DUSA PHARMACEUTICALS INC Form 10-Q November 05, 2010

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

(Mark One)

Description of the securities of the security period ended: September 30, 2010

• 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 b No o Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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	Accelerated filer o	Non-accelerated filer þ	Smaller reporting
filer o		(Do not check if a smaller reporting	company o
		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 b

As of November 4, 2010, the registrant had 24,228,215 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	
 <u>- Condensed Consolidated Balance Sheets at September 30, 2010 and December 31, 2009 (Unaudited)</u> <u>- Condensed Consolidated Statements of Operations for the three- and nine-month periods ended</u> 	3
September 30, 2010 and 2009 (Unaudited)	4
- Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2010 and 2009 (Unaudited)	5
- Notes to the Condensed Consolidated Financial Statements (Unaudited)	6
Troug to the Condensed Consendated I maneral Statements (Chaudhed)	0
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	25
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	26
Item 1A. Risk Factors	26
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	36
Item 3. Defaults Upon Senior Securities	36
Item 4. Removed and reserved	36
Item 5. Other Information	36
Item 6. Exhibits	36
SIGNATURES	37
Exhibit Index	38
EX-31.A: SECTION 302 CERTIFICATION OF THE C.E.O.	00
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-31.A	
<u>EX-31.B</u> <u>EX-32.A</u>	
<u>EX-32.B</u>	
<u>EX-99.1</u>	

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

ASSETS	Se	eptember 30, 2010	D	ecember 31, 2009
CURRENT ASSETS Cash and cash equivalents Marketable securities, at fair value Accounts receivable, net of allowance for doubtful accounts of \$63,000 and	\$	6,184,261 10,796,735	\$	7,613,378 9,055,959
\$86,000 in 2010 and 2009, respectively Inventory Prepaid and other current assets		2,451,709 2,269,605 935,815		2,629,189 2,170,275 1,561,467
TOTAL CURRENT ASSETS Restricted cash Property, plant and equipment, net Deferred charges and other assets		22,638,125 174,587 1,494,630 68,099		23,030,268 174,255 1,660,755 68,099
TOTAL ASSETS	\$	24,375,441	\$	24,933,377
LIABILITIES AND SHAREHOLDERS EQUITY CURRENT LIABILITIES				
Accounts payable Accrued compensation Other accrued expenses	\$	675,870 1,029,035 2,128,985	\$	630,144 1,260,609 2,456,612
Deferred revenues TOTAL CURRENT LIABILITIES		475,034 4,308,924		902,597 5,249,962
Deferred revenues Warrant liability Other liabilities		2,255,650 1,299,869 80,015		2,906,020 812,905 123,016
TOTAL LIABILITIES		7,944,458		9,091,903
COMMITMENTS AND CONTINGENCIES (NOTE 13) SHAREHOLDERS EQUITY Capital Stock Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in Series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding: 24,221,715 and 24,108,908 shares of common stock, no par, at September 30, 2010 and				
December 31, 2009, respectively Additional paid-in capital Accumulated deficit Accumulated other comprehensive income		151,801,550 9,077,912 (144,562,682) 114,203		151,683,399 8,291,805 (144,359,217) 225,487

```
Table of Contents
```

TOTAL SHAREHOLDERS EQUITY TOTAL LIABILITIES AND SHAREHOLDERS EQUITY

16,430,98315,841,474\$ 24,375,441\$ 24,933,377

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

	Three-months ended September 30,			Nine-months ended September 30,			,	
		2010	2009			2010		2009
Product revenues	\$	8,015,546	\$	6,930,110	\$2	25,430,363		,033,920
Cost of product revenues		1,627,782		1,594,692		5,228,075	4	,973,782
GROSS MARGIN Operating costs:		6,387,764		5,335,418	2	20,202,288	16	,060,138
Research and development		1,283,771		963,245		3,643,849	3	,225,049
Marketing and sales		2,792,780		3,013,351		9,544,564	9	,460,766
General and administrative		2,208,898		1,877,928		6,919,128	6	,360,325
Settlements, net								75,000
TOTAL OPERATING COSTS		6,285,449		5,854,524	2	20,107,541	19	,121,140
INCOME (LOSS) FROM OPERATIONS		102,315		(519,106)		94,747	(3	,061,002)
Other income		61,183		79,815		188,752	,	223,801
(Loss) gain on change in fair value of								
warrants		(130,674)		24,051		(486,964)		(37,679)
NET INCOME (LOSS)	\$	32,824	\$	(415,240)	\$	(203,465)	\$ (2	,874,880)
BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE	\$	0.00	\$	(0.02)	\$	(0.01)	\$	(0.12)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING, BASIC	,	24,209,215	2	24,108,908	2	24,173,399	24	,099,786
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING, DILUTED	,	24,658,844	2	24,108,908	2	24,173,399	24	,099,786

See the accompanying Notes to the Condensed Consolidated Financial Statements.

