be other compounding pharmacies which are following FDA guidelines, or others conducting illegal activities of which we are not aware, which may be negatively impacting our sales revenues.

##### RIVER'S EDGE

On March 28, 2006, a lawsuit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division by River's Edge Pharmaceuticals, LLC, or River's Edge, against us alleging, among other things, that, prior to our merger with the former Sirius Laboratories, Inc., Sirius 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. On June 19, 2006, the Georgia court dismissed the River's Edge complaint.

River's Edge also filed an application with the United States Patent and Trademark Office, or USPTO, requesting an inter partes reexamination of the Nicomide(R) patent. The USPTO has accepted the application and the parties have submitted their responses to the USPTO's first office action.

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

On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that River's Edge's niacinamide product infringes our United States patent 6,979,468. We posted \$750,000 with the court that is being held in an interest bearing account. The court also ordered that the parties participate in a non-binding mediation which occurred on August 9, 2007.

On October 28, 2007, we entered into a settlement and mutual release agreement, or settlement agreement, to dismiss the lawsuit brought by DUSA against River's Edge, asserting a number of claims arising out of River's Edge's alleged infringement of U.S. Patent No. 6,979,468 under which DUSA has marketed, distributed and sold Nicomide(R). Under the terms of the settlement agreement, River's Edge unconditionally acknowledges the validity and enforceability of the Nicomide(R) patent. River's Edge has made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages and will pay to DUSA a per unit amount for every bottle of NIC 750 above a certain number of units that is substituted

43

for Nicomide(R) after September 30, 2007. River's Edge shall be responsible for all returns of NIC 750 from the distribution chain and/or order its destruction and will immediately cease the manufacture, distribution and sale of NIC 750. River's Edge is obligated to withdraw and cease participating in the re-examination of the Nicomide(R) patent and has consented to the return to us of the \$750,000 bond that is currently being held by the court with all accrued interest.

As part of the settlement, DUSA and River's Edge have also entered into a license agreement, dated October 28, 2007 (the "License Agreement") whereby DUSA granted a perpetual, exclusive license to River's Edge to manufacture and sell four of products from the AVAR(R) line, including AVAR cleanser, AVAR gel, AVAR E-emollient cream and AVAR E-green in exchange for a royalty on net sales of these products, including a guaranteed minimum royalty of \$300,000, payable in equal annual installments of \$100,000 for three years. DUSA provided its on-hand inventory of these products to River's Edge for no cost. We will participate in returns of split lots based on the two company's respective pro-rata sales of these lots.

### ITEM 1A. RISK FACTORS.

A description of the risk factors associated with our business is set forth below. This description includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1A. of our 2006 Annual Report on Form 10-K for the year ended December 31, 2006 and Item 1 of our Form S-8 filed in March 2007.

You should carefully consider and evaluate all of the information in, or incorporated by reference in, this Quarterly Report on Form 10-Q. The following are among the risks we face related to our business, assets and operations. They are not the only ones we face. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the value of our securities.

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

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

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.

NICOMIDE(R) WILL LIKELY LOSE SIGNIFICANT MARKET SHARE IN ANOTHER GENERIC PRODUCT ENTERS THE MARKET AND OUR ABILITY TO BECOME PROFITABLE WILL BE MORE DIFFICULT

In March 2006, we acquired Nicomide(R), in connection with our merger with Sirius Laboratories, Inc. Shortly after the closing of the merger, we became engaged in patent litigation with River's Edge Pharmaceuticals, LLC, or River's Edge, a company that launched a niacinamide-based product in competition with our Nicomide(R) product. River's Edge has also requested that the United States Patent and Trademark Office reexamine the Nicomide(R) patent claiming that it is invalid. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. Nicomide(R) sales were adversely impacted throughout the litigation process and had a material negative impact on our revenues, results of operations and liquidity. On October 28, 2007, we entered into a settlement and mutual release agreement, or settlement agreement, to dismiss the lawsuit brought by DUSA against River's Edge, asserting a number of claims arising out of River's Edge's alleged infringement of U.S. Patent No. 6,979,468 under which DUSA has marketed, distributed and sold Nicomide(R). Under the terms of the settlement agreement, River's Edge unconditionally acknowledges the

