DUSA PHARMACEUTICALS INC Form 10-Q November 06, 2009

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549 FORM 10-O

(Mark One)

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

For the quarterly period ended: September 30, 2009

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

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

Large accelerated filer o Accelerated filer o Non-accelerated filer b Smaller reporting

company o

(Do not check if a smaller reporting company)

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

As of November 5, 2009, the registrant had 24,108,908 shares of Common Stock, no par value per share, outstanding.

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

PART I. FINANCIAL INFORMATION	Page Number
PART I, FINANCIAL INFORMATION	
Item 1. Financial Statements	
- Condensed Consolidated Balance Sheets at September 30, 2009 and December 31, 2008 (Unaudited)	3
- Condensed Consolidated Statements of Operations for the three- and nine-month periods ended	ı
<u>September 30, 2009 and 2008 (Unaudited)</u> - <u>Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30,</u>	4
2009 and 2008 (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	14
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	24
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	25
Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	35
Item 3. Defaults Upon Senior Securities	35
Item 4. Submission of Matters to a Vote of Security Holders	35
Item 5. Other Information	35
Item 6. Exhibits	36
SIGNATURES	37
Exhibit Index	38
EX-10: FIFTH AMENDMENT TO SUPPLY AGREEMENT WITH SOCHINAZ, S.A.	
EX-31.A: SECTION 302 CERTIFICATION OF THE C.E.O.	
EX-31.B: SECTION 302 CERTIFICATION OF THE C.F.O.	
EX-32.A: SECTION 906 CERTIFICATION OF THE C.E.O	
EX-32.B: SECTION 906 CERTIFICATION OF THE C.F.O.	
EX-99.1: PRESS RELEASE EX-10	
<u>EX-31.A</u>	
EX-31.B	
EX-32.A EX-32.B	

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

ACCETC	September 30, 2009	December 31, 2008
ASSETS CURRENT ASSETS		
Cash and cash equivalents	\$ 5,016,994	\$ 3,880,673
Marketable securities, at fair value	10,012,948	15,002,830
Accounts receivable, net of allowance for doubtful accounts of	- ,- ,	- , ,
\$90,000 and \$98,000 in 2009 and 2008, respectively	2,519,214	2,367,803
Inventory	2,336,167	2,812,825
Prepaid and other current assets	1,647,408	1,873,801
TOTAL CURRENT ASSETS	21,532,731	25,937,932
Restricted cash	174,170	173,844
Property, plant and equipment, net	1,721,488	1,937,978
Deferred charges and other assets	68,099	160,700
TOTAL ASSETS	\$ 23,496,488	\$ 28,210,454
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES	ф 100 41 <b>7</b>	Φ 205.724
Accounts payable Accrued compensation	\$ 188,417 889,230	\$ 305,734 1,515,912
Other accrued expenses	2,343,822	3,226,571
Deferred revenues	1,045,505	611,602
Deterred revenues	1,043,303	011,002
TOTAL CURRENT LIABILITIES	4,466,974	5,659,819
Deferred revenues	3,061,700	4,157,305
Warrant liability	474,137	436,458
Other liabilities	133,544	244,673
TOTAL LIABILITIES	8,136,355	10,498,255
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. Issued and		
outstanding: 24,108,908 and 24,089,452 shares of common stock, no par, at September 30, 2009 and December 31, 2008, respectively	151,683,399	151,663,943
Additional paid-in capital	8,122,801	7,514,900
Accumulated deficit	(144,725,805)	(141,850,925)
Accumulated other comprehensive income	279,738	384,281
	2.7,7.00	201,201
TOTAL SHAREHOLDERS EQUITY	15,360,133	17,712,199

TOTAL LIABILITIES AND SHAREHOLDERS EQUITY

\$ 23,496,488

\$ 28,210,454

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 en- September 30					
		2	009	2008		2009		2008	
Product revenues	\$	6,9	930,110	\$	5,726,071	\$21	,033,920	\$21.	767,810
Cost of product revenues			594,692		1,462,028		,973,782		950,039
GROSS MARGIN		5,3	335,418		4,264,043	16	,060,138	16,	817,771
Operating costs:									
Research and development			963,245		1,487,816		,225,049		049,327
Marketing and sales		3,0	13,351		2,967,431	9	,460,766	9,	520,865
General and administrative		1,8	377,928		1,911,028	6	,360,325	6,	603,989
Impairment charge related to contingent									
consideration					1,500,000			1,	500,000
Settlements, net					650		75,000	(	282,775)
TOTAL OPERATING COSTS		5,8	354,524		7,866,925	19	,121,140	22,	391,406
LOSS FROM OPERATIONS		(5	519,106)		(3,602,882)	(3	,061,002)	(5,	573,635)
Other income, net			79,815		114,260		223,801		538,212
Gain (loss) on change in fair value of									
warrants			24,051		651,767		(37,679)		775,636
NET LOSS	\$	(4	115,240)	\$	(2,836,855)	\$ (2	,874,880)	\$ (4,	259,787)
BASIC AND DILUTED NET LOSS									
PER COMMON SHARE	\$		(0.02)	\$	(0.12)	\$	(0.12)	\$	(0.18)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND									
DILUTED	2	24,1	08,908	2	24,078,610	24,099,786		24,078,546	
See the accompanying Notes to the Condensed Consolidated Financial Statements									

See the accompanying Notes to the Condensed Consolidated Financial Statements.

4

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

	Nine-months ended September 30,		
	2009	2008	
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (2,874,880)	\$ (4,259,787)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Accretion (amortization) of premiums and discounts on marketable			
securities	43,407	(95,139)	
Realized loss on sales of marketable securities	43,678	42,989	
Share-based compensation	631,770	1,042,811	
Impairment charge related to contingent consideration		1,500,000	
Depreciation and amortization	345,720	441,829	
Loss (gain) on change in fair value of warrants	37,679	(775,636)	
Deferred revenues recognized	(675,037)	(761,302)	
Changes in other assets and liabilities impacting cash flows used in			
operations:			
Accounts receivable	(151,411)	1,093,357	
Inventory	476,658	(327,363)	
Prepaid and other current assets	226,393	(277,174)	
Deferred charges and other assets	92,601	80,146	
Accounts payable, accrued compensation and other accrued expenses	(1,626,748)	28,036	
Deferred revenues	13,335	1,510,712	
Other liabilities	(111,129)	(53,083)	
NET CASH USED IN OPERATING ACTIVITIES	(3,527,964)	(809,604)	
CASH FLOWS FROM INVESTING ACTIVITIES			
Cash paid for contingent consideration		(1,750,000)	
Purchases of marketable securities	(12,049,905)	(22,964,544)	
Proceeds from maturities and sales of marketable securities	16,848,159	26,368,809	
Restricted cash	(326)	(2,875)	
Purchases of property, plant and equipment	(129,230)	(333,526)	
NET CASH PROVIDED BY INVESTING ACTIVITIES CASH FLOWS FROM FINANCING ACTIVITIES	4,668,698	1,317,864	
Proceeds from exercise of options		4,000	
Settlements of restricted stock for tax withholding obligations	(4,413)		
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES	(4,413)	4,000	
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,136,321	512,260	
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,880,673	4,713,619	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 5,016,994	\$ 5,225,879	

See the accompanying Notes to the Condensed Consolidated Financial Statements.

5

# DUSA PHARMACEUTICALS, INC. NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) 1) BASIS OF PRESENTATION

The Condensed Consolidated Balance Sheet as of September 30, 2009, the Condensed Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2009 and 2008, and the Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2009 and 2008 of DUSA Pharmaceuticals, Inc. (the Company or DUSA) have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). These condensed consolidated financial statements are unaudited but include all normal recurring adjustments, which management of the Company believes to be necessary for fair presentation of the periods presented. The results of the Company is operations for any interim period are not necessarily indicative of the results of the Company is operations for any other interim period or for a full year. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements should be read in conjunction with the Consolidated Financial Statements and Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission. The balance sheet as of December 31, 2008 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

We evaluated all subsequent events that occurred after the balance sheet date through November 5, 2009, the day prior to the issuance of these financial statements.

# 2) NEW ACCOUNTING PRONOUNCEMENTS

# Recently Adopted Accounting Standards

In April 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Codification (ASC) 320-10-65 (formerly FSP No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*), which establishes a new method of recognizing and reporting other-than-temporary impairments of debt securities and requires additional disclosures related to debt and equity securities. ASC 320-10-65 does not change existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. The adoption of this statement was not material to our financial position or results of operations.

In May 2009, the FASB issued ASC 855-10 (formerly SFAS No. 165, *Subsequent Events*), which provides guidance to establish general standards of accounting for, and disclosures of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855-10 is effective for interim or fiscal periods ending after June 15, 2009. We adopted this statement effective June 15, 2009.

In June 2009, the FASB issued ASC 105-10 (formerly SFAS 168), *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*. ASC 105-10 will become the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernment entities. It also modifies the GAAP hierarchy to include only two levels of GAAP; authoritative and non-authoritative. ASC 105-10 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. Therefore, the Company adopted ASC 105-10 for the reporting in our 2009 third quarter. The adoption did not have a significant impact on the reporting of our financial position, results of operations or cash flows.

# Recently Issued Accounting Standards

In October 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB Accounting Standards Codification, or ASC, Subtopic 605-25 (previously included within EITF 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). The consensus to EITF Issue No. 08-01, Revenue Arrangements with Multiple Deliverables, or EITF 08-01, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the

selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective

6

#### **Table of Contents**

prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company will have to evaluate the impact of this standard on future revenue arrangements that the Company may enter into.

# 3) FAIR VALUE MEASUREMENTS

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets and liabilities carried at fair value are classified and disclosed in one of the following three categories:

- Level 1: Quoted market prices in active markets for identical assets or liabilities.
- Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.
- Level 3: Unobservable inputs that are not corroborated by market data.

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

Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, prepayment speeds, default rates, loss severity, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace. Financial instruments in this category include corporate debt and government-backed securities.

Level 3 is comprised of financial instruments whose fair value is estimated based on internally developed models or methodologies utilizing significant inputs that are generally less readily observable.

The following table presents information about the Company s assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2009, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

Assets:

Cash equivalents	Level 1 \$ 3,634,000
United States government-backed securities Corporate debt securities	Level 2 \$ 9,104,000 909,000
Total assets	\$ 13,647,000
	Level 3
Liabilities:	Level 3
Warrant liability	474,000
Total liabilities	\$ 474,000

# **Changes in Level 3 Recurring Fair Value Measurements:**

The table below includes a rollforward of the balance sheet amounts for the nine-month period ended September 30, 2009 for the warrant liability, which is classified as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable parameters to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable components, observable components (that is, components that are actively quoted and can be validated

to external sources). Accordingly, the gains and losses in the table below include changes in fair value due in part to observable factors that are part of the methodology.

7

									Cł	nange in
									Ur	realized
									Loss	es/(Gains)
									Re	elated to
					Purchases,				Fi	inancial
					Sales,	Transfers			Ins	truments
	F	air Value				In	F	air Value		
		at		Total	Issuances,	and/or		at	I	Held at
							S	eptember	Se	ptember
	J	anuary 1,	Ur	nrealized	Settlements,	Out of		30,		30,
						Level				
		2009	Loss	ses/(Gains)	net	3		2009		2009
Warrant Liability	\$	436,000	\$	38,000	\$	\$	\$	474,000	\$	38,000

The recorded amounts of the Company s cash and cash equivalents, accrued interest receivable, accounts receivable and accounts payable at September 30, 2009 approximate fair value.

# 4) WARRANTS

On October 29, 2007, the Company sold, through a private placement, 4,581,043 shares of its common stock and warrants to purchase 1,145,259 shares of common stock with an exercise price of \$2.85. The warrants have a 5.5 year term and became exercisable on April 30, 2008. The warrants are recorded as a derivative liability at fair value. Assumptions used for the Black-Scholes option-pricing models to determine the fair value of the warrant liability as of September 30, 2009 and December 31, 2008 are as follows:

	September	December
	30,	31,
	2009	2008
Expected volatility	84.4%	75.0%
Remaining contractual term (years)	3.58	4.33
Risk-free interest rate	1.67%	1.55%
Expected dividend yield	0%	0%
Common stock price	\$ 1.09	\$ 1.05

# 5) MARKETABLE SECURITIES

The Company s investment securities consist of securities of the U.S. government and its agencies, and investment grade corporate bonds. The Company has historically classified all investment securities as available-for-sale and recorded such investments at fair market value. Since the Company s investments are managed by a third-party investment advisor pursuant to a discretionary arrangement, for securities with unrealized losses at September 30, 2009 and 2008, which totaled \$7,000 and \$36,000, respectively, an other-than-temporary impairment was considered to have occurred and the cost basis of such securities was written down to their fair values with the amount of the write-down included in earnings as realized losses in the accompanying Condensed Consolidated Statements of Operations. As of September 30, 2009, current yields range from 0.76% to 6.01% and maturity dates range from November 2009 to January 2013. The estimated fair value and cost of marketable securities at September 30, 2009 and December 31, 2008 are as follows:

	September 30, 2009			
	Amortized Cost	Unrealized Gains	Fair Value	
United States government-backed securities	\$8,912,000	\$192,000	\$ 9,104,000	

Corporate securities	821,000	88,000	909,000
Total marketable securities available-for-sale	\$9,733,000	\$280,000	\$10,013,000
	Amortized Cost	December 31, 2008 Unrealized Gains	Fair Value
United States government-backed securities Corporate securities	\$11,956,000 2,662,000	\$357,000 28,000	\$12,313,000 2,690,000
Total marketable securities available-for-sale	\$14,618,000	\$385,000	\$15,003,000
	8		

# **Table of Contents**

The increase (decrease) in net unrealized gains on such securities for the three- and nine-month periods ended September 30, 2009 was (\$34,000) and (\$105,000), respectively, as compared to \$58,000 and \$45,000 for the three-and nine-month periods ended September 30, 2008, and has been recorded in accumulated other comprehensive income, which is reported as part of shareholders equity in the Condensed Consolidated Balance Sheets.

# 6) CONCENTRATIONS

The Company is exposed to concentrations of credit risk related to accounts receivable that are generated from its customers. From time to time, the Company is also exposed to concentrations of revenues with significant customers, including its international distribution partners and domestic wholesalers. To manage credit risk, the Company performs regular credit evaluations of its customers. As the Company believes appropriate, the Company provides allowances for bad debts. Concentrations in the Company s total revenues for the three- and nine-months ended September 30, 2009 and 2008, and accounts receivable as of September 30, 2009 and December 31, 2008 are as follows:

	% of Revenue		% of I	Revenue			
						Accounts	
	Three mo	onths ended	Nine mo	nths ended	Receivable		
	September	•	tember September 30, 30,	September 30,	September 30,	December 31,	
	30,						
	2009	2008	2009	2008	2009	2008	
Customer A	2%	1%	3%	2%	7%	11%	
Customer B	1%	1%	1%	9%	2%		
Customer C	1%		1%	8%			
Customer D				4%			
Customer E	3%	4%	3%	3%	3%	1%	
Customer F	1%	8%	1%	2%	3%	9%	
Other customers	92%	86%	91%	72%	85%	79%	
Total	100%	100%	100%	100%	100%	100%	

# 7) INVENTORY

Inventory consisted of the following:

	September 30, 2009	December 31, 2008
Finished goods	\$1,298,000	\$1,348,000
BLU-U® evaluation units	37,000	166,000
Work in process	433,000	698,000
Raw materials	568,000	601,000
Total	\$2,336,000	\$2,813,000

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

# 8) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

		September 30, 2009	December 31, 2008
Research and development costs Marketing and sales costs Reserve for sales returns and allowances Accrued FDA fees		\$ 115,000 228,000 300,000	\$ 190,000 191,000 500,000 589,000
Due to former Sirius shareholders Other product related costs Legal and other professional fees Employee benefits Other expenses		210,000 757,000 386,000 284,000 64,000	824,000 467,000 278,000 188,000
Total	9	\$2,344,000	\$3,227,000

# **Table of Contents**

# 9) 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, 2009 and 2008 included the following line items:

	Three-m	onths ended	Nine-months ended		
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008	
Cost of product revenues	\$ 13,000	\$ 18,000	\$ 47,000	\$ 59,000	
Research and development	31,000	70,000	112,000	260,000	
Marketing and sales	62,000	88,000	65,000	61,000	
General and administrative	101,000	177,000	408,000	662,000	
Share-based compensation expense	\$207,000	\$ 353,000	\$632,000	\$ 1,042,000	

The weighted-average estimated fair values of employee stock options granted during the three- and nine-month periods ended September 30, 2009 were \$0.80 and \$0.81 per share, respectively, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

Three-months

Nine-months

		ended September 2009		ended eptember 30, 2009
Expected volatility Risk-free interest rate Expected dividend yield		75.5 2.58		73.6% 2% 0%
Expected term-directors and officers (years)		6.5		6.5
Expected term-non-officer employees (years) A summary of stock option activity is as follows:		5.7		5.7
Outstanding, beginning of period, July 1, 2009 Options granted Options forfeited Options expired Options exercised	3,593,275 20,000 (24,025)	Weighted Average Exercise Price \$ 8.14 \$ 1.22 \$ 6.47 \$	Average Remaining Contractua Term (Years)	
Outstanding, end of period	3,589,250	\$ 8.11	3.72	\$ 25
Exercisable, end of period	2,535,400	\$10.67	2.75	

Options vested and expected to vest, end of period

3,445,703

\$ 8.39

3.62

\$21

At September 30, 2009 the total amount of unrecognized compensation expense related to grants of options was \$1,038,000.

10

# **Table of Contents**

During the first quarter of 2009 and the second quarter of 2008, respectively, the Company issued 280,000 and 102,000 unvested shares of common stock to its officers. The Company also issued 45,000 shares of unvested common stock to its Board of Directors during the first quarter of 2009. The unvested shares of common stock vest over 4 years at a rate of 25% per year. The fair value on the date of grant was \$1.22 and \$2.20 per share in 2009 and 2008, respectively. At September 30, 2009 the total amount of unrecognized compensation expense related to grants of unvested common stock was \$442,000. The unrecognized compensation related to unvested common stock will be recognized over a weighted-average period of 3.2 years. The weighted average grant date fair value of the 22,750 shares that vested in 2009 and the 393,250 unvested shares of common stock at September 30, 2009 were \$2.20 and \$1.39, respectively.

# 10) BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per common share is based on the weighted-average number of shares outstanding during each period. For the three- and nine-month periods ended September 30, 2009, and 2008, stock options, unvested shares of common stock, warrants and rights totaling approximately 5,378,000 and 4,521,000 shares, respectively, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive.

# 11) SEGMENT REPORTING

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

	Three-month	period ended	Nine-month period ended		
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008	
REVENUES					
PDT drug and device product revenues	\$6,700,000	\$5,157,000	\$19,836,000	\$16,416,000	
Non-PDT product revenues	230,000	569,000	1,198,000	5,352,000	
Total revenues	6,930,000	5,726,000	21,034,000	21,768,000	
COSTS OF REVENUES PDT drug and device cost of product					
revenues	1,226,000	1,146,000	4,227,000	3,589,000	
Non-PDT cost of product revenues	369,000	316,000	747,000	1,361,000	
Total costs of product revenues	1,595,000	1,462,000	4,974,000	4,950,000	
GROSS MARGIN PDT drug and device product gross					
margin	5,474,000	4,011,000	15,609,000	12,827,000	
Non-PDT product gross margin	(139,000)	253,000	451,000	3,991,000	
Total gross margin	\$5,335,000	\$4,264,000	\$16,060,000	\$16,818,000	

During the three- and nine-month periods ended September 30, 2009 and 2008, the Company derived revenues from the following geographies based on the location of the customer (as a percentage of product revenues):

	Three-mo	Nine-months ended			
	September	September September		September	
	30,	30,	30,	30,	
	2009	2008	2009	2008	
United States	93%	93%	94%	93%	
Canada	2%	1%	2%	2%	
Korea	3%	4%	2%	3%	
Other	2%	2%	2%	2%	
Total	100%	100%	100%	100%	
	11				

# **Table of Contents**

#### 12) COMPREHENSIVE LOSS

For the three- and nine-month periods ended September 30, 2009 and 2008, comprehensive loss consisted of the following:

	Three-months ended September 30,		- 1	nths ended aber 30,
	2009	2008	2009	2008
NET LOSS Change in net unrealized (losses) gains on	\$(415,000)	\$(2,837,000)	\$(2,875,000)	\$(4,259,000)
marketable securities available-for-sale	(34,000)	58,000	(105,000)	45,000
COMPREHENSIVE LOSS	\$(449,000)	\$(2,779,000)	\$(2,980,000)	\$(4,214,000)

# 13) STIEFEL AGREEMENT

In January 2006, as amended in September 2007, the Company licensed to Stiefel Laboratories, Inc. the exclusive Latin American rights to market Levulan® PDT for payments by Stiefel of up to \$2,250,000. The Company 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 the Company as follows: (i) \$375,000 upon launch of the product in either Mexico or Argentina; (ii) \$375,000 upon receipt of acceptable pricing approval in Brazil; (iii) two installments of \$375,000 each for cumulative end-user sales in Brazil totaling 150,000 units and 300,000 units, and (iv) two installments of \$375,000 each for cumulative sales in countries excluding Brazil totaling 150,000 units and 300,000 units. Stiefel launched the product in October 2007 in Mexico and Argentina and in April 2008 in Brazil. The Company is deferring and recognizing approval and sales milestones as license revenues on a straight-line basis. beginning on the date the milestone is achieved through the fourth quarter of 2015, which is the term of the Stiefel Agreement. Stiefel pays a fixed price per unit for the inventory as well as a royalty based on a percentage of the net sales price to end-users. During the nine-month periods ended September 30, 2009 and 2008 the Company s sales of Levulan® Kerastick® to Stiefel were \$18,000 and \$303,000, respectively. At September 30, 2009 and December 31, 2008 the total revenues deferred associated with shipments to Stiefel were \$313,000 and \$389,000, respectively, in accordance with the Company s policy of deferring revenues during a product s launch phase and recognizing revenues based on end-user demand. Deferred revenues at September 30, 2009 and December 31, 2008 associated with milestone payments received from Stiefel were \$556,000 and \$621,000, respectively.

The agreement with Stiefel also establishes minimum purchase quantities over the first five years following regulatory approval. The first contract year for all countries other than Brazil began in October 2007, and for Brazil began in April 2008. For the contract years ended in October 2008 and 2009 and April 2009 Stiefel did not meet its minimum purchase obligations under the agreement. The agreement provides that within 60 days of the year end, Stiefel is required to pay the Company the difference between its actual purchases and the contractual minimums (a gross-up payment). To date, Stiefel has failed to make the gross-up payments, and accordingly, the Company is considering its remedies, which include, without limitation, appointing one or more other distributors in the territory or terminating the agreement. Also, since Stiefel s sales to third parties during the contract years ended October 2008 and 2009 and April 2009 were below its minimum purchase obligations, Stiefel has the unilateral right to terminate the contract. Stiefel has not exercised this right.

# 14) DAEWOONG AGREEMENT

In January 2007 the Company licensed to Daewoong Pharmaceutical Co., LTD. and its wholly-owned subsidiary DNC Daewoong Derma & Plastic Surgery Network Company, the exclusive rights to market Levulan® PDT in Korea and other Asia Pacific countries for payments by Daewoong of up to \$3,500,000. The Company also manufactures and supplies finished product for Daewoong, which the Company began shipping in October 2007. In consideration for the transaction Daewoong agreed to pay the Company as follows: (i) \$1,000,000 upon contract signing; (ii) \$1,000,000 upon achieving regulatory approval in Korea; and (iii) two installments of \$750,000 each for cumulative

end-user sales totaling 200,000 units and 500,000 units. Daewoong launched the product in November 2007 in Korea. The Company is deferring and recognizing the up-front and regulatory approval milestones as license revenues on a straight-line basis, beginning with product launch in the territory through the fourth quarter of 2016, which is the term of the Daewoong Agreement. Daewoong pays a fixed price per unit for the inventory and an Excess Purchase Price, as defined in the Agreement, if the Average Selling Price to end-users during any calendar quarter exceeds a certain threshold. During the nine-month periods ended September 30, 2009 and 2008, the Company s sales of Levulan Kerastick® to Daewoong were \$0 and \$998,000, respectively. At September 30, 2009 and December 31, 2008 the total revenues deferred associated with shipments to Daewoong were \$801,000 and \$1,144,000, respectively, in accordance with the Company s policy of deferring revenues during a product s launch phase and recognizing revenues based on end-user demand. Deferred revenues at September 30, 2009 and December 31, 2008 associated with milestone payments received from Daewoong were \$1,489,000 and \$1,643,000, respectively. The agreement with Daewoong also establishes a cumulative minimum purchase quantity over the first five years following regulatory approval. If Daewoong fails to meet its minimum purchase quantities, the Company may, in addition to other remedies, at its sole discretion, appoint one or more other distributors in the covered territories, or terminate the agreement.

12

#### **Table of Contents**

# 15) SETTLEMENTS, NET

# River s Edge Litigation Settlement

As part of the settlement of litigation between DUSA and River s Edge Pharmaceuticals, LLC in October 2007, the parties entered into a Settlement Agreement and Mutual Release (the Settlement Agreement ) to dismiss the lawsuit brought by DUSA against River s Edge asserting a number of claims arising out of River s Edge s alleged infringement of the Company s Nicomide patent, U.S. Patent No. 6,979,468, under which DUSA formerly marketed, distributed and sold Nicomide<sup>®</sup>. As part of the terms of this agreement, River s Edge agreed to pay to DUSA \$25.00 for every bottle of River's Edge product above 5,000 bottles that was substituted for Nicomide after September 30, 2007. The net (loss) gain from settlement of the River s Edge litigation for the three- and nine-month periods ended September 30, 2008 was (\$1,000) and \$283,000, respectively, and is recorded in the accompanying Condensed Consolidated Statement of Operations in Settlements, net. There were no related gains or losses recorded in 2009. On August 12, 2008, the Company entered into a worldwide non-exclusive patent License Agreement to its patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to its Settlement Agreement with River s Edge. The amendment to the Settlement Agreement, which has been further amended in April 2009 as described in the following paragraph, had allowed River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changed certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, the Company was being paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement. Royalty revenues recorded pursuant to the License Agreement are recorded in Product Revenues in the accompanying Consolidated Statements of Operations.

In April 2009, the Company and River s Edge entered into an Amendment to their License Agreement (the License Amendment ). The License Amendment granted River s Edge an exclusive license to U.S. Patent, No. 6,979,468, and a license to use all know-how and the trademark associated with the Licensed Products worldwide. Under the License Amendment, DUSA is required to transfer all of its rights, title and interest in and to the DUSA s patent, know-how and trademark relating to the Licensed Products (but not the copyright registration relating to product labeling) to River s Edge upon the Company s receipt of \$5,000,000. Of the \$5,000,000, River s Edge is required to make a minimum guaranteed payment to the Company of \$2,600,000, in thirteen monthly installments of \$200,000, subject to reduction under certain conditions, and pay additional consideration of \$2,400,000 payable over time based on a share of River s Edge s net revenues as defined in the License Amendment. The License Agreement, as amended, has a term of 30 months, subject to a further extension under certain circumstances to 48 months, and may be terminated early by River s Edge on 30 days prior written notice to the Company. Under the License Agreement, River s Edge has assumed all regulatory responsibilities for the Licensed Products. If the License Agreement is terminated prior to the payment of the \$5,000,000, all of the rights and licenses granted by the Company to River s Edge will revert to the Company. The Company is recording the revenue from the License Amendment on a cash basis. The Company received the first \$200,000 installment payment under the License Amendment during the second quarter of 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations, but has not received any further payments. In the event that the Company terminates the License Agreement, which it has the right to do for non-payment, the Company will consider introducing a niacinamide product under the Dietary Supplement Health and Education Act, but in that case, the Company would expect volume and revenues to be lower than historical levels of Nicomide. As of November 6, 2009, payments due from River s Edge are six months, or \$1.2 million, in arrears. The Company is evaluating its options for termination of the License Agreement, the potential to market a niacinamide product under the Dietary Supplement Health and Education Act, and the collection of the amounts due from River s

In 2009, another company has launched a substitutable niacinamide product. In July 2009, River s Edge filed a lawsuit against it alleging infringement of the Nicomide® patent. The validity of the patent is being tested again as a request for *ex parte* reexamination of this patent was filed by an unknown third party with the U.S. Patent and Trademark Office, or USPTO, on August 19, 2009. An order issued by the USPTO on October 16, 2009 accepted the reexamination. Also, other new products have been launched that are competing with Nicomide®.

Winston Laboratories Arbitration Settlement

In October 2008, the Company was notified that Winston Laboratories, Inc. had filed a demand for arbitration against the Company. The demand for arbitration arose out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement (together the Agreement), and claimed that the Company breached the Agreement. Winston Laboratories claimed damages in excess of \$2.0 million. The matter was settled on April 28, 2009 for cash consideration of \$75,000, and a mutual release.

13

# 16) COMMITMENTS AND CONTINGENCIES

# **Business Acquisition**

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius Laboratories, Inc (Sirius). The Company agreed to pay additional consideration in future periods to the former Sirius shareholders based upon the achievement of total cumulative sales milestones for the Sirius products over the period beginning with the closing of the acquisition and ending December 31, 2011. The first cumulative sales milestone was achieved during 2008, and accordingly a cash payment in the amount of \$1.5 million was paid to the former Sirius shareholders in that year. The payment made during 2008 was recorded initially as goodwill and then subsequently deemed impaired and expensed during the same period as described below.

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

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

# **Third Amendment to Merger Agreement**

In April 2009, the Company and the former shareholders of Sirius entered into a letter agreement providing for the consent of the former Sirius shareholders to the Amendment to the License Agreement with River's Edge mentioned above in Note 15 Settlements, Net, a release, and the Third Amendment to the Merger Agreement, dated as of December 30, 2005, by and among the DUSA Pharmaceuticals, Inc., Sirius and the shareholders of Sirius. Pursuant to the Merger Agreement prior to this amendment, the Company agreed to pay additional consideration after the closing of the merger to the former shareholders of Sirius based upon the attainment of pre-determined total cumulative sales milestones for the products acquired from Sirius over the period ending 50 months from the date of the March 2006 closing of the original Merger Agreement. Pursuant to the agreements entered into in April 2009, the Company has agreed to extend the Milestone Termination Date from 50 months from the date of the closing of the original Merger Agreement until December 31, 2011 and to include in the definition of Net Sales in the Merger Agreement payments which the Company may receive from the divestiture of Sirius products. The Third Amendment to the Merger Agreement also removes the Company so obligation to market the Sirius products according to certain previously required standards and allows the Company to manage all business activities relating to the products acquired from Sirius without further approval from the former Sirius shareholders.

In April 2009 the Company paid to the former Sirius shareholders, on a pro rata basis, \$100,000. In addition, in the event that the \$1,000,000 milestone payment that would become due to the former Sirius shareholders under the Merger Agreement if cumulative Net Sales of the Sirius products reach \$35,000,000 is not, in fact, triggered by the new Milestone Termination Date, then the Company has agreed to pay \$250,000 to the former Sirius shareholders on a pro rata basis on or before January 6, 2012. The \$100,000 payment to Sirius shareholders, along with the present value of the guaranteed \$250,000 milestone payment, or \$210,000, have been included in general and administrative expense for the nine-month period ended September 30, 2009 in the accompanying Condensed Consolidated Statement of Operations.

#### Other

The amount of the net operating loss carryforwards and other tax attributes that may be utilized to offset future taxable income, when earned, may be subject to certain limitations, based upon changes in the ownership of the Company s common stock under IRC Section 382 that may have occurred in the public market. The Company is in the process of analyzing whether such ownership changes may have occurred and will assess the effects of prior ownership changes, if any, on its ability to utilize its net operating loss carryforwards and other tax attributes.

The Company has not accrued amounts for any other potential contingencies as of September 30, 2009.

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

# **OVERVIEW**

We are a vertically integrated dermatology company that is developing and marketing Levulan® photodynamic therapy, or PDT, and other products for common skin conditions. Our marketed products include Levulan® Kerastick® 20% Topical Solution with PDT, the BLU-U® brand light source, and ClindaReach®.

14

# **Table of Contents**

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

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

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide®, or License Agreement, with River s Edge Pharmaceuticals, LLC, or River s Edge, and an amendment to our Settlement Agreement with River s Edge regarding earlier litigation. See Note 15 of the Notes to the Condensed Consolidated Financial Statements. The amendment to the Settlement Agreement allowed River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changed certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we were paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales. In April 2009, we and River s Edge entered into an Amendment to the License Agreement, or License Amendment. The License Amendment grants River s Edge an exclusive license to U.S. Patent, No. 6,979,468, and a license to use all know-how and the trademark associated with the Licensed Products worldwide. Under the License Amendment, we are required to transfer all of our rights, title and interest in and to DUSA s patent, know-how and trademark relating to the Licensed Products (but not the copyright registration relating to product labeling) to River s Edge upon our receipt of \$5,000,000. Of the \$5,000,000, River s Edge is required to make a minimum guaranteed payment to us of \$2,600,000, in thirteen monthly installments of \$200,000, subject to reduction under certain conditions, and pay additional consideration of \$2,400,000 payable over time based on a share of River s Edge s net revenues as defined in the License Amendment. The License Agreement, as amended, has a term of 30 months, subject to a further extension under certain circumstances to 48 months, and may be terminated early by River s Edge on 30 days prior written notice. Under the License Agreement, River s Edge has assumed all regulatory responsibilities for the Licensed Products. If the License Agreement is terminated prior to the payment of the \$5,000,000, all of the rights and licenses granted by us to River s Edge will revert to us. We are recording the revenue under the License Amendment on a cash basis. We received the first \$200,000 installment payment under the License Amendment during the second quarter of 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations, but have not received any further payments. In the event that we terminate the License Agreement, which we have the right to do for non-payment, we will consider introducing a niacinamide product under the Dietary Supplement Health and Education Act, but in that case, the Company would expect volume and revenues to be lower than historical levels of Nicomide. As of November 6, 2009, payments due from River s Edge are six months, or \$1.2 million, in arrears. We are evaluating our options for termination of the License Agreement, the potential to market a niacinamide product under the Dietary Supplement Health and Education Act, and the collection of the amounts due from River s Edge.

We are marketing Levulan<sup>®</sup> PDT under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen s University, Kingston, Ontario, Canada. In January, 2009, we filed a request for reexamination with the USPTO of one of the Queen s patents that cover our approved indication for AK. We responded to the first office action on October 27, 2009. We also own or license certain other patents relating to our BLU-U<sup>®</sup> device and methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA<sup>®</sup>, DUSA Pharmaceuticals, Inc.<sup>®</sup>, Levulan<sup>®</sup>, Kerastick<sup>®</sup>, BLU-U<sup>®</sup>, Nicomide<sup>®</sup>, Nicomide-T<sup>®</sup>, ClindaReach<sup>®</sup>, Meted<sup>®</sup>, and Psoriacap<sup>®</sup> are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Numerous other trademark applications are pending.

As of September 30, 2009, we had an accumulated deficit of approximately \$144,726,000. 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.

15

# 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, 2008. Since not all of these accounting policies require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting policies with our Audit Committee. With the exception of the updated accounting policies listed below, there have been no material changes to our critical accounting policies in the nine months ended September 30, 2009. Fair Value Measurements of Marketable Securities

In determining the fair value of our marketable securities, we consider the level of market activity and the availability of prices for the specific securities that we hold. For our Level 2 financial instruments, comprising our corporate debt and United States government-backed securities, we use quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency in the determination of value. We also access publicly available market activity from third party databases and credit ratings of the issuers of the securities we hold to corroborate the data used in the fair value calculations obtained from our primary source. We also take into account credit rating changes, if any, of the securities or recent marketplace activity. We do not have any Level 1 or Level 3 marketable securities.

# RESULTS OF OPERATIONS THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 VERSUS SEPTEMBER 30, 2008

**REVENUES** Total revenues for the three- and nine-month periods ended September 30, 2009 were \$6,930,000 and \$21,034,000, respectively, as compared to \$5,726,000 and \$21,768,000 in 2008, and were comprised of the following:

		nths ended aber 30,			nths ended aber 30,	
	2009	2008	INCREASE/ (DECREASE)	2009	2008	INCREASE/ (DECREASE)
PDT product revenues Levulan® Kerastick® product revenues						
United States	\$5,790,000	\$4,374,000	\$1,416,000	\$17,096,000	\$13,720,000	\$ 3,376,000
Canada	162,000	72,000	90,000	404,000	449,000	(45,000)
Korea	201,000	186,000	15,000	498,000	710,000	(212,000)
Other	91,000	99,000	(8,000)	261,000	289,000	(28,000)
Subtotal Levulan® Kerastick® product revenues	6,244,000	4,731,000	1,513,000	18,259,000	15,168,000	3,091,000
BLU-U® product revenues United States	456,000	376,000	80,000	1,577,000	1,198,000	379,000
Korea		50,000	(50,000)		50,000	(50,000)
Subtotal BLU-U® product revenues	456,000	426,000	30,000	1,577,000	1,248,000	329,000
Total PDT product revenues	6,700,000	5,157,000	1,543,000	19,836,000	16,416,000	3,420,000
Total Non-PDT product revenues	230,000	569,000	(339,000)	1,198,000	5,352,000	(4,154,000)

Total product revenues

\$6,930,000 \$5,726,000 \$1,204,000 \$21,034,000 \$21,768,000 \$ (734,000)

16

# **Table of Contents**

For the three- and nine-month periods ended September 30, 2009, total PDT Drug and Device Products revenues, comprised of revenues from our Kerastick® and BLU-U® products, were \$6,700,000 and \$19,836,000, respectively. This represents an increase of \$1,543,000, or 30%, and \$3,420,000, or 21%, over the comparable 2008 totals of \$5,157,000 and \$16,416,000, respectively. The incremental revenue was driven primarily by increased Kerastick® revenues and BLU-U® revenues in the United States.

For the three- and nine-month periods ended September 30, 2009, Kerastick® revenues were \$6,244,000, and \$18,259,000, respectively, representing a \$1,513,000, or 32%, and \$3,091,000, or 20%, increase over the comparable 2008 totals of \$4,731,000 and \$15,168,000, respectively. Kerastick® unit sales to end-users were 53,622 and 155,384, for the three- and nine-month periods ended September 30, 2009, respectively. Included in revenues for the nine months ended September 30, 2009, are 4,500 units sold in Canada and 6,606 sold in Korea. This represents an increase from 44,668 and 145,256 Levulan® Kerastick® units sold in the three- and nine-month periods ended September 30, 2008, respectively. Included in revenues for the nine months ended September 30, 2008, are 5,700 units sold in Canada and 10,692 sold in Korea. Our overall average net selling price for the Kerastick® increased to \$115.87 per unit for the first nine months of 2009 from \$102.79 per unit for the first nine months of 2008. Our average net selling price for the Kerastick® in the United States increased to \$121.66 per unit in 2009 from \$110.15 per unit in 2008. The increase in 2009 Kerastick® revenue was driven by increased sales volumes in the United States along with the increase in our overall average unit selling price.

For the three- and nine-month periods ended September 30, 2009, BLU-U® revenues were \$456,000 and \$1,577,000, respectively, representing a \$30,000, or 7%, and \$329,000, or 26%, increase over the comparable 2008 totals of \$426,000 and \$1,248,000, respectively. The increase in year-to-date 2009 BLU-U® revenues was driven by increased overall sales volumes, partially offset by a decrease in our average selling price. In the three- and nine-month periods ended September 30, 2009, there were 59 and 198 units sold, respectively, versus 57 and 154 units sold, respectively, in the comparable 2008 periods. All of the units sold in 2009 were sold in the United States. For the nine months ended September 30, 2008, 149 of the units were sold in the United States with 5 sold in Korea. For the first nine months of 2009, our average net selling price for the BLU-U® decreased to \$7,591 from \$7,820 in 2008. Our BLU-U® evaluation program allows customers to take delivery for a limited number of BLU-U<sup>®</sup> units for a period of up to four months for private practitioners and up to one year for hospital clinics, before a purchase decision is required. At September 30, 2009, there were approximately 9 units in the field pursuant to this evaluation program, compared to 58 units in the field at December 31, 2008. The units are classified as inventory in the financial statements and are being amortized during the evaluation period to cost of goods sold using an estimated life for the equipment of three years. Non-PDT Drug Product Revenues reflect the revenues generated by the products acquired as part of our acquisition of Sirius. Total Non-PDT Product revenues for the three- and nine-month periods ended September 30, 2009 were \$230,000 and \$1,198,000, respectively, compared to \$569,000 and \$5,352,000, respectively for the comparable 2008 periods. The substantial majority of the Non-PDT product revenues were from Nicomide® related royalties from River s Edge, as further described below, and sales of ClindaReach. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide<sup>®</sup>, that Actavis would cease manufacturing several prescription vitamins, including Nicomide<sup>®</sup>, due to continuing discussions with the FDA. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008. The decrease in our total revenues for the nine month period ended September 30, 2009 compared with the comparable period in 2008 results from decreases in Non-PDT revenues and international Kerastick® revenues, partially offset by increased PDT segment revenues in the United States. We must continue to increase sales from these levels in order for us to become profitable. We cannot provide any assurance that we will be able to increase sales sufficiently to become profitable, and we cannot provide assurance that a material increase in sales will necessarily cause us to be profitable. PhotoCure received FDA approval to market Metvixia® for treatment of AKs in July 2004, and this product, which is directly competitive with our Levulan® Kerastick® product, is now commercially available. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. While we are entitled to royalties on net sales of Metvixia, Galderma has a large sales force and considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share. However, our PDT segment revenues in the United States have grown during 2009, due in part to the

6% increase in Medicare reimbursement of our PDT-related procedure fee, which became effective January 1, 2009, as well as our pricing strategies. Although we expect growth in our PDT segment revenues, we are susceptible to the uncertain economic conditions, particularly with our customer base in the U.S. that focuses on the cosmetic market and with the international markets. Reduced sales to the cosmetic customer base and softness in the international markets could be expected until the economy recovers. We expect our Non-PDT revenues for the full year 2009 to be significantly reduced compared to 2008 since we are no longer manufacturing and marketing Nicomide® and are experiencing difficulty collecting payments due under the License Agreement with River s Edge.

COST OF PRODUCT REVENUES Cost of product revenues for the three- and nine-month periods ended September 30, 2009 were \$1,595,000 and \$4,974,000 as compared to \$1,462,000 and \$4,950,000 in the comparable

17

periods in 2008. A summary of the components of cost of product revenues and royalties is provided below:

# **Table of Contents**

	THREE MONTHS ENDED SEPTEMBER			BER 30, ICREASE/		
		2009		2008		ECREASE)
Levulan® Kerastick® cost of product revenues and royalties						
Direct Levulan® Kerastick® product costs Other Levulan® Kerastick® production costs including	\$	583,000	\$	547,000	\$	36,000
internal costs assigned to support products, net Royalty and supply fees (1)		50,000 238,000		2,000 197,000		48,000 41,000
Subtotal Levulan® Kerastick® cost of product revenues and royalties	\$	871,000	\$	746,000	\$	125,000
BLU-U® cost of product revenues						
Direct BLU-U <sup>®</sup> product costs Other BLU-U <sup>®</sup> product costs including internal costs assigned to support products; as well as, costs incurred to	\$	212,000	\$	205,000	\$	7,000
ship and install the BLU-U® in physicians offices		143,000		195,000		(52,000)
Subtotal BLU-U® cost of product revenues	\$	355,000	\$	400,000	\$	(45,000)
TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	\$1	,226,000	<b>\$</b> 1	1,146,000	\$	80,000
Non-PDT cost of product revenues and royalties	\$	369,000	\$	316,000	\$	53,000
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$1	,595,000	<b>\$</b> 1	1,462,000	\$	133,000
	NINE MONTHS ENDED SEPTEMBER 3		ER 30, ICREASE/			
		2009		2008		ECREASE)
Levulan® Kerastick® cost of product revenues and royalties						
Direct Levulan® Kerastick® product costs Other Levulan® Kerastick® production costs including	\$1	,686,000	\$1	1,778,000	\$	, , ,
internal costs assigned to support products, net Royalty and supply fees (1)		498,000 726,000		5,000 668,000		493,000 58,000

Subtotal Levulan® Kerastick® cost of product revenues and royalties	\$2,910,000	\$2,451,000	\$ 459,000
BLU-U® cost of product revenues Direct BLU-U® product costs	\$ 712,000	\$ 553,000	\$ 159,000
Other BLU-U <sup>®</sup> product costs including internal costs assigned to support products; as well as, costs incurred to ship and install the BLU-U <sup>®</sup> in physicians offices	605,000	585,000	20,000
Subtotal BLU-U® cost of product revenues	\$1,317,000	\$1,138,000	\$ 179,000
TOTAL PDT DRUG AND DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	\$4,227,000	\$3,589,000	\$ 638,000
Non-PDT cost of product revenues and royalties	\$ 747,000	\$1,361,000	\$(614,000)
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	\$4,974,000	\$4,950,000	\$ 24,000
18	3		

1) Royalty and supply fees reflect amounts paid to our licensor, **PARTEQ** Research and Development Innovations, the licensing arm of Queen s University, Kingston, Ontario, and ongoing royalties paid to Draxis Health, Inc., on sales of the Levulan® Kerastick® in Canada.

*MARGINS* Total product margins for the three- and nine-month periods ended September 30, 2009 were \$5,335,000 and \$16,060,000, respectively, as compared to \$4,264,000 and \$16,818,000 for the comparable 2008 periods, as shown below:

	ТН	REE MONTHS ENDED SI	EPTEMBER 30, INCREASE/
	2009	2008	(DECREASE)
Levulan® Kerastick® gross margin BLU-U® gross margin	\$ 5,373,000 101,000	86% \$ 3,986,000 22% 25,000	84% \$ 1,387,000 6% 76,000
Total PDT drug & device gross margin	\$ 5,474,000	82% \$ 4,011,000	78% \$ 1,463,000
Total Non-PDT gross margin	(139,000)	(60)% 253,000	44% \$ (392,000)
TOTAL GROSS MARGIN	\$ 5,335,000	77% \$ 4,264,000	74% \$ 1,071,000
	N	INE MONTHS ENDED SE	•
	2009	2008	INCREASE/ (DECREASE)
Levulan® Kerastick® gross margin	\$ 15,349,000	84% \$12,717,000	84% \$ 2,632,000

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BLU-U® gross margin	260,000	16%	110,000	9%	150,000
Total PDT drug & device gross margin	\$ 15,609,000	79%	\$ 12,827,000	78%	\$ 2,782,000
Total Non-PDT gross margin	451,000	38%	3,991,000	75%	\$ (3,540,000)
TOTAL GROSS MARGIN	\$ 16,060,000	76%	\$ 16,818,000	77%	\$ (758,000)