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

	Nine-months ended September 30,	
	2010	2009
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (203,465)	\$ (2,874,880)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Accretion of premiums and discounts on marketable securities	5,236	43,407
Realized loss on sales of marketable securities		43,678
Share-based compensation	920,755	631,770
Depreciation and amortization	295,020	345,720
Loss on change in fair value of warrants	486,964	37,679
Deferred revenues recognized	(1,077,933)	(661,702)
Changes in other assets and liabilities impacting cash flows from operations:		
Accounts receivable	177,480	(151,411)
Inventory	(99,330)	476,658
Prepaid and other current assets	625,652	318,994
Accounts payable, accrued compensation and other accrued expenses	(513,474)	(1,626,748)
Other liabilities	(43,001)	(111,129)
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES CASH FLOWS FROM INVESTING ACTIVITIES	573,904	(3,527,964)
Purchases of marketable securities	(12,742,296)	(12,049,905)
Proceeds from maturities and sales of marketable securities	10,885,000	16,848,159
Restricted cash	(332)	(326)
Purchases of property, plant and equipment	(128,896)	(129,230)
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES CASH FLOWS FROM FINANCING ACTIVITIES	(1,986,524)	4,668,698
Proceeds from exercise of stock options	25,993	
Settlements of restricted stock for tax withholding obligations	(42,490)	(4,413)
NET CASH USED IN FINANCING ACTIVITIES	(16,497)	(4,413)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	(1,429,117) 7,613,378	1,136,321 3,880,673
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 6,184,261	\$ 5,016,994

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, 2010, the Condensed Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2010 and 2009, and the Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2010 and 2009 of DUSA Pharmaceuticals, Inc. (the Company or DUSA) have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). These condensed consolidated financial statements are unaudited but include all normal recurring adjustments, which management of the Company believes to be necessary for fair presentation of the periods presented. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any of the year. Certain information and footnote disclosures normally included in 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, 2009 filed with the Securities and Exchange Commission. The balance sheet as of December 31, 2009 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

2) NEW ACCOUNTING PRONOUNCEMENTS

Accounting Standards Recently Adopted

In April 2010, the FASB issued ASU 2010-17, *Revenue Recognition Milestone Method (Topic 605): Milestone Method of Revenue Recognition* (ASU 2010-17). ASU 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and non-substantive milestones, and each milestone should be evaluated individually to determine if it is substantive. ASU 2010-17 became effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after September 15, 2010, with early adoption permitted. The Company adopted this guidance as of July 1, 2010. The adoption of ASU 2010-17 did not have a material impact on the Company.

Accounting Standards To Be Adopted

In October 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-13, Multiple-Deliverable Revenue Arrangements (ASU No. 2009-13). ASU No. 2009-13, which amends existing revenue recognition accounting pronouncements, 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. Previous accounting principles 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. 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 prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after September 15, 2010, which for the Company means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 will require the Company to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. The potential impact of this standard is being evaluated.

3) FINANCIAL INSTRUMENTS

Fair Value Measurements

equities.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, financial instruments are categorized based on a hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below: Level 1: Quoted market prices in active markets for identical assets or liabilities. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed

Level 2: Observable market based inputs for similar assets or unobservable inputs that are corroborated by market data. Level 2 consists of financial instruments that are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency in the determination of value. The Company accesses publicly available market activity from third-party databases and credit ratings of the issuers of the securities it holds to corroborate the data used in the fair value calculations obtained from its primary pricing source. The Company also takes into account credit rating changes, if any, of the securities or recent marketplace activity. Level 3: Unobservable inputs that are not corroborated by market data. Level 3 is comprised of financial instruments whose fair value is estimated based on internally developed models or methodologies utilizing significant inputs that are generally less readily observable. We initially recorded the warrant liability at its fair value using the Black-Scholes option-pricing model and revalue it at each reporting date until the warrants are exercised or expire. The fair value of the warrants is subject to significant fluctuation based on changes in our stock price, expected volatility, remaining contractual life and the risk-free interest rate.

The following table presents the Company s financial instruments recorded at fair value in the Consolidated Balance Sheet, classified according to the three categories described above:

Fair Value Measurements at September 30,

		2010			
	Carrying				
	Value	(Level 1)	(Level 2)	(Level 3)	
Assets					
Cash and cash equivalents	\$ 6,184,000	\$ 6,184,000	\$	\$	
United States government-backed securities	10,010,000		10,010,000		
Corporate debt securities	787,000		787,000		
Total assets at fair value	16,981,000	6,184,000	10,797,000		
Liabilities					
Warrant liability	1,300,000			1,300,000	
Total liabilities at fair value	\$ 1,300,000	\$	\$	\$ 1,300,000	

		Fair Value M	ecember 31,	
	Carrying			
	Value	(Level 1)	(Level 2)	(Level 3)
Assets				
Cash and cash equivalents	\$ 7,613,000	\$ 7,613,000	\$	\$
United States government-backed securities	8,150,000		8,150,000	
Corporate debt securities	906,000		906,000	
Total assets at fair value	16,669,000	7,613,000	9,056,000	
Liabilities				
Warrant liability	813,000			813,000
Total liabilities at fair value	\$ 813,000	\$	\$	\$ 813,000

The Company reviewed the level classifications of its investments at September 30, 2010 compared to December 31, 2009 and determined that there were no significant transfers between levels in the nine-month period ended September 30, 2010.