44

validity and enforceability of the Nicomide(R) patent. River's Edge has made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages and will pay to DUSA a per unit amount for every bottle of NIC 750 above a certain number of units that is substituted for Nicomide(R) after September 30, 2007. River's Edge shall be responsible for all returns of NIC 750 from the distribution chain and/or order its destruction and will immediately cease the manufacture, distribution and sale of NIC 750. River's Edge is obligated to withdraw and cease participating in the re-examination of the Nicomide(R) patent and has consented to the return to us of the \$750,000 bond that is currently being held by the court with all accrued interest.

If another company launches a substitutable niacinamide product, or if the USPTO finds that the Nicomide(R) patent is invalid, our revenues from sales of Nicomide(R) will decrease, perhaps permanently, and our ability to become profitable will be more difficult.

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

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

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

approval, and

- control of marketing activities, including advertising and labeling.

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

- send us warning letters,
- impose fines and other civil penalties on us,
- seize our products,
- suspend our regulatory approvals,
- cease the manufacture of our products
- refuse to approve pending applications or supplements to approved applications filed by us,
- refuse to permit exports of our products from the United States,
- require us to recall products,
- require us to notify physicians of labeling changes and/or product related problems,
- impose restrictions on our operations, and/or
- criminally prosecute us.

45

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

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide(R). The FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with the FDA to begin that process. The FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and the FDA may bring an action against a drug or a firm when the FDA concludes that such other violations exist. The contract manufacturer of Nicomide(R) has received notice

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

that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide(R) could not be marketed as a dietary supplement with its current labeling. We believe that the cGMP issues do not directly involve Nicomide. There can be no assurance that the FDA will continue this policy or not take a contrary position with Nicomide(R). If the FDA were to take further action,, we believe that we may be required to make certain labeling changes and market Nicomide(R) as an over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenues. Label changes eliminating claims of certain medicinal benefits could make it more difficult to market these products and could therefore, negatively affect our revenues and profits.

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 manufacturer of Nicomide(R), who has received warning letters from the FDA, fail to maintain compliance with FDA regulatory requirements, it would be time consuming and costly to remedy the problem(s) or to qualify other sources. These consequences could have a significant adverse effect on our financial condition and operations.

As part of our FDA approval for the Levulan(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 labeling restrictions or withdrawal of the product from the market may occur. We have implemented changes in our marketing materials due to the warning letter we recently received from the FDA. This letter caused us to cease using a good portion of our marketing materials which made the selling effort of our Levulan(R) Kerastick(R) more difficult. If we receive other warning letters, our revenues may suffer.

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-parties may

46

infringe one or more of our patents, and we are spending significant resources to enforce our patent rights. Also, in a lawsuit against a third-party for infringement of our patents in the United States, that third-party may challenge the validity of our patent(s). We cannot guarantee that a third-party will not claim, with or without merit, that our patents are not valid, as in the case described below, or that we have infringed their patent(s) or misappropriated their proprietary material. Defending these types of legal actions involve considerable expense and could negatively affect our financial results.

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 April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that River's Edge's niacinamide-based product infringed our United States Patent No. 6,979,468. River's Edge requested that the United States Patent and Trademark Office reexamine the patent. Although we have now settled the litigation, if we do not ultimately prevail in the reexamination process, our revenues from sales of Nicomide(R) will decrease permanently.

During 2005 and 2006, we filed several lawsuits against chemical suppliers, compounding pharmacies, a light device company, its distributor and a sales representative, and physicians alleging violations of patent law. In the lawsuit with a chemical supplier that is in progress, the defendant has filed an answer and counterclaim alleging that the patents we license from PARTEQ are invalid. While we have been successful in obtaining a default judgment against one compounding pharmacy, and settled other suits favorably to us, 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.

IF PRODUCT SALES DO NOT INCREASE SIGNIFICANTLY WE MAY NOT BE ABLE TO ADVANCE DEVELOPMENT OF OUR OTHER POTENTIAL PRODUCTS AS QUICKLY AS WE WOULD LIKE TO, WHICH WOULD DELAY THE APPROVAL PROCESS AND MARKETING OF NEW POTENTIAL PRODUCTS.

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

IF WE ARE UNABLE TO OBTAIN THE NECESSARY CAPITAL TO FUND OUR OPERATIONS, WE WILL HAVE TO DELAY OUR DEVELOPMENT PROGRAMS AND MAY NOT BE ABLE TO COMPLETE OUR CLINICAL TRIALS.

While we recently completed a private placement raising net proceeds of approximately \$10.3 million, 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 additional financing will be available at all or on acceptable terms. Depending on the extent of available funding, we may delay, reduce in scope or eliminate some of our research and development programs. We may also choose to license rights to third parties to commercialize products or technologies that we would otherwise have attempted to develop and commercialize on our own which could reduce our potential revenues.

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

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

SINCE WE NOW OPERATE THE ONLY FDA APPROVED MANUFACTURING FACILITY FOR THE KERASTICK(R) AND CONTINUE TO RELY HEAVILY ON SOLE SUPPLIERS FOR THE MANUFACTURE OF LEVULAN(R), THE BLU-U(R), NICOMIDE(R), NICOMIDE-T(R), METED(R), PSORIIACAP(R) AND PSORIIATEC(R), ANY SUPPLY OR MANUFACTURING PROBLEMS COULD NEGATIVELY IMPACT OUR SALES.

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

The sole supplier of Nicomide(R) has received warning letters from the FDA regarding certain regulatory observations. The primary observations noted in the warning letters were not related to Nicomide(R). However, with respect to Nicomide(R) and certain other products manufactured by this supplier, the FDA also notified the manufacturer that the FDA believes that Nicomide(R) could not be marketed as a dietary supplement with its current labeling. The FDA regulates such products under the compliance policy guide described above entitled, "Marketed New Drugs without Approved NDAs or ANDAs."

Nicomide(R) is one of the key products DUSA acquired from Sirius in connection with our merger completed in March, 2006. Nicomide(R) is an oral prescription vitamin supplement. If the FDA is not satisfied with the response to the warning letters issued to the manufacturer of Nicomide(R) and causes the manufacturer to cease operations, our revenues will be significantly negatively affected.

We have recently been advised that the sole manufacturer of our product, Psoriatec(R), may have produced batches that are not meeting stability specifications. We are currently conducting testing of these batches and may have to recall the product that is in the distribution channel which will impact our sales of this product. We do not expect the costs of the potential recall, if any, to be material. The license agreement for Psoriatec expires January 31, 2008 and we do not intend to renew the license.

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:

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

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

changes to manufacturing processes and/or facilities.

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

48

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.

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 products in the United States and the rest of the world, except Canada, Latin America and parts of Asia, where we have distributors. We are doing so without the experience of having marketed pharmaceutical products prior to 2000. In October 2003, DUSA began hiring a small direct sales force and we increased the size of our sales force to market our products in the United States. In addition, our sales personnel have only recently begun to sell and market the products we acquired in our merger with Sirius. If our sales and marketing efforts fail, then sales of the Levulan(R) Kerastick(R), the BLU-U(R), Nicomide(R) and other products will be adversely affected.

IF WE CANNOT IMPROVE PHYSICIAN REIMBURSEMENT AND/OR CONVINCING 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, a broader adoption of our therapy and sales of our products could be negatively impacted. Although positive reimbursement changes related to AK were made in 2005 and 2006, some physicians still believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices.

If insurance companies do not cover, or stop covering products which are covered, including Nicomide(R), our sales could be dramatically reduced.

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



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

revenues, and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the effectiveness, or perceived effectiveness, of our products in comparison to competing products;
- the existence of any significant side effects, as well as their severity in comparison to any competing products;
- potential advantages over alternative treatments;
- the ability to offer our products for sale at competitive prices;

49

- relative convenience and ease of administration;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

### WE HAVE SIGNIFICANT LOSSES AND ANTICIPATE CONTINUED LOSSES

We have a history of operating losses. We expect to have continued losses until sales of our products increase substantially. We incurred net losses of \$1,878,000 and \$7,726,000 for the three and nine-month periods ended September 30, 2007, respectively. As of September 30, 2007, our accumulated deficit was approximately \$128,613,000. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable on a sustainable basis.

IF 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:

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

We have limited ALA patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counterparts in only six foreign countries, and certain countries under the European Patent Convention. Even where we have

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

patent protection, there is no guarantee that we will be able to enforce our patents. Additionally, enforcement of a given patent may not be practicable or an economically viable alternative.

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

Nicomide(R) is covered by a United States patent which issued in December 2005. River's Edge Pharmaceuticals, LLC filed an application with the U.S. Patent and Trademark Office, or USPTO, for the

50

reexamination of the patent. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. If the USPTO finds that the patent is invalid, generic products will be able to lawfully compete with Nicomide(R). Also, recently two new products have been launched that could compete with Nicomide(R). These events could cause us to lose significant revenues and put our ability to be profitable at risk.

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

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

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

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

WE HAVE ONLY 3 THERAPIES THAT HAVE RECEIVED REGULATORY APPROVAL OR CLEARANCE AND WE CANNOT PREDICT WHETHER WE WILL EVER DEVELOP OR COMMERCIALIZE ANY OTHER LEVULAN(R) PRODUCTS.

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

OUR POTENTIAL PRODUCTS ARE IN EARLY STAGES OF DEVELOPMENT AND MAY NEVER RESULT IN ANY COMMERCIALY SUCCESSFUL PRODUCTS.

To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products. Except for Levulan(R) PDT for AKs, the BLU-U(R) for acne, the ClindaReach(TM) pledget and the currently marketed products we acquired in our merger with Sirius, all of our other potential Levulan(R) and other potential product candidates are at an early stage of development and subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

- delays in product development, clinical testing or manufacturing,
- unplanned expenditures in product development, clinical testing or manufacturing,
- failure in clinical trials or failure to receive regulatory approvals,
- emergence of superior or equivalent products,
- inability to market products due to third-party proprietary rights, and
- failure to achieve market acceptance.

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

51

WE MUST RECEIVE SEPARATE APPROVAL FOR EACH OF OUR POTENTIAL PRODUCTS BEFORE WE CAN SELL THEM COMMERCIALY 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

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

issued guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. We are developing Levulan(R) PDT for acne. We have received comments on our acne development program from the FDA statistical reviewer assigned to our investigational new drug application or IND. In this letter, the reviewer stated concern about whether we will have sufficient data to select an appropriate dosing regimen for Phase III trials. We believe that we have the data to indicate that sufficient drug dose ranging has been done; however, if the FDA does not accept our rationale, additional clinical trials and/or formulation development work may be required for the acne development program, which may extend the expected development time lines for such program. 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 products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide(R). FDA regulates such products under its marketed unapproved drugs 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. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with FDA to begin that process. FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and FDA may bring an action against a drug or a firm when FDA concludes that such other violations exist. The contract manufacturer of Nicomide(R) has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide could not be marketed as a dietary supplement with its current labeling. We believe that the cGMP issues do not directly involve Nicomide(R). There can be no assurance that the FDA will continue this policy or not take a contrary position with Nicomide(R). If the FDA were to take further action, we believe that we may be required to make certain labeling changes and market Nicomide(R) as over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval.

52

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 86 employees, including 4 part-time employees as of September 30, 2007. We are highly dependent on several key officer/employees with specialized scientific and technical skills without whom our business, financial condition and results of operations would suffer, especially in the photodynamic therapy portion of our business. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very few people with their expertise could be hired. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain other qualified personnel in our specialty drug and light

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

device areas.

COLLABORATIONS WITH OUTSIDE SCIENTISTS MAY BE SUBJECT TO RESTRICTION AND CHANGE.

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

### RISKS RELATED TO OUR INDUSTRY

PRODUCT LIABILITY AND OTHER CLAIMS AGAINST US MAY REDUCE DEMAND FOR OUR PRODUCTS OR RESULT IN DAMAGES.

WE ARE SUBJECT TO RISK FROM POTENTIAL PRODUCT LIABILITY LAWSUITS WHICH COULD NEGATIVELY AFFECT OUR BUSINESS.

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

OUR BUSINESS INVOLVES ENVIRONMENTAL RISKS AND WE MAY INCUR SIGNIFICANT COSTS COMPLYING WITH ENVIRONMENTAL LAWS AND REGULATIONS.

We have used various hazardous materials, such as mercury in fluorescent tubes in our research and development activities. We are subject to federal, state and local laws and regulations which govern the use, manufacture, storage, handling and disposal of hazardous materials and specific waste products. Now that we have established our own production line for the manufacture of the Kerastick(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

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

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, 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.

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

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

- price reductions,
- lower levels of third-party reimbursements,
- failure to achieve market acceptance, and
- loss of market share, any of which could adversely affect our business. Further, we cannot give any assurance that developments by our competitors or future competitors will not render our technology obsolete.

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

WE HAVE LEARNED THAT SOME COMPOUNDING PHARMACIES ARE PRODUCING A FORM OF AMINOLEVULINIC ACID HCL AND ARE MARKETING IT TO THE MEDICAL COMMUNITY.

We are aware that there are compounding pharmacies that market compounded versions of aminolevulinic acid HCl as an alternative to our Levulan(R) product. Since December 2004, we filed lawsuits against some compounding pharmacies and physicians alleging violations of the Lanham Act for false advertising and trademark infringement, and of United States patent law. All of the lawsuits that have been concluded settled favorably to us. More recently, we have sued chemical suppliers, and a light

device company, its distributor and a sales representative, alleging that they induce physicians to infringe patents licensed to us, among other things. While we believe that certain actions of compounding pharmacies and others 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 companies or that regulatory authorities will intervene to stop their activities. In addition, there may be other compounding pharmacies which are following FDA guidelines, or others conducting illegal activities of which we are not aware, which may be negatively impacting our sales revenues.

#### GENERIC MANUFACTURERS MAY LAUNCH PRODUCTS AT RISK OF PATENT INFRINGEMENT

If generic manufacturers, like River's Edge, launch products to compete with Nicamide(R) in spite of our patent position, or if the United States Patent and Trademark Office determines that our patent is invalid, these manufacturers 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 are aware of several companies commercializing and/or conducting research with ALA or ALA-related compounds, including: medac GmbH and photonamic GmbH & Co. KG (Germany); Biofrontera, PhotoTherapeutics, Inc. (U.K.) and PhotoCure ASA (Norway) which entered into a marketing agreement with Galderma S.A. for countries outside of Nordic countries for certain dermatology indications. We also anticipate that we will face increased competition as the scientific development of PDT and PD advances and new companies enter our markets. Several companies are developing PDT agents other than Levulan(R). These include: QLT Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); and Pharmacyclics, Inc. (U.S.). There are many pharmaceutical companies that compete with us in the field of dermatology, particularly in the acne and rosacea markets.

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound for PDT treatment of AKs and basal cell carcinoma in the European Union, New Zealand, Australia and countries in Scandinavia. PhotoCure's marketing partner, a large dermatology company, could begin to market its product in direct competition with Levulan(R) in the U.S., at any time, under the terms of our patent license agreement and we may lose market share.

Axcan Pharma Inc. has received FDA approval for the use of its product, PHOTOFRIN(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 for which we designed our proprietary sheath device and have conducted pilot clinical trials.

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

- the ease of administration of our method of PDT,
- the degree of generalized skin sensitivity to light,
- the number of required doses,

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

- the selectivity of our drug for the target lesion or tissue of interest, and
- the type and cost of our light systems.

Our primary competition in the acne and rosacea markets 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

55

than we do which could make it difficult for us to penetrate the market. We are also aware of new products that were launched recently which will compete with Nicamide(R) and the AVAR(R) line of products which could negatively impact our market share. In addition, River's Edge's niacinamide-based product which competes with our Nicamide(R) product has reentered the market, and other generic companies may also decide to enter the market while our patent litigation and reexamination process are proceeding, or thereafter if the court or if the USPTO finds that our Nicamide patent is invalid. The entry of new products from time to time would likely cause us to lose market share.

### RISKS RELATED TO OUR STOCK

IF THE SHARES OF COMMON STOCK HELD BY FORMER SIRIUS SHAREHOLDERS OR OUR NEW INVESTORS ARE SOLD, THE PRICE OF THE SHARES COULD BECOME DEPRESSED

All of the shares of DUSA's common stock which were issued to the former Sirius shareholders were subject to a lock-up provision under the terms of the merger agreement. On March 10, 2007, the lock-up provision on 1,380,151 shares was lifted. These shares have been registered and are freely tradable. If these shareholders decide to sell their shares, the price of the shares on NASDAQ could be depressed. If the shares of DUSA's common stock which were issued in the recent private placement are sold following the effective date of the registration statement which we are obligated to file, the price of our shares could be depressed.

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 September 30, 2007 there were outstanding options and warrants to purchase 3,264,000 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, 2006 to September 30, 2007, the price of our stock has ranged from a low of \$1.63 to a high of \$11.12. Factors that contributed to the volatility of our stock during this period included:



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

- quarterly levels of product sales;
- clinical trial results;
- general market conditions;
- patent litigation;
- increased marketing activities or press releases; and
- changes in third-party payor reimbursement for our therapy.

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

56

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.

EFFECTING A CHANGE OF CONTROL OF DUSA WOULD BE DIFFICULT, WHICH MAY DISCOURAGE OFFERS FOR SHARES OF OUR COMMON STOCK.

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

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

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Person", as such term is defined in the rights plan. The rights may be redeemed by DUSA at a redemption price of one one-hundredth of a cent per right until ten days following the date the person or group acquires, or discloses an intention to acquire, 15% or more, as the case may be, of DUSA, or until such later date as may be determined by the our board of directors.

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

57

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

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

None.

ITEM 5. OTHER INFORMATION.

None.

58

ITEM 6. EXHIBITS

EXHIBIT NO.	DESCRIPTION OF EXHIBIT
10(a)	Amendment to the Marketing, Distribution and Supply Agreement dated September 26, 2007, between the Company and Stiefel Laboratories, Inc. 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.
31(a)	Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
31(b)	Certification pursuant to Rule 13a-14(a)/15d-14(a) of the

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

Securities Exchange Act of 1934.

- 32(a) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32(b) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99.1 Press Release dated November 9, 2007

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: November 9, 2007

By: /s/ Robert F. Doman

-----  
Robert Doman  
President and Chief  
Executive Officer  
(principal executive officer)

Date: November 9, 2007

By: /s/ Richard C. Christopher

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

60

EXHIBIT INDEX

- 10(a) Amendment to the Marketing, Distribution and Supply Agreement dated September 26, 2007, between the Company and Stiefel Laboratories, Inc. 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.
- 31(a) Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
- 31(b) Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
- 32(a) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-Q

32(b) Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

99.1 Press Release dated November 9, 2007