The table below includes a rollforward of the balance sheet amounts for the nine-month periods ended September 30, 2010 and 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.

			Purchases,			Change in Unrealized Gains Related to Financial
	Fair Value		Sales,	Transfers In		Instruments
	at	Total	Issuances,	and/or	Fair Value at	Held at September
	January 1,	Unrealized	Settlements,	Out of Level	September 30,	30
	2010	Loss	net	3	2010	2010
Warrant Liability	\$813,000	\$487,000	\$	\$	\$1,300,000	\$(487,000)

Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Nine-month Period Ended September 30, 2010

Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Nine-month Period Ended September 30, 2009

	Foir Volue		Purchases,	Tuonsform	Foir Volue	Change in Unrealized Gains Related to Financial
	Fair Value		Sales,	Transfers	Fair Value	Instruments
				In		
	at	Total	Issuances,	and/or	at	Held at
			,		September	September
	January 1,	Unrealized	Settlements,	Out of	30,	30,
	2009	Loss	net	Level 3	2009	2009
Warmant Lightlitz.						
Warrant Liability	\$436,000	\$38,000	\$	\$	\$474,000	\$(38,000)

Marketable Securities

The Company s marketable securities consist of the following:

	September 30, 2010					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value		
United States government-backed securities Corporate debt securities	\$ 9,955,000 728,000	\$ 55,000 59,000	\$	\$ 10,010,000 787,000		
Total marketable securities	\$10,683,000	\$ 114,000	\$	\$10,797,000		

December 31, 2009 Gross Gross

	Amortized	Unrealized	Unrealized	Fair
	Cost	Gains	Losses	Value
United States government-backed securities	\$ 8,005,000	\$ 145,000	\$	\$ 8,150,000
Corporate debt securities	826,000	80,000		906,000
Total marketable securities	\$ 8,831,000	\$ 225,000	\$	\$9,056,000

The Company amortizes or accretes the premiums and discounts paid for the securities into interest income over the period to maturity of the securities. The decrease in net unrealized gains on such securities for the nine-month periods ended September 30, 2010 and 2009 was \$111,000 and \$105,000, respectively, which has been recorded in accumulated other comprehensive income and is reported as part of shareholders equity in the Condensed Consolidated Balance Sheets. Realized losses on sales of marketable securities were \$0 and \$44,000 for the nine-month periods ended September 30, 2010 and 2009, respectively. As of September 30, 2010, current yields range from 0.1% to 6.1% and maturity dates range from January 2011 to December 2013.

Common Stock Warrants

Warrants that are classified as a liability are revalued at each reporting date until the warrants are exercised or expire with changes in the fair value reported in the Company s Condensed Consolidated Statements of Operations as gain or loss on fair value of warrants. Non-cash (losses) gains for the three and nine-month periods ended September 30, 2010 were \$(131,000) and \$(487,000), respectively, compared with \$24,000 and \$(38,000), respectively, for the comparable 2009 periods. At September 30,

2010 and December 31, 2009, the aggregate fair value of these warrants was \$1,300,000 and \$813,000, respectively. Assumptions used for the Black-Scholes option-pricing models in determining the fair value as of September 30, 2010 and December 31, 2009 are as follows:

	September 30,	December 31,	
	2010	2009	
Expected volatility	83.6%	88.0%	
Remaining contractual term (years)	2.6	3.3	
Risk-free interest rate	0.53%	1.9%	
Expected dividend yield	0%	0%	
Common stock price	\$ 2.45	\$ 1.60	
4) 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. 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 months ended September 30, 2010 and 2009, and accounts receivable as of September 30, 2010 and December 31, 2009 are as follows:

	% of I	Revenue	% of F	Revenue		
					,	accounts
	Three months ended		Nine months ended		Receivable	
	September	September	September	September	September	December
	30,	30,	30,	30,	30,	31,
	2010	2009	2010	2009	2010	2009
Customer A	3%	3%	3%	3%	5%	3%
Customer B	2%	3%	2%	3%	5%	5%
Customer C	2%	2%	2%	3%	3%	4%
Other customers	93%	92%	93%	91%	87%	88%
Total	100%	100%	100%	100%	100%	100%

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

5) INVENTORY

Inventory consisted of the following:

	September 30, 2010	Dee	cember 31, 2009
Finished goods	\$ 1,157,000	\$	974,000
BLU-U [®] evaluation units	121,000		58,000
Work in process	345,000		398,000

Raw materials	647,000	740,000
Total	\$ 2,270,000	\$ 2,170,000

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

6) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following:

