ZIOPHARM ONCOLOGY INC
Form 10-Q
November 04, 2010

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(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, 2010

OR

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

Commission File Number 001-33038

ZIOPHARM Oncology, Inc.
(Exact name of registrant as specified in its charter)

Delaware	84-1475642
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1180 Avenue of the Americas, 19th Floor, New York, NY 10036
(646) 214-0700
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: þ No: ¨

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes: ¨ No: ¨

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

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

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

The number of shares of the registrant's Common Stock, $.001 par value, outstanding as of November 1, 2010, was 48,557,678 shares.

ZIOPHARM Oncology, Inc. (a development stage company)

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Part I - Financial Information

Item 1. Consolidated Financial Statements

ZIOPHARM Oncology, Inc. (a development stage company)

BALANCE SHEETS
(unaudited)

(in thousands, except share and per share data)

	September 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,471	$ 48,839
Prepaid expenses and other current assets	352	354
Total current assets	66,823	49,193
Property and equipment, net	230	255
Deposits	87	46
Other non-current assets	310	242
Total assets	$ 67,450	$ 49,736
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,088	$ 1,789
Accrued expenses	2,978	1,261
Deferred rent - current portion	40	45
Total current liabilities	4,106	3,095
Deferred rent	55	66
Warrant liabilities	21,085	18,471
Total liabilities	25,246	21,632
Commitments and contingencies (note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 30,000,000 shares authorized and no shares issued and outstanding	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized; 48,557,678 and 41,583,528 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	49	42
Additional paid-in capital - common stock	131,284	96,133
Additional paid-in capital - warrants issued	22,834	23,073
Deficit accumulated during the development stage	(111,963)	(91,144)
Total stockholders' equity	42,204	28,104

Total liabilities and stockholders' equity	$	67,450	$	49,736

The accompanying notes are an integral part of the unaudited interim financial statements.

ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF OPERATIONS
(unaudited)

(in thousands, except share and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,		Period from September 9, 2003 (date of inception) through
	2010	2009	2010	2009	September 30, 2010
Research contract revenue	$ -	$ -	$ -	$ -	$ -
Operating expenses:					
Research and development, including costs of research contracts	5,711	1,231	9,872	3,340	68,778
General and administrative	2,789	1,339	8,313	4,754	50,488
Total operating expenses	8,500	2,570	18,185	8,094	119,266
Loss from operations	(8,500)	(2,570)	(18,185)	(8,094)	(119,266)
Other income, net	7	(1)	29	1	3,939
Change in fair value of warrants	(3,712)	(304)	(2,663)	(520)	3,364
Net loss	$ (12,205)	$ (2,875)	$ (20,819)	$ (8,613)	$ (111,963)
Net loss per share - basic	$ (0.26)	$ (0.13)	$ (0.48)	$ (0.40)	
Net loss per share - diluted	$ (0.26)	$ (0.13)	$ (0.48)	$ (0.40)	
Weighted average common shares outstanding used to compute net loss per share - basic	47,426,991	21,759,309	43,333,663	21,458,150	
Weighted average common shares outstanding used to compute net loss per share - diluted	47,426,991	21,759,309	43,333,663	21,458,150	

The accompanying notes are an integral part of the unaudited interim financial statements.

ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
For the Nine Months Ended September 30, 2010
(unaudited)

(in thousands, except share and per share data)

	Stockholders' Equity							
	Preferred Stock		Common Stock		Additional Paid-in Capital Common Stock	Additional Paid-in Capital Warrants	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2009	-	$ -	41,583,528	$ 42	$ 96,133	$ 23,073	$ (91,144)	$ 28,104
Stock-based compensation	-	-	-	-	3,198	-	-	3,198
Exercise of employee stock options	-	-	196,167	-	225	-	-	225
Exercise of warrants to purchase common stock	-	-	39,225	-	360	(239)	-	121
Issuance of restricted common stock	-	-	115,000	-	-	-	-	-
Repurchase of shares of common stock	-	-	(364,992)	-	(1,429)	-	-	(1,429)
Forfeiture of unvested restricted common stock	-	-	(11,250)	-	-	-	-	-
Issuance of common stock in a securities offering, net of commissions and expenses of $2,203	-	-	7,000,000	7	32,797	-	-	32,804
Net loss	-	-	-	-	-	-	(20,819)	(20,819)
Balance at September 30, 2010	-	$ -	48,557,678	$ 49	$ 131,284	$ 22,834	$ (111,963)	$ 42,204

The accompanying notes are an integral part of the unaudited interim financial statements.

ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)

	For the Nine Months Ended September 30,		Period from September 9, 2003 (date of inception) through
	2010	2009	September 30, 2010
Cash flows from operating activities:			
Net loss	$ (20,819)	$ (8,613)	$ (111,963)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	153	252	1,614
Stock-based compensation	3,198	1,264	12,103
Change in fair value of warrants	2,663	520	(3,365)
Loss on disposal of fixed assets	-	-	9
Change in operating assets and liabilities:			
(Increase) decrease in:			
Prepaid expenses and other current assets	3	(43)	(352)
Other noncurrent assets	(67)	49	(310)
Deposits	(41)	-	(87)
Increase (decrease) in:			
Accounts payable	(703)	(1,080)	1,088
Accrued expenses	1,717	(1,228)	2,978
Deferred rent	(15)	(22)	95
Net cash used in operating activities	(13,911)	(8,901)	(98,190)
Cash flows from investing activities:			
Purchases of property and equipment	(128)	(3)	(1,853)
Proceeds from sale of property and equipment	-	-	1
Net cash used in investing activities	(128)	(3)	(1,852)
Cash flows from financing activities:			
Stockholders' capital contribution	-	-	500
Proceeds from exercise of stock options	225	-	364
Payments to employees for repurchase of common stock	(1,429)	-	(1,809)
Proceeds from exercise of warrants	71	-	349
Proceeds from issuance of common stock and warrants, net	32,804	4,605	150,349
Proceeds from issuance of preferred stock, net	-	-	16,760
Net cash provided by financing activities	31,671	4,605	166,513
Net increase (decrease) in cash and cash equivalents	17,632	(4,299)	66,471
Cash and cash equivalents, beginning of period	48,839	11,379	-
Cash and cash equivalents, end of period	$ 66,471	$ 7,080	$ 66,471
Supplementary disclosure of cash flow information:			
Cash paid for interest	$ -	$ -	$ -

Cash paid for income taxes	$ -	$ -	$ -
Supplementary disclosure of noncash investing and financing activities:			
Warrants issued to placement agents and investors	$ -	$ 4,207	$ 47,276
Preferred stock conversion to common stock	$ -	$ -	$ 16,760
Exercise of equity-classified warrants to common shares	$ 239	$ -	$ 257
Exercise of liability-classified warrants to common shares	$ 49	$ -	$ 49

The accompanying notes are an integral part of the unaudited interim financial statements.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS
(unaudited)

1. Nature of the Business and Basis of Presentation

ZIOPHARM Oncology, Inc. ("ZIOPHARM" or the "Company") is a biopharmaceutical company that seeks to acquire, develop and commercialize, on its own or with other commercial partners, products for the treatment of important unmet medical needs in cancer.

The Company has had limited operations to date and its activities have consisted primarily of raising capital and conducting research and development. Accordingly, the Company is considered to be in the development stage at September 30, 2010. The Company's fiscal year ends on December 31.

The Company has operated at a loss since its inception in 2003 and has no revenues. The Company anticipates that losses will continue for the foreseeable future. At September 30, 2010, the Company's accumulated deficit was approximately $112.0 million. The Company currently believes that it has sufficient capital to fund development and commercialization activities, principally for palifosfamide, well into mid-2012. The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing and achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be realized by the Company, or if realized, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company's working capital requirements until it achieves profitable operations. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate additional funds are not available when required, or if unsuccessful in entering into partnership agreements for the further development of its products, the Company will be required to delay, reduce or eliminate planned preclinical and clinical trials and terminate the approval process for its product candidates from the U.S. Food and Drug Administration ("FDA") or other regulatory authorities. In addition, the Company could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities, pursue merger or divestiture strategies, cease operations or declare bankruptcy. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The accompanying unaudited interim financial statements have been prepared in accordance with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and note disclosures required by generally accepted accounting principles ("GAAP") in the United States of America have been condensed or omitted pursuant to such rules and regulations.

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent liabilities at the dates of the financial statements. Actual amounts may differ from these estimates.

It is management's opinion that the accompanying unaudited interim financial statements reflect all adjustments (which are normal and recurring) that are necessary for a fair statement of the results for the interim periods. The

unaudited interim financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2009 included in the Company's Form 10-K for such fiscal year.

The year-end balance sheet data was derived from the audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America.

The results disclosed in the Statements of Operations for the three and nine months ended September 30, 2010 are not necessarily indicative of the results to be expected for the full fiscal year.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

2. Summary of Significant Accounting Policies

Our significant accounting policies were identified in the Company's Form 10-K for the fiscal year ended December 31, 2009.

3. Fair Value Measurements

The Company follows FASB Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurements. The accounting standard defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

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

- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value on a recurring basis as of September 30, 2010 are as follows:

($ in thousands)	Fair Value Measurements at Reporting Date Using			
Description	Balance as of September 30, 2010	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liability	$ 21,085	$ -	$ 21,085	$ -

The warrants were valued using a Black-Scholes valuation model. See Note 7 for additional disclosures on the valuation methodology and significant assumptions.

In January 2010, the FASB issued Accounting Standards Update ("ASU") No. 2010-06 Fair Value Measurements and Disclosures (Topic 820) which improves disclosures about fair value measurements. More specifically, ASU 2010-06 updates subtopic 820-10 to require disclosure of transfers in and out of levels 1 and 2 and the reason for the transfers. Additionally, it requires separate reporting of purchases, sales, issuances and settlements for level 3. This update is effective for interim periods beginning after December 15, 2009 except for the level 3 rollforward disclosure

which is effective for periods beginning after December 15, 2010. The adoption of this standard did not have an impact on our financial position, results of operations or financial statement disclosure nor do we anticipate any impact upon the adoption of the Level 3 rollforward disclosure in 2011.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

4. Subsequent Events

The Company evaluated all events or transactions that occurred after the balance sheet date through the date these financial statements were available to be issued. During this period the Company did not have any material recognizable subsequent events and one disclosable event.

On October 5, 2010, a milestone was reached under the Company's license agreement with DEKK-Tec, Inc. requiring a $300 thousand payment and vesting of options to purchase 6,904 shares of the Company's common stock that are exercisable at $0.02 per share.

On November 1, 2010, the Company was notified that it was awarded cash grants totaling approximately $733 thousand under the U.S. Government's Qualifying Therapeutic Discovery Project ("QTDP") program.

5. Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period. Diluted loss per share is computed using the weighted-average number of common shares outstanding during the period, plus the dilutive effect of outstanding options and warrants, using the treasury stock method and the average market price of our common stock during the applicable period.

Certain shares related to some of the Company's outstanding common stock options, unvested restricted stock and warrants, have not been included in the computation of diluted net loss per share for the three and nine months ended September 30, 2010 and 2009 as the result would be antidilutive. Such potential common shares at September 30, 2010 and 2009 consist of the following:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2010	2009	2010	2009
Stock options	3,528,852	3,151,249	3,528,852	3,151,249
Unvested restricted common stock	518,334	1,491,667	518,334	1,491,667
Warrants	15,924,642	7,950,613	15,924,642	7,950,613

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies

Patent and Technology License Agreement—The University of Texas M. D. Anderson Cancer Center and the Texas A&M University System.

On August 24, 2004, the Company entered into a patent and technology license agreement with The Board of Regents of the University of Texas System, acting on behalf of The University of Texas M. D. Anderson Cancer Center and the Texas A&M University System (collectively, the "Licensors"). Under this agreement, the Company was granted an exclusive, worldwide license to rights (including rights to U.S. and foreign patent and patent applications and related improvements and know-how) for the manufacture and commercialization of two classes of organic arsenicals (water- and lipid-based) for human and animal use. The class of water-based organic arsenicals includes darinaparsin.

As partial consideration for the license rights obtained, the Company made an upfront payment in 2004 of $125 thousand and granted the Licensors 250,487 shares of the Company's common stock. In addition, the Company issued options to purchase an additional 50,222 shares outside the 2003 Stock Option Plan for $0.002 per share following the successful completion of certain clinical milestones, which vested with respect to 12,555 shares upon the filing of an Investigation New Drug application ("IND") for darinaparsin in 2005 and vested with respect to another 25,111 shares upon the completion of dosing of the last patient for both Phase I clinical trials in 2007. The Company recorded $120 thousand of stock based compensation expense related to the vesting in 2007. The remaining 12,556 shares will vest upon enrollment of the first patient in a multi-center pivotal clinical trial i.e. a human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of an approvable New Drug Application ("NDA"). In addition, the Licensors are entitled to receive certain milestone payments, including $100 thousand that was paid in 2005 upon the commencement of Phase I clinical trial and $250 thousand that was paid in 2006 upon the dosing of the first patient in the Registrant-sponsored Phase II clinical trial for darinaparsin. The Company may be required to make additional payments upon achievement of certain other milestones in varying amounts which on a cumulative basis could total up to an additional $4.5 million. In addition, the Licensors are entitled to receive single digit percentage royalty payments on sales from a licensed product and will also be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. In addition, the Company also paid the Licensors $100 thousand in 2006 and 2007 to conduct scientific research with the Company obtaining exclusive right to all resulting intellectual property rights. The sponsored research agreements governing this research and any related extensions expired in February 2008 with no payments being made subsequent to that date.

The license agreement also contains other provisions customary and common in similar agreements within the industry, such as the right to sublicense the Company rights under the agreement. However, if the Company sublicenses its rights prior to the commencement of a pivotal study i.e. a human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of an approvable NDA, the Licensors will be entitled to receive a share of the payments received by the Company in exchange for the sublicense (subject to certain exceptions). The term of the license agreement extends until the expiration of all claims under patents and patent applications associated with the licensed technology, subject to earlier termination in the event of defaults by the Company or the Licensors under the license agreement, or if the Company becomes bankrupt or insolvent. No milestones under the license agreement were reached or expensed during the nine months ended September 30, 2010.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies – (continued)

License Agreement with DEKK-Tec, Inc.

On October 15, 2004, the Company entered into a license agreement with DEKK-Tec, Inc., pursuant to which it was granted an exclusive, worldwide license for palifosfamide. As part of the signing of license agreement with DEKK-Tec, the Company expensed an upfront $50 thousand payment to DEKK-Tec in 2004.

In consideration for the license rights, DEKK-Tec is entitled to receive payments upon achieving certain milestones in varying amounts which on a cumulative basis may total $4.0 million. Of the aggregate milestone payments, most will be creditable against future royalty payments as referenced below. The Company expensed a $100 thousand milestone payment upon achieving Phase II milestones during the year ended December 31, 2006. Additionally, in 2004 the Company issued DEKK-Tec an option to purchase 27,616 shares of the Company's common stock for $0.02 per share. Upon the execution of the license agreement, 6,904 shares vested and were subsequently exercised in 2005 and the remaining options will vest upon certain milestone events, culminating with final FDA approval of the first NDA submitted by the Company (or by its sublicensee) for palifosfamide. None of the remaining options have vested as of September 30, 2010. DEKK-Tec is entitled to receive single digit percentage royalty payments on the sales of palifosfamide should it be approved for commercial sale. On March 16, 2010, the Company expensed a $100 thousand milestone payment upon receiving a United States Patent for palifosfamide. There were no payments made during the first nine months of 2009. The Company's obligation to pay royalties will terminate on a country-by-country basis upon the expiration of all valid claims of patents in such country covering licensed product, subject to earlier termination in the event of defaults by the parties under the license agreement.

Option Agreement with Southern Research Institute ("SRI")

On December 22, 2004, the Company entered into an Option Agreement with SRI (the "Option Agreement"), pursuant to which the Company was granted an exclusive option to obtain an exclusive license to SRI's interest in certain intellectual property, including exclusive rights related to certain isophosphoramide mustard analogs.

Also on December 22, 2004, the Company entered into a Research Agreement with SRI pursuant to which the Company agreed to spend a sum not to exceed $200 thousand between the execution of the agreement and December 21, 2006, including a $25 thousand payment that was made simultaneously with the execution of the agreement, to fund research and development work by SRI in the field of isophosphoramide mustard analogs. The Option Agreement was exercised on February 13, 2007. Under the license agreement entered into upon exercise of the option, the Company is required to remit minimum annual royalty payments of $25 thousand until the first commercial sale of a licensed product. These payments were made in the years ended December 31, 2008 and 2007 and the 2009 royalty payment was made during the first three months of 2010. The Company may be required to make payments upon achievement of certain milestones in varying amounts which on a cumulative basis could total up to $775,000. In addition, SRI will be entitled to receive single digit percentage royalty payments on the sales of a licensed product in any country until all licensed patents rights in that country which are utilized in the product have expired. No milestones under the license agreement were reached or expensed during the nine months ended September 30, 2010.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies – (continued)

License Agreement with Baxter Healthcare Corporation (“Baxter”)

On November 3, 2006, the Company entered into a definitive Asset Purchase Agreement for indibulin and a License Agreement to proprietary nanosuspension technology with affiliates of Baxter Healthcare S.A. The purchase included the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories. The terms of the Asset Purchase Agreement included an upfront cash payment of approximately $1.1 million and an additional $100 thousand payment for existing inventory, both of which were expensed in 2006. In addition to the upfront costs, the Asset Purchase Agreement includes additional diligence and milestone payments that could amount to approximately $8 million in the aggregate and royalties on net sales of products covered by a valid claim of a patent for the life of the patent on a country-by-country basis. The Company expensed a $625 thousand milestone payment upon the successful U.S. IND application for indibulin in 2007. The License Agreement requires payment of a $15 thousand annual patent and license prosecution/maintenance fee through the expiration of the last of the Licensed Patents which is expected to expire in 2025, and single digit royalties on net sales of licensed products covered by a valid claim of a patent for the life of the patent on a country-by-country basis. The term of the license agreement extends until the expiration of the last to expire of the patents covering the licensed products, subject to earlier termination in the event of defaults by the parties under the license agreement.

In October 2009, the Baxter License Agreement was amended to allow the Company to manufacturer indibulin. No milestones under the license agreement were reached or expensed during the nine months ended September 30, 2010.

Collaboration Agreement with Harmon Hill, LLC

On April 8, 2008, the Company signed a collaboration agreement for Harmon Hill, LLC (“Harmon Hill”) to provide consulting and other services for the development and commercialization of oncology therapeutics by ZIOPHARM. Under the agreement the Company has agreed to pay Harmon Hill $20 thousand per month for the consulting services and has further agreed to pay Harmon Hill (a) $500 thousand upon the first patient dosing of the Specified Drug in a pivotal trial, which trial uses a dosing Regime introduced by Harmon Hill; and (b) provided that the Specified Drug receives regulatory approval from the FDA, the EMEA or another regulatory agency for the marketing of the Specified Drug, a 1% royalty of the Company’s net sales will be awarded to Harmon Hill. If the Specified Drug is sublicensed to a third party, the agreement entitles Harmon Hill to 1% award of royalties or other payments received from a sublicense. Subject to renewal or extension by the parties, the term of the agreement was for a one year period that expired April 7, 2009. Although the Company and Harmon Hill have not entered into a formal written renewal or extension, the parties continued to operate under the terms of the agreement at September 30, 2010. The Company expensed $180 thousand during the first nine months of 2009 and 2010 for consulting services per the aforementioned agreement. No milestones under the collaboration agreement were reached or expensed during the nine months ended September 30, 2010.

CRO Services Agreement with PPD Development, L. P.

The Company and PPD Development, L. P. ("PPD") are parties to a master clinical research organization services agreement dated January 29, 2010 and a related work order dated June 25, 2010 under which PPD provides clinical research organization ("CRO") services in support of the Company's clinical trials. PPD is entitled to cumulative payments of up to $21.5 million under these arrangements, which is payable by the Company in varying

amounts upon PPD achieving specified milestones. During the nine months ended September 30, 2010, the Company expensed $1.8 million upon contract execution and $1.1 million upon a clinical study commencement of enrollment in North America.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

7. Warrants

The Company has issued both warrants that are accounted for as liabilities and warrants that are accounted for as equity instruments. The number of warrants at September 30, 2010 and December 31, 2009 were as follows:

	September 30, 2010	December 31, 2009
Liability-classified warrants	8,590,456	8,615,223
Equity-classified warrants	7,334,186	7,404,924
Total warrants	15,924,642	16,020,147

Liability-Classified Warrants

In May 2005, the Company issued 419,786 warrants to placement agents for services performed in connection with a securities offering conducted by the Company, 11,083 of which were subsequently exercised. The remaining 408,703 warrants were originally valued at $1.6 million. Subject to certain exceptions, these warrants provide for anti-dilution protection should common stock or common stock equivalents be subsequently issued at a price per share less than the exercise price of the warrants then in effect, which was initially $4.75 per share. This protection was triggered in 2006 when the Company sold stock in a securities offering at $4.63 per share. Accordingly, the warrants were re-priced at $4.69. The protection was triggered a second time upon the September 2009 consummation of a securities offering in which the Company sold stock at $1.825 per share and the warrants were subsequently re-priced at $4.25. The protection was triggered again with the Company's December 2009 securities offering when the Company sold stock at $3.10 per share and the warrants were subsequently re-priced at $3.93.

Also, in connection with the December 2009 public offering, the Company issued warrants to purchase an aggregate of 8,206,520 shares of common stock (including 7,742,000 warrants issued to investors in the offering and 464,520 warrants issued to the Underwriters). The investor warrants were exercisable immediately and the underwriter warrants were exercisable six months after the date of issuance. The warrants have an exercise price of $4.02 per share and have a five year term. Subject to certain exceptions, these warrants provide for anti-dilution protection should common stock or common stock equivalents be subsequently issued at a price less than the exercise price of the warrants then in effect.

Accounting standards require an entity to assess whether an equity-issued financial instrument is indexed to an entity's own stock for purposes of determining whether a financial instrument should be treated as a derivative. Accounting standards further require that liability-classified warrants be revalued at each financial reporting period and the resulting gain or loss be recorded as other income (expense) in the Statements of Operations. Fair value is measured using the Black-Scholes valuation model.

The Company assessed whether the warrants issued in connection with the May 2005 and December 2009 securities offerings require accounting as derivatives and, based on the anti-dilution protection provided to the warrantholders, determined that the warrants were not indexed to the Company's own stock in accordance with accounting standards

codification Topic 815, Derivatives and Hedging. As such, the Company has concluded the warrants did not meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in liabilities.

The change in the fair value of the warrant liability was a loss of $3.7 million and $2.7 million for the three and nine months ended September 30, 2010 and a loss of $304 thousand and $520 thousand for the three and nine months ended September 30, 2009, respectively, and was charged to other income (expense) in the Statements of Operations. The following assumptions were used in the Black-Scholes valuation model at September 30, 2010 and December 31, 2009:

	September 30, 2010	December 31, 2009
Risk-free interest rate	0.37 - 1.01%	1.37 - 2.65%
Expected life in years	1.67 - 4.18	2.42 - 4.92
Expected volatility	94.9 - 101.5%	105%
Expected dividend yield	0	0

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

7. Warrants – (continued)

During the first nine months of 2010, warrant exercises were as follows:

in thousands, except share data	Equity Warrants	Liability Warrants	Common Stock Issued	Cash Received
Cash exercises	3,292	16,000	19,292	$ 72
Cashless exercises	67,446	8,767	19,933	-
	70,738	24,767	39,225	$ 72

There were no warrant exercises in the first nine months of 2009.

8. Common Stock

On May 27, 2010, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Jefferies & Company, Inc. (the "Representative") relating to the issuance and sale of 7,000,000 shares of the Company's common stock, par value $0.001 per share. The Representative, on behalf of itself and JMP Securities LLC, as underwriters for the offering, purchased 7,000,000 shares from the Company pursuant to the Underwriting Agreement and offered the shares to the public at a price of $5.00, and to certain dealers at that price less a concession not in excess of $0.18 per share of common stock. The net proceeds to the Company from this offering were $32.8 million, after deducting underwriting discounts, commissions and other offering expenses of $2.2 million. The offering was completed on June 2, 2010. Under the terms of the Underwriting Agreement, the Company granted the Representative an option, exercisable for 30 days, to purchase up to an additional 1,050,000 shares of common stock to cover over-allotments, if any. The overallotment expired on July 2, 2010, without being exercised.

9. Stock-Based Compensation

The Company recognized stock-based compensation expense on all employee and non-employee awards as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
(in thousands)	2010	2009	2010	2009
Research and development, including costs of research contracts	$ 199	$ 140	$ 613	$ 295
General and administrative	824	375	2,585	969
Stock-based employee compensation expense	$ 1,023	$ 515	$ 3,198	$ 1,264

The Company granted 42 thousand and 197 thousand stock options during the three and nine months ended September 30, 2010 that had a weighted-average grant date fair value of $2.66 and $3.42 per share, respectively. During the nine months ended September 30, 2009, the Company granted 815 thousand stock options that had a weighted-average grant date fair value of $0.53 per share. There were no stock options granted during the three month period ended September 30, 2009.

At September 30, 2010, there is $2.5 million stock compensation expense related to outstanding unvested stock options and restricted stock that will be expensed over a weighted average 23 months.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

9. Stock-Based Compensation – (continued)

For the nine months ended September 30, 2010 and 2009, the fair value of stock options was estimated on the date of grant using a Black-Scholes option valuation model with the following assumptions:

	For the nine months ended September 30,	
	2010	2009
Risk-free interest rate	1.28-2.75%	1.31-1.44%
Expected life in years	5	5
Expected volatility	89.2-90.6%	102-103%
Expected dividend yield	0	0

Stock option transactions under the Company's stock option plan for the nine months ended September 30, 2010 are as follows:

(in thousands, except share and per share data)	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2009	3,534,686	$ 2.82		
Granted	197,000	4.86		
Exercised	196,167	1.19		
Cancelled	6,667	5.19		
Outstanding, September 30, 2010	3,528,852	$ 3.02	6.88	$ 4,249,255
Options exercisable, September 30, 2010	2,568,019	$ 3.00	6.12	$ 3,375,200
Options available for future grant	3,074,734			

A summary of the status of non-vested restricted stock for the nine months ended September 30, 2010 is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2009	1,467,167	$ 2.30
Granted	115,000	$ 5.15
Vested	1,052,583	$ 2.11
Cancelled	11,250	$ 4.34
Non-vested, September 30, 2010	518,334	$ 3.29

On June 23, 2010, the date of the Company's annual stockholders meeting, the Company's stockholders approved an amendment to the 2003 Stock Option Plan increasing the total shares reserved by 3,000,000 shares for a total of 9,002,436.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward Looking Statements

This quarterly report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In particular, statements contained in this Form 10-Q, including but not limited to, statements regarding our future results of operations and financial position, business strategy and plan prospects, projected revenue or costs and objectives of management for future research, development or operations, are forward-looking statements. These statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as "may," "will," "should," "expects," "plans," "anticipates," "intends," "targets," "projects," "contemplates," "believes," "seeks," "goals," "estimates," "p and "continue" or similar words. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 1A. "Risk Factors" and elsewhere herein. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

Business Overview

ZIOPHARM Oncology, Inc. is a biopharmaceutical company that is seeking to develop and commercialize a diverse, risk-sensitive portfolio of in-licensed cancer drugs that can address unmet medical needs through enhanced efficacy and/or safety and quality of life. Our principal focus is on the licensing and development of proprietary small molecule drug candidates that are related to cancer therapeutics already on the market or in development and that can be administered by intravenous and/or oral dosing. We believe this strategy will result in lower risk and expedited drug development programs with product candidates having a low cost of manufacturing to address changing reimbursement requirements around the world. While we may endeavor to commercialize our products on our own in North America, we recognize that favorable clinical trial results can be better addressed by partnering with companies with the requisite financial resources. With partnering, we could also negotiate the right to complete development and marketing in certain geographies, especially for certain limited (niche) indications. Although we are currently in Phase I, II and/or III studies for three product candidates identified as darinaparsin (ZinaparTM, ZIO-101), palifosfamide (ZymafosTM, ZIO-201), and indibulin (ZybulinTM, ZIO-301), our primary focus has been and remains on palifosfamide development and specifically on completing the recently initiated palifosfamide pivotal Phase III trial to support registration in combination with doxorubicin in the front -line setting of soft tissue sarcoma.

- ZIO-101 or darinaparsin (ZinaparTM) is an anti-mitochondrial (organic arsenic) compound covered by issued patents and pending patent applications in the U.S. and in foreign countries. A form of commercially available inorganic arsenic (arsenic trioxide [Trisenox ®] or "ATO") has been approved in the United States, the European Union and Japan for the treatment of acute promyelocytic leukemia, a precancerous condition. In the United States, ATO is on the compendia listing for the therapy of multiple myeloma, and has been studied for the treatment of various other cancers. Nevertheless, ATO has been shown to be toxic to the heart, liver, and brain, which limits its use as an anti-cancer agent. ATO carries a "black box" warning for ECG abnormalities since arsenic trioxide has been shown to cause QT interval prolongation and complete atrioventricular block. QT prolongation can lead to a torsade de pointes-type ventricular arrhythmia, which can be fatal. Inorganic arsenic has also been shown to cause cancer of the skin and lung in humans. The toxicity of arsenic is generally correlated to its accumulation in organs and tissues. Our preclinical and clinical studies to date have demonstrated that darinaparsin is considerably less toxic than ATO, particularly with regard to cardiac toxicity. In vitro testing of darinaparsin using the National Cancer Institute's human cancer cell panel demonstrated activity against a series of tumor cell lines including lung, colon, brain, melanoma, ovarian, and kidney cancer. Moderate activity was shown against breast and prostate cancer tumor cell lines. In addition to solid tumors, in vitro testing in both the National Cancer Institute's cancer cell panel and in vivo

testing in a leukemia animal model demonstrated substantial activity against hematological cancers (cancers of the blood and blood-forming tissues) such as leukemia, lymphoma, myelodysplastic syndromes, and multiple myeloma. Results indicate significant activity against the HuT 78 cutaneous T-cell lymphoma, the NK-G2MI natural killer-cell NHL, KARPAS-299 T-cell NHL, SU-DHL-8 B-cell NHL, SU-DHL-10 B-cell NHL and SU-DHL-16 B-cell NHL cell lines. Preclinical studies have also established anti-angiogenic properties of darinaparsin and provided support for the development of an oral form of the drug, and established synergy of darinaparsin in combination with other approved anti-cancer agents.

Phase I testing of the intravenous (IV) form of darinaparsin in solid tumors and hematological cancers was completed and we reported clinical activity and, importantly, a safety profile from these studies as predicted by preclinical results. We subsequently completed Phase II studies in advanced myeloma, primary liver cancer and in certain other hematological cancers. In addition, we have re-opened Phase I study with an oral form. At the May 2009 annual meeting of the American Society of Clinical Oncology, we reported favorable results from the trial with IV-administered darinaparsin in lymphoma, particularly peripheral T-cell lymphoma. We have established a Phase I protocol to study darinaparsin with the combination treatment regimen called "CHOP", which is standard of care for front-line peripheral T-cell lymphoma ("PTCL"). With the requisite financial resources, we would intend to follow this Phase I trial into a pivotal trial as determined by trial data. Orphan Drug Designation was recently obtained in the United States for the treatment of peripheral T-cell lymphoma and the Japan Patent Office issued a patent with claims covering pharmaceutical composition.

- ZIO-201 or palifosfamide (ZymafosTM), comprises the active metabolite of ifosfamide, a compound chemically related to cyclophosphamide. Patent applications covering proprietary forms of palifosfamide for pharmaceutical composition and method of use have been filed in the U.S. and internationally and in the U.S. we recently received a patent covering pharmaceutical composition. Like cyclophosphamide, ifosfamide and bendamustine, palifosfamide is a DNA alkylating agent, a form of cancer therapy to treat a wide range of solid tumors and hematological malignancies. We believe that cyclophosphamide is the most widely used alkylating agent in cancer therapy, with significant use in the treatment of breast cancer and non-Hodgkin's lymphoma. Bendamustine has been recently approved and successfully launched by Cephalon Oncology in the U.S. and Europe to treat certain hematological malignancies. Ifosfamide has been shown to be effective in the treatment of sarcoma and lymphoma, either by itself or in combination with other anticancer agents. Ifosfamide is approved by the FDA as a treatment for testicular cancer while ifosfamide-based treatment is a standard of care for sarcoma, although it is not approved for this indication by the FDA. Preclinical studies have shown that palifosfamide has activity against leukemia and solid tumors. These studies also indicate that palifosfamide may have a better safety profile than ifosfamide or cyclophosphamide because it does not appear to produce known toxic metabolites of ifosfamide, such as acrolein and chloroacetaldehyde. Acrolein, which is toxic to the kidneys and bladder, can mandate the administration of a protective agent called mesna, which is inconvenient and expensive. Chloroacetaldehyde is toxic to the central nervous system, causing "fuzzy brain" syndrome for which there is currently no protective measure. Similar toxicity concerns pertain to high-dose cyclophosphamide, which is widely used in bone marrow and blood cell transplantation. Palifosfamide has evidenced activity against ifosfamide- and/or cyclophosphamide-resistant cancer cell lines. Also in preclinical cancer models, palifosfamide was shown to be orally active and encouraging results have been obtained with palifosfamide in combination with doxorubicin, an agent approved to treat sarcoma.

Following completion of Phase I study, we completed Phase II testing of the intravenous form of palifosfamide as a single agent to treat advanced sarcoma. In both Phase I and Phase II testing, palifosfamide has been administered without the "uroprotectant" mesna, and the toxicities associated with acrolein and chloroacetaldehyde have not been observed. We reported clinical activity of palifosfamide when used alone in the Phase II study addressing advanced sarcoma. Following review of preclinical combination studies, clinical data, and discussion with sarcoma experts, we initiated a Phase I dose escalation study of palifosfamide in combination with doxorubicin primarily in patients with soft tissue sarcoma. We reported favorable results and safety profile from this study at ASCO's 2009 annual meeting. In light of reported favorable Phase II clinical activity data and with the combination being well tolerated in the Phase I trial, we initiated a Phase II randomized controlled trial in the second half of 2008 to compare doxorubicin plus palifosfamide to doxorubicin alone in patients with front and second-line metastatic or unresectable soft tissue sarcoma. The study generated positive top line interim data in 2009. Upon reaching a pre-specified efficacy milestone and following safety and efficacy data review by the Data Committee, sarcoma experts, and our Medical Advisory Board, we elected to suspend enrollment in the trial in October 2009. We subsequently presented further positive interim data from the trial at the 15th Annual Connective Tissue Oncology Society meeting held in November 2009 and again at the 2010 ASCO Annual Meeting where the presentation was also selected for Best of ASCO. In

July 2010, we announced the initiation of a worldwide registration trial with FDA on a protocol design developed through an End of Phase II meeting and the Special Protocol Assessment (SPA) process. Although the Company did engage in the SPA process, the Company, with guidance from the FDA, elected to initiate the trial without having obtained formal SPA. The Phase III trial is in front-line metastatic soft tissue sarcoma, entitled PICASSO 3, and is an international, randomized, double-blinded, placebo-controlled trial with a targeted enrollment of 424 patients. The study is designed to evaluate the safety and efficacy of palifosfamide administered with doxorubicin compared with doxorubicin administered with placebo, with no cross-over between the arms. Progression-free survival is the primary endpoint for accelerated approval, with overall survival as the primary endpoint for full approval. Orphan Drug Designation for palifosfamide has been obtained in both the United States and the European Union for the treatment of soft tissue sarcomas.

We are also initiating a Phase I trial with palifosfamide in combination with etoposide and carboplatin for front-line small-cell lung cancer ("SCLC") and we expect a Phase II randomized trial to follow. An oral form of palifosfamide is entering Phase I study while additional preclinical work continues.

- ZIO-301 or indibulin (ZybulinTM), is a novel, orally available small molecular-weight inhibitor of tubulin polymerization that we acquired from Baxter Healthcare in 2006 and is the subject of numerous patents worldwide, including the United States, the European Union and Japan. The microtubule component, tubulin, is one of the more well established drug targets in cancer. Microtubule inhibitors interfere with the dynamics of tubulin polymerization, resulting in inhibition of chromosome segregation during mitosis and consequently inhibition of cell division. A number of marketed IV anticancer drugs target tubulin, such as the taxane family members, paclitaxel (Taxol ®), docetaxel (Taxotere ®) , the Vinca alkaloid family members, vincristine and vinorelbine, and the new class of epothilones with IxempraTM marketed. This class of agents is typically the mainstay of therapy in a wide variety of indications. In spite of their effectiveness, the use of these drugs is associated with significant toxicities, notably peripheral neurotoxicity.

Preclinical studies with indibulin demonstrate significant and broad antitumor activity, including activity against taxane-refractory cell lines. The cytotoxic activity of indibulin was demonstrated in several rodent and human tumor cell lines derived from prostate, brain, breast, pancreas, lung, ovary, and cervical tumor tissues and in rodent tumor and human tumor xenograft models. In addition, indibulin was effective against multidrug resistant tumor cell lines (breast, lung, and leukemia) both in vitro and in vivo. Indibulin is potentially safer than other tubulin inhibitors. No neurotoxicity has been observed at therapeutic doses in rodents and in the Phase I trials. Indibulin has also demonstrated synergy with approved anti-cancer agents in preclinical studies. The availability of an oral formulation of indibulin creates significant commercial opportunity because no oral capsule formulations of the taxane family are currently on the market in the United States.

Indibulin, as a single agent, has completed Phase I trials in patients with advanced solid tumors. We have reported clinical activity at well-tolerated doses using a continuous dosing scheme without the development of clinically relevant peripheral neuropathy. Following encouraging results obtained with indibulin in combination with erlotinib, and 5-FU in preclinical models, two Phase I combination studies were initiated with TarcevaTM and XelodaTM, respectively. Favorable activity and safety profile of oral indibulin with oral XelodaTM were reported at ASCO's annual meeting in May 2009. Preclinical work with our consultant, Dr. Larry Norton, to explore dose scheduling for the clinical setting have been completed, with results supporting the recently initiated Phase I safety trial necessary for a Phase II breast cancer trial and using the mathematical dosing schedule established preclinically.

We intend to continue with our principal focus on the clinical development of IV palifosfamide for soft tissue sarcoma, completing the ongoing Phase II trial and the recently initiated Phase III pivotal trial while also initiating the SCLC Phase I trial and Phase I study with the oral form. The successful development of our product candidates is highly uncertain. Product development costs and timelines can vary significantly for each product candidate, are difficult to accurately predict, and will require us to obtain additional funding, either alone or in connection with partnering arrangements. Various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of each product. The lengthy process of seeking approval and the subsequent compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially, adversely affect our business. To date, we have not received approval for the sale of any drug candidates in any market and, therefore, have not generated any revenues from our drug candidates.

Patents and Other Proprietary Rights

Our goal is to obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies in order to preserve our trade secrets and to operate without infringing upon the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek the broadest possible intellectual property protection for our product candidates through a combination of contractual arrangements and patents, both in the United States and abroad.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection offering by a patent, which can vary from country to country, depends of the type of patent, the scope of its coverage and the availability of legal remedies in the country.

We also depend upon the skills, knowledge, and experience of our scientific and technical personnel, as well as those of our advisors, consultants, and other contractors, none of which is patentable. To help protect proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely, and in the future will continue to rely, on trade secret protection and confidentiality agreements to protect our interests. To this end, we generally require employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Our patent position and proprietary rights are subject to certain risks and uncertainties. Please read the “Risk Factors” section of this report for information about certain risks and uncertainties that may affect our patent position and proprietary rights.

Additional information about material patents and other proprietary rights covering our product candidates is set forth below.

Darinaparsin

The patent estate covering darinaparsin compositions, methods of use and methods of manufacture includes three issued United States patents, as well as issued patents in certain foreign jurisdictions, all of which are scheduled to expire in 2023. We license these patents, as well as pending applications in various foreign jurisdictions, from The University of Texas M. D. Anderson Cancer Center and the Texas A&M University System pursuant to an agreement dated August 24, 2004. We have also filed pending applications in the United States and various foreign jurisdictions.

Palifosfamide

The patent estate covering palifosfamide compositions, methods of use and methods of manufacture includes one issued United States patent that is scheduled to expire in 2029, as well as pending applications in the United States and various foreign jurisdictions. We license the issued patent and the patent applications from DEKK-Tec, Inc. pursuant to an agreement dated October 15, 2004. We have also filed pending applications in the United States and various foreign jurisdictions.

Indibulin

The patent estate covering indibulin compositions, methods of use and methods of manufacture includes pending applications in the United States, and various foreign jurisdictions, all of which we license from affiliates of Baxter Healthcare Corporation pursuant to an agreement dated November 6, 2006. We also have five issued United States patents that are scheduled to expire at varying times between 2017 and 2019, as well as issued patents in various foreign jurisdictions, and have filed pending applications in the United States and various foreign jurisdictions.

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Development Plan

Our development plan for the next twelve months remains focused on the following endeavors:

- completing the randomized Phase II trial for IV palifosfamide in soft tissue sarcoma;
- implementation of the Phase III registration trial for IV palifosfamide in soft tissue sarcoma, as well as initiating the SCLC and oral Phase I trials while conducting manufacturing scale-up;
- completing the Phase I oral darinaparsin trial, while starting a Phase I trial with CHOP for front-line PTCL study; and
- conducting the Phase I safety trial following into a Phase II trial of oral indibulin in breast cancer.

We expect our material expenditures during this time to be predominately for palifosfamide clinical trial expense, employment expense (we currently have 21 full time employees) and other expenses associated with clinical trials.

We continue to use senior advisors, consultants, clinical research organizations, and other third parties to perform certain aspects of product development, manufacturing, clinical, and preclinical development, and regulatory, safety and quality assurance functions.

Given our current plans to use internal financial resources to develop palifosfamide and pursue the clinical work discussed above, but with the intention of partnering or otherwise raising additional resources to support further development activities for all three product candidates, we expect to incur the following expenses during the next twelve months: approximately $28.2 million on research and development expenses and approximately $ 10.0 million on general corporate and administrative expenses. With our current cash position, and ongoing aggressive cash management strategy, we believe that we currently have sufficient capital that will support our current operations well into mid-2012. Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to complete development of products and the cost to commercialize our future products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the "Risk Factors" section of this report. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Specifically, we commenced a registration trial for IV palifosfamide early in the third quarter of 2010. We have estimated the sufficiency of our cash resources based this trial design. However, the actual costs may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. In addition to the amount and timing of expenses related to the IV palifosfamide registration trial, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights.

Product Candidate Development and Clinical Trials

Intravenous darinaparsin, an organic arsenic, has been tested in patients with advanced myeloma, other hematological malignancies, and liver cancer. At the May 2009 ASCO Annual Meeting, we reported positive results in patients with lymphoma, particularly PTCL, which has led to the planning of a pivotal trial in PTCL subject to regulatory guidance and the availability of sufficient financial resources. We intend to initiate a Phase I trial with CHOP and continue to evaluate the options for a pivotal trial. The Phase I trial with an oral form of darinaparsin is again ongoing. The Company is actively seeking sources of funding for continuing the development program of the IV form in a pivotal trial for PTCL and for continuing additional studies for both IV and oral administration. Technology transfer and scale-up for the commercial manufacture of the active pharmaceutical ingredient and final product specification will continue as the development program and resources allow. Orphan Drug Designation has been obtained for the United States for the treatment of PTCL.

Intravenous palifosfamide, the proprietary stabilized form of isophosphoramide mustard, is being developed presently to treat soft tissue sarcoma. A Phase II trial in advanced sarcoma has been completed with favorable activity and with the expected safety profile. Favorable activity and safety data from a Phase I trial of IV palifosfamide in combination with doxorubicin were reported at the 2009 ASCO Annual Meeting. The Company subsequently initiated a randomized Phase II trial designed to compare palifosfamide in combination with doxorubicin to doxorubicin alone in the front or second-line treatment of metastatic or unresectable soft tissue sarcoma and recently announced favorable interim efficacy data, thereby ending further enrollment, and presented the results at the November 2009 CTOS Annual Meeting and the 2010 ASCO Annual Meeting. The Company initiated a global registration trial during the third quarter of 2010. We also plan to study IV palifosfamide in SCLC and to initiate a Phase I clinical study will be initiated with the oral form. Orphan Drug Designation has been obtained for both the United States and the European Union for the treatment of soft tissue sarcomas. Technology transfer and scale-up for the commercial manufacture of the active pharmaceutical ingredient and final product specification will continue as the program demands.

Indibulin, a novel anti-cancer agent that targets mitosis by inhibiting tubulin polymerization, is administered as an oral formulation. Indibulin has completed Phase I trials with favorable results of activity and safety profile reported for all trials. Phase I trials of indibulin in combination with Tarceva TM and also with Xeloda TM have been conducted. At the 2009 ASCO Annual Meeting, the Company presented favorable preliminary activity and safety data of oral indibulin with oral XelodaTM . Preclinical studies under the direction of Dr. Larry Norton to support clinical study of “dose dense” dosing are completed and were also reported at 2009 ASCO Annual Meeting. The Company has initiated a Phase I/II trial to determine maximum tolerated dose and activity in breast cancer with the schedule identified preclinically.

Financial Overview

Overview of Results of Operations

Three and nine months ended September 30, 2010 compared to three and nine months ended September 30, 2009

Revenue. We had no revenues for the three and nine months ended September 30, 2010 and 2009.

Research and development expenses. Research and development expenses during the three and nine months ended September 30, 2010 and 2009 were as follows:

($ in thousands)	Three months ended September 30, 2010	2009	Change		Nine months ended September 30, 2010	2009	Change	
Research and development	$ 5,711	$ 1,231	$ 4,480	364%	$ 9,872	$ 3,340	$ 6,532	196%

Research and development expenses for the three months ended September 30, 2010 increased by $4.5 million from the three months ended September 30, 2009. The increase was primarily due to increased manufacturing activity of $455 thousand to replenish drug inventories, clinical costs of $3.6 million related to the Phase III palifosfamide study and other costs of $378 thousand.

Research and development expenses for the nine months ended September 30, 2010 increased by $6.5 million from the nine months ended September 30, 2009. The increase was primarily due to increased manufacturing activity of $1.3 million to replenish drug inventories, stock-based compensation expense of $318 thousand, clinical costs of $4.3 million related to the Phase III trial with palifosfamide study and other costs of $696 thousand.

We expect our research and development expenses to increase as we start our pivotal Phase III palifosfamide and other studies for palifosfamide, darinaparsin and indibulin.

Overview

Our research and development expense consists primarily of salaries and related expenses for personnel, costs of contract manufacturing services, costs of facilities and equipment, fees paid to professional service providers in conjunction with our clinical trials, fees paid to research organizations in conjunction with pre-clinical animal studies, costs of materials used in research and development, consulting, license and milestone payments and sponsored research fees paid to third parties.

We have not accumulated and tracked our internal historical research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources are allocated across several projects, and many of our costs are directed to broadly applicable research endeavors. As a result, we cannot state the costs incurred for each of our oncology programs on a program-by-program basis.

In 2010, our clinical projects consisted primarily of a Phase III project for our lead product candidate palifosfamide. This project was initiated during 2010. The expenses incurred by us to third parties were $2.5 million and $3.1 million for the three and nine months ended September 30, 2010, respectively and $3.1 million for project to date.

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Our future research and development expenses in support of our current and future programs will be subject to numerous uncertainties in timing and cost to completion. We test potential products in numerous pre-clinical studies for safety, toxicology and efficacy. We may conduct multiple clinical trials for each product. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products or indications. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product. It is not unusual for pre-clinical and clinical development of each of these types of products to require the expenditure of substantial resources.

We estimate that clinical trials of the type generally needed to secure new drug approval are typically completed over the following timelines:

Clinical Phase	Estimated Completion Period
Phase 1	1 - 2 years
Phase 2	2 - 3 years
Phase 3	2 - 4 years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others, the following:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patents;
- the number of patients that ultimately participate in the trials;
- the duration of patient follow-up to ensure the absence of long-term product-related adverse events; and
- the efficacy and safety profile of the product.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our programs or when and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our programs in a timely manner or our failure to enter into appropriate collaborative agreements could significantly increase our capital requirements and could inversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time-to-time in order to continue with our product development strategy. Our ability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

General and administrative expenses. General and administrative expenses during the three and nine months ended September 30, 2010 and 2009 were as follows:

($ in thousands)	Three months ended September 30, 2010	2009	Change		Nine months ended September 30, 2010	2009	Change	
General and administrative	$ 2,789	$ 1,339	$ 1,450	108%	$ 8,313	$ 4,754	$ 3,559	75%

General and administrative expenses for the three months ended September 30, 2010 increased by $1.5 million from the three months ended September 30, 2009. The increase was primarily due to increased stock-based compensation of $450 thousand, salaries of $241 thousand, consulting of $157 thousand, legal and patent costs of $241 thousand and other costs of $362 thousand. The increased general and administrative activity was related to support in preparation for new clinical studies.

General and administrative expenses for the nine months ended September 30, 2010 increased by $3.6 million from the nine months ended September 30, 2009. The increase was primarily due to increased stock-based compensation of $1.6 million, salaries of $495 thousand, consulting of $410 thousand, legal and patent costs of $374 thousand, payments of $125 thousand upon achieving license related milestones and other costs of $539 thousand. The increased general and administrative activity was related to support in preparation for new clinical studies.

We expect our general and administrative expenses to increase moderately due to increased activity to support the new clinical studies.

Other income (expense). Other income (expense) for the three and nine months ended September 30, 2010 and 2009 were as follows:

($ in thousands)	Three months ended September 30, 2010	2009	Change		Nine months ended September 30, 2010	2009	Change	
Other income (expense), net	$ 7	$ (1)	$ 8	-800%	$ 29	$ 1	$ 28	2800%
Change in fair value of warrants	(3,712)	(304)	(3,408)	-1121%	(2,663)	(520)	(2,143)	-412%
Total	$ (3,705)	$ (305)	$ (3,400)		$ (2,634)	$ (519)	$ (2,115)	

The decrease in other income (expense) from the three months ended September 30, 2009 compared to the three months ended September 30, 2010 was due primarily to the increased non-cash expense recorded from the change in the fair value of liability-classified warrants. The increased expense directly correlates with the Company's increased stock price during the three months ended September 30, 2010. Additionally, increased cash balances resulted in increased interest income.

The decrease in other income (expense) from the nine months ended September 30, 2009 compared to the nine months ended September 30, 2010 was due primarily to the increased non-cash expense recorded from the change in the fair value of liability-classified warrants. The increased expense directly correlates with the Company's increased stock

price during the nine months ended September 30, 2010. Additionally, increased cash balances during the first nine months of 2010 resulted in increased interest income.

Liquidity and Capital Resources

As of September 30, 2010, we had approximately $66.5 million in cash and cash equivalents, compared to $48.8 million in cash and cash equivalents as of December 31, 2009. We believe that our existing cash will be sufficient to fund our operations well into mid-2012. We expect that we will need additional financing to support our long-term plans for clinical trials and new product development. We expect to finance our cash needs through the sale of equity securities, strategic collaborations and/or debt financings, or through other sources that may be dilutive to existing stockholders. There can be no assurance that we will be able to obtain funding from any of these sources or, if obtained, what the terms of such funding(s) may be, or that any amount that the Company is able to obtain will be adequate to support the Company's working capital requirements until it achieves profitable operations. Currently, we have no committed sources of additional capital. Recently, capital markets have experienced a period of instability that may severely hinder our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. If we are unable to raise additional funds when needed, we may not be able to continue development and regulatory approval of our products, or we could be required to delay, scale back or eliminate some or all our research and development programs.

The following table summarizes our net increase (decrease) in cash and cash equivalents for the nine months ended September 30, 2010 and 2009:

	Nine months ended September 30,	
	2010	2009
($ in thousands)		
Net cash provided by (used in):		
Operating activities	$ (13,911)	$ (8,901)
Investing activities	(128)	(3)
Financing activities	31,671	4,605
Net increase (decrease) in cash and cash equivalents	$ 17,632	$ (4,299)

Net cash used in operating activities was $13.9 million for the nine months ended September 30, 2010 compared to $8.9 million for the nine months ended September 30, 2009. The $5.0 million increase was primarily due to an increase in the net loss from operations, caused by increased research and development activities, partially offset by increases in accrued liabilities, stock based compensation and change in fair value of warrants.

Net cash used in investing activities was $128 thousand for the nine months ended September 30, 2010 compared to $3 thousand for the nine months ended September 30, 2009. The increase was due to increased purchases of property plant and equipment.

Net cash provided by financing activities was $31.7 million for the nine months ended September 30, 2010 compared to $4.6 million for the nine months ended September 30, 2009. The increase of $27.1 million is attributable to a financing that resulted in $32.8 million of cash proceeds, in addition to stock option exercises partially offset by the re-purchase of common stock by the Company to cover taxes upon vesting of previously granted restricted stock awards.

Operating capital and capital expenditure requirements

The Company anticipates that losses will continue for the foreseeable future. At September 30, 2010, the Company's accumulated deficit was approximately $112.0 million. Our actual cash requirements may vary materially from those planned because of a number of factors including:

- Changes in the focus, direction and pace of our development programs;
- Competitive and technical advances;
- Internal costs associated with the development of palifosfamide and indibulin and our ability to secure further financing for darinaparsin development from a partner;
- Costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights, or other developments, and
- Other matters identified under Part II – Item 1A. "Risk Factors" below.

Working capital as of September 30, 2010 was $62.7 million, consisting of $66.8 million in current assets and $4.1 million in current liabilities. Working capital as of December 31, 2009 was $46.1 million, consisting of $49.2 million in current assets and $3.1 million in current liabilities.

Contractual obligations

The following table summarizes our outstanding obligations as of September 30, 2010 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

($ in thousands)	Total	Less than 1 year	2 - 3 years	4 - 5 years	More than 5 years
Operating leases	$ 1,063	$ 417	$ 541	$ 105	$ -
Royalty and license fees	1,625	25	300	800	500
Contract milestone payments	15,805	5,046	9,331	1,428	-
Total	$ 18,493	$ 5,488	$ 10,172	$ 2,333	$ 500

Our commitments for operating leases relate to the lease for our corporate headquarters in New York, New York and our operations center in Boston, Massachusetts. Our commitments for royalty and license fees relate to our patent agreement with Baxter Healthcare Corporation and our royalty agreements with Southern Research Institute and Baxter Healthcare Corporation. The contract milestone payments relate to our CRO agreement with PPD Development, L. P. The timing of the remaining contract milestone payments are dependent upon factors that are beyond our control, including our ability to recruit patients, the outcome of future clinical trials and any requirements imposed on our clinical trials by regulatory agencies. However, for the purpose of the above table, we have assumed that the payment of the milestones will occur within five years of September 30, 2010.

Off-balance sheet arrangements

During the nine months ended September 30, 2010 and 2009, we did not engage in any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

In our Form 10-K for the fiscal year ended December 31, 2009, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to stock-based compensation; net operating losses and tax credit carryforwards; and impairment of long-lived assets. We reviewed our policies and determined that those policies remain our most critical accounting policies for the nine months ended September 30, 2010.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is limited to our cash. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain our cash in interest-bearing bank accounts in global banks, United States treasuries and other Government backed investments, which are subject to minimal interest rate risk.

Item 4. Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) as of the end of the period covered by this report. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

No change in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) occurred during the period covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

Not applicable.

Item 1A. Risk Factors

The following important factors could cause our actual business and financial results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or elsewhere by management from time to time. The risk factors in this report have been revised to incorporate changes to our risk factors from those included in our quarterly report on Form 10-Q for the quarter ended September 30, 2010. The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, which may be material, from the risk factors previously disclosed in Item 1A of our quarterly report on Form 10-Q for the quarter ended September 30, 2010, as filed with the Securities and Exchange Commission.

RISKS RELATED TO OUR BUSINESS

* We will require additional financial resources in order to continue on-going development of our product candidates; if we are unable to obtain these additional resources, we may be forced to delay or discontinue clinical testing of our product candidates.

We have never generated revenue and have incurred significant net losses in each year since our inception. For the nine months ended September 30, 2010, we had a net loss of $20.8 million and we had incurred approximately $112.0 million of cumulative net losses since our inception in 2003. We expect to continue to incur significant operating expenditures. Although we took near-term cost cutting measures in 2009 aimed at preserving capital while we pursued sources of potential additional financing, further development of our product candidates will likely require substantial increases in our expenses as we:

- Continue to undertake clinical trials for product candidates;
- Scale-up the formulation and manufacturing of our product candidates;
- Seek regulatory approvals for product candidates;
- Implement additional internal systems and infrastructure; and
- Hire additional personnel.

We continue to seek additional financial resources to fund the further development of palifosfamide, darinaparsin and indibulin and in particular the planned pivotal trial of darinaparsin in front-line PTCL. If we are unable to obtain sufficient additional capital, one or more of these programs could be placed on hold. Because we are currently devoting a significant portion of our resources to the development of palifosfamide, further progress with the development of darinaparsin and indibulin may be significantly delayed and may depend on the success of our ongoing clinical trial involving palifosfamide.

Currently, we have no committed sources of additional capital. We do not know whether additional financing will be available on terms favorable or acceptable to us when needed, if at all. Our business is highly cash-intensive and our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional

financing and achieve profitable operations, as to which no assurances can be given. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for the further development of our products, we will be required to delay, reduce or eliminate planned preclinical and clinical trials and may be forced to terminate the approval process for our product candidates from the FDA or other regulatory authorities. In addition, we could be forced to discontinue product development, forego attractive business opportunities or pursue merger or divestiture strategies. In the event we are unable to obtain additional financing, we may be forced to cease operations altogether.

* We need to raise additional capital to fund our operations. The manner in which we raise any additional funds may affect the value of your investment in our common stock.

As of September 30, 2010, we had incurred approximately $112.0 million of cumulative net losses and had approximately $66.5 million of cash and cash equivalents. Given our current plans for development of our product candidates, we anticipate that our cash resources will be sufficient to fund our operations well into mid-2012. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our research and development efforts and changes in governmental regulation. Specifically, we have commenced a registration trial for IV palifosfamide early in the third quarter of 2010. We have estimated the sufficiency of our cash resources based on this trial design. However, the actual costs may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. In addition to the amount and timing of expenses related to the IV palifosfamide registration trial, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights.

Recently, capital markets have experienced a period of unprecedented instability that may severely hinder our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. Moreover, if we fail to advance one or more of our current product candidates to later-stage clinical trials, successfully commercialize one or more of our product candidates, or acquire new product candidates for development, we may have difficulty attracting investors that might otherwise be a source of additional financing.

In the current economic environment, our need for additional capital and limited capital resources may force us to accept financing terms that could be significantly more dilutive than if we were raising capital when the capital markets were more stable. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience dilution. In addition, we may grant future investors rights superior to those of our existing stockholders. If we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies, product candidates or products, or grant licenses on terms that are not favorable to us. If we raise additional funds by incurring debt, we could incur significant interest expense and become subject to covenants in the related transaction documentation that could affect the manner in which we conduct our business.

We may not be able to commercialize any products, generate significant revenues, or attain profitability.

To date, none of our product candidates have been approved for commercial sale in any country. The process to develop, obtain regulatory approval for, and commercialize potential drug candidates is long, complex, and costly. Unless and until we receive approval from the FDA and/or other regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenues. Even if we obtain regulatory approval for one or more of our product candidates, if we are unable to successfully commercialize our products, we may not be able to generate sufficient revenues to achieve or maintain profitability, or to continue our business without raising significant additional capital, which may not be available. Our failure to achieve or maintain profitability could negatively impact the trading price of our common stock.

We have a limited operating history upon which to base an investment decision.

We are a development-stage company that was incorporated in September 2003. To date, we have not demonstrated an ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- Continuing to undertake preclinical development and clinical trials;
- Participating in regulatory approval processes;
- Formulating and manufacturing products; and
- Conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our Company, acquiring, developing, and securing our proprietary product candidates, and undertaking preclinical and clinical trials of our product candidates: darinaparsin, palifosfamide, and indibulin. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

The success of our growth strategy depends upon our ability to identify, select, and acquire additional pharmaceutical product candidates for development and commercialization. Because we currently neither have nor intend to establish internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and academic and other researchers to sell or license us their product candidates.

Proposing, negotiating, and implementing an economically viable product acquisition or license is a lengthy and complex process. We compete for partnering arrangements and license agreements with pharmaceutical, biopharmaceutical, and biotechnology companies, many of which have significantly more experience than we do, and have significantly more financial resources. Our competitors may have stronger relationships with certain third parties including academic research institutions, with whom we are interested in collaborating and may have, therefore, a competitive advantage in entering into partnering arrangements with those third parties. We may not be able to acquire rights to additional product candidates on terms that we find acceptable, or at all.

We expect that any product candidate to which we acquire rights will require significant additional development and other efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All drug product candidates are subject to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe or effective for approval by regulatory authorities. Even if our product candidates are approved, they may not be economically manufactured or produced, or be successfully commercialized.

We actively evaluate additional product candidates to acquire for development. Such additional product candidates, if any, could significantly increase our capital requirements and place further strain on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing product candidates. We must manage our development efforts and clinical trials effectively, and hire, train and integrate additional management, administrative, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our Company.

We may not be able to successfully manage our growth.

In the future, if we are able to advance our product candidates to the point of, and thereafter through, clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide for these capabilities. Any future growth will place a significant strain on our management and on our administrative, operational, and financial resources. Therefore, our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To manage this growth, we must expand our facilities, augment our operational, financial and management systems, and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business may be harmed.

Our business will subject us to the risk of liability claims associated with the use of hazardous materials and chemicals.

Our contract research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could have a materially adverse effect on our business, financial condition, and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require our contractors to incur substantial compliance costs that could materially adversely affect our business, financial condition, and results of operations.

We rely on key executive officers and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on Dr. Jonathan Lewis, our Chief Executive Officer and Chief Medical Officer, Richard Bagley, our President, Chief Operating Officer and Chief Financial Officer, and our principal scientific, regulatory, and medical advisors. Dr. Lewis' and Mr. Bagley's employment are governed by written employment agreements that provide for terms that expire in January 2011 and July 2011, respectively. Dr. Lewis and Mr. Bagley may terminate their employment with us at any time, subject, however, to certain non-compete and non-solicitation covenants. The loss of the technical knowledge and management and industry expertise of Dr. Lewis and Mr. Bagley, or any of our other key personnel, could result in delays in product development, loss of customers and sales, and diversion of management resources, which could adversely affect our operating results. We do not carry "key person" life insurance policies on any of our officers or key employees.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in preclinical and clinical research and testing, government regulation, formulation and manufacturing, and eventually, sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities, and other research institutions. Competition for such individuals is intense and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merit or eventual outcome, liability claims may result in:

- Decreased demand for our product candidates;
- Injury to our reputation;
- Withdrawal of clinical trial participants;
- Withdrawal of prior governmental approvals;
- Costs of related litigation;
- Substantial monetary awards to patients;
- Product recalls;
- Loss of revenue; and
- The inability to commercialize our product candidates.

We currently carry clinical trial insurance and product liability insurance. However, our inability to renew our policies or to obtain sufficient insurance at an acceptable cost could prevent or inhibit the commercialization of pharmaceutical products that we develop, alone or with collaborators.

RISKS RELATED TO THE CLINICAL TESTING, REGULATORY APPROVAL AND MANUFACTURING OF OUR PRODUCT CANDIDATES

If we are unable to obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate, our business will suffer.

We may not be able to obtain the approvals necessary to commercialize our product candidates, or any product candidate that we may acquire or develop in the future for commercial sale. We will need FDA approval to commercialize our product candidates in the U.S. and approvals from regulatory authorities in foreign jurisdictions equivalent to the FDA to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a New Drug Application, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity, and novelty of the product candidate, and will require substantial resources for research, development, and testing. We cannot predict whether our research, development, and clinical approaches will result in drugs that the FDA will consider safe for humans and effective for their intended uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future

legislation, or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- Delay commercialization of, and our ability to derive product revenues from, our product candidates;
- Impose costly procedures on us; and
- Diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval for our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any potential revenue source, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate or that we will obtain FDA approval if we are able to do so.

In foreign jurisdictions, we similarly must receive approval from applicable regulatory authorities before we can commercialize any drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

Our product candidates are in various stages of clinical trials, which are very expensive and time-consuming. We cannot be certain when we will be able to file an NDA with the FDA and any failure or delay in completing clinical trials for our product candidates could harm our business.

Our product candidates are in various stages of development and require extensive clinical testing. Notwithstanding our current clinical trial plans for each of our existing product candidates, we may not be able to commence additional trials or see results from these trials within our anticipated timelines. As such, we cannot predict with any certainty if or when we might submit an NDA for regulatory approval of our product candidates or whether such an NDA will be accepted. Because we do not anticipate generating revenues unless and until we submit one or more NDAs and thereafter obtain requisite FDA approvals, the timing of our NDA submissions and FDA determinations regarding approval thereof, will directly affect if and when we are able to generate revenues.

*Clinical trials are very expensive, time-consuming, and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process itself is also time-consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- Unforeseen safety issues;
- Determination of dosing issues;
- Lack of effectiveness during clinical trials;
- Slower than expected rates of patient recruitment;
- Inability to monitor patients adequately during or after treatment; and
- Inability or unwillingness of medical investigators to follow our clinical protocols.

We have received “Orphan Drug” status for palifosfamide in both the United States and Europe, for darinaparsin in the United States and we are hopeful that we may be able to obtain “Fast Track” and/or additional Orphan Drug status from the FDA, Europe and Japan for our product candidates. Fast Track allows the FDA to facilitate development and expedite review of drugs that treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Fast Track status does not apply to a product alone, but applies to a combination of a product and the specific indications for which it is being studied. Therefore, it is a drug’s development program for a specific

indication that receives Fast Track designation. Orphan Drug status promotes the development of products that demonstrate the promise for the diagnosis and treatment of one disease or condition and affords certain financial and market protection benefits to successful applicants. However, there is no guarantee that any of our product candidates, other than palifosfamide, will be granted Orphan Drug status or will be granted Fast Track status by the FDA or that, even if such product candidate is granted such status, the product candidate's clinical development and regulatory approval process will not be delayed or will be successful.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submission or in the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for future clinical trials.

The results of our clinical trials may not support our product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be certain that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for the indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve small patient populations. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

Because we are dependent upon clinical research institutions and other contractors for clinical testing and for research and development activities, the results of our clinical trials and such research activities are, to a certain extent, beyond our control.

We materially rely upon independent investigators and collaborators, such as universities and medical institutions, to conduct our preclinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors to our detriment, our competitive position would be harmed.

Our reliance on third parties to formulate and manufacture our product candidates exposes us to a number of risks that may delay the development, regulatory approval and commercialization of our products or result in higher product costs.

We do not have experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We currently are contracting for the manufacture of our product candidates. We intend to contract with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our clinical trials. If a product candidate we develop or acquire in the future receives FDA approval, we will rely on one or more third-party contractors to manufacture our drugs. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

RISKS RELATED TO OUR ABILITY TO COMMERCIALIZE OUR PRODUCT CANDIDATES

If we are unable either to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize our product candidates successfully.

We currently have no marketing, sales, or distribution capabilities. If and when we become reasonably certain that we will be able to commercialize our current or future products, we anticipate allocating resources to the marketing, sales and distribution of our proposed products in North America; however, we cannot assure that we will be able to market, sell, and distribute our products successfully. Our future success also may depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities and to encourage the collaborator's strategic interest in the products under development, and such collaborator's ability to successfully market and sell any such products. Although we intend to pursue certain collaborative arrangements regarding the sale and marketing of our products, there are no assurances that we will be able to establish or maintain collaborative arrangements or, if we are able to do so, whether we would be able to conduct our own sales efforts. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would harm our business. If we rely on pharmaceutical or biotechnology companies with established distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties that may not be successful and that will be only partially in our control.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If a product candidate receives FDA approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have products already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- Developing drugs;
- Undertaking preclinical testing and human clinical trials;
- Obtaining FDA and other regulatory approvals of drugs;

- Formulating and manufacturing drugs; and
- Launching, marketing, and selling drugs.

If physicians and patients do not accept and use our product candidates, our ability to generate revenue from sales of our products will be materially impaired.

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our products will depend upon a number of factors including:

- Perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
- Pharmacological benefit and cost-effectiveness of our products relative to competing products;
- Availability of reimbursement for our products from government or other healthcare payors;
- Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- The price at which we sell our products.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of a drug to find market acceptance would harm our business and could require us to seek additional financing in order to fund the development of future product candidates.

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- Government and health administration authorities;
- Private health maintenance organizations and health insurers; and
- Other healthcare payers.

Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. As a result, we cannot provide any assurances that third-party payors will provide adequate coverage of and reimbursement for any of our product candidates. If we are unable to obtain adequate coverage of and payment levels for our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability and future success.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory policies and proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (“MMA”), which contains, among other changes to the law, a wide variety of changes that have and will impact Medicare reimbursement of pharmaceuticals to physicians and hospitals.

There also likely will continue to be legislative and regulatory proposals that could bring about significant changes in the healthcare industry. We cannot predict what form those changes might take or the impact on our business of any

legislation or regulations that may be adopted in the future. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.

Our success, competitive position, and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights, and to operate without infringing the proprietary rights of third parties.

To date, we have exclusive rights to certain U.S. and foreign intellectual property. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- The degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- If and when patents will be issued;
- Whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- Whether we will need to initiate litigation or administrative proceedings that may be costly whether we win or lose.

Our success also depends upon the skills, knowledge, and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, it is our general policy to require our employees, consultants, advisors, and contractors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries, and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Third-party claims of intellectual property infringement would require us to spend significant time and money and could prevent us from developing or commercializing our products.

In order to protect or enforce patent rights, we may initiate patent litigation against third parties. Similarly, we may be sued by others. We also may become subject to proceedings conducted in the U.S. Patent and Trademark Office, including interference proceedings to determine the priority of inventions, or reexamination proceedings. In addition, any foreign patents that are granted may become subject to opposition, nullity, or revocation proceedings in foreign jurisdictions having such proceedings opposed by third parties in foreign jurisdictions having opposition proceedings. The defense and prosecution, if necessary, of intellectual property actions are costly and divert technical and management personnel away from their normal responsibilities.

No patent can protect its holder from a claim of infringement of another patent. Therefore, our patent position cannot and does not provide any assurance that the commercialization of our products would not infringe the patent rights of another. While we know of no actual or threatened claim of infringement that would be material to us, there can be no

assurance that such a claim will not be asserted.

If such a claim is asserted, there can be no assurance that the resolution of the claim would permit us to continue marketing the relevant product on commercially reasonable terms, if at all. We may not have sufficient resources to bring these actions to a successful conclusion. If we do not successfully defend any infringement actions to which we become a party or are unable to have infringed patents declared invalid or unenforceable, we may have to pay substantial monetary damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay commercialization and development of the affected products.

Any legal action against us or our collaborators claiming damages and seeking to enjoin developmental or marketing activities relating to affected products could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain licenses to continue to develop, manufacture, or market the affected products. Such a license may not be available to us on commercially reasonable terms, if at all.

An adverse determination in a proceeding involving our owned or licensed intellectual property may allow entry of generic substitutes for our products.

OTHER RISKS RELATED TO OUR COMPANY

*We are subject to Sarbanes-Oxley and the reporting requirements of federal securities laws, which can be expensive.

As a public reporting company, we are subject to the Sarbanes-Oxley Act of 2002, as well as to the information and reporting requirements of the Securities Exchange Act of 1934, as amended, and other federal securities laws. As a result, we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs associated with our public company reporting requirements and corporate governance requirements. As an example of public reporting company requirements, we evaluate the effectiveness of disclosure controls and procedures and of our internal control over financing reporting in order to allow management to report on such controls. Sarbanes-Oxley generally requires that a public reporting company's independent registered public accounting firm attest to the effectiveness of the company's internal control over financial reporting as of the end of each fiscal year in the company's Annual Report on Form 10-K. While our management has not currently identified any material weaknesses in our internal control over financial reporting, there can be no assurance that we will not identify identified any material weaknesses during the current year or that our systems will be deemed effective when our independent registered public accounting firm reviews the systems during 2010 and tests transactions. In addition, any updates to our finance and accounting systems, procedures and controls, which may be required as a result of our ongoing analysis of internal controls, or results of testing by our independent auditor, may require significant time and expense.

As a company with limited capital and human resources, our management has identified that there is a potential for a lack of segregation of duties due to the limited number of employees within our company's financial and administrative functions. Management believes that, based on the employees involved and the increased monitoring control procedures in place, risks associated with such lack of segregation are not significant and that the potential benefits of adding employees to segregate duties more clearly do not justify the associated added expense. However, our management is working to continuously monitor and improve internal controls and has set in place controls to mitigate the potential segregation of duties risk. In the event significant deficiencies or material weaknesses are indentified in our internal control over financial reporting that we cannot remediate in a timely manner, investors and others may lose confidence in the reliability of our financial statements and the trading price of our common stock and ability to obtain any necessary equity or debt financing could suffer. In addition, in the event that our independent registered public accounting firm is unable to rely on our internal controls over financial reporting in connection with its audit of our financial statements, and in the further event that it is unable to devise alternative procedures in order to satisfy itself as to the material accuracy of our financial statements and related disclosures, we may be unable to file our periodic reports with the Securities and Exchange Commission. This would likely have an adverse affect on the trading price of our common stock and our ability to secure any necessary additional equity or debt financing, and could result in the delisting of our common stock from the NASDAQ Capital Market, which would severely limit the liquidity of our common stock.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt, and limit who may call a special meeting of stockholders. In addition, Section 203 of the Delaware General Corporation Law, which prohibits business combinations between us and one or more significant stockholders unless specified conditions are met, may discourage, delay or prevent a third party from acquiring us.

Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at profit.

We have never paid dividends on our capital stock and we do not anticipate that we will pay any dividends for the foreseeable future. Accordingly, any return on an investment in our Company will be realized, if at all, only when you sell shares of our common stock.

Item 2. Unregistered Sale of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

During the nine months ended September 30, 2010, we purchased 364,993 shares of common stock in settlement of employee tax withholding obligations due upon the vesting of restricted stock. The following table provides information about these purchases of restricted shares for the nine months ended September 30, 2010:

Period	Total Number of Shares Purchased	Average Price Paid Per Share ($)
January 1 to 30, 2010	15,283	$ 3.10
February 1 to 28, 2010	-	$ -
March 1 to 31, 2010	-	$ -
April 1 to 30, 2010	-	$ -
May 1 to 31, 2010	-	$ -
June 1 to 30, 2010	-	$ -
July 1 to 31, 2010	-	$ -
August 1 to 31, 2010	-	$ -
September 1 to 30, 2010	349,710	$ 3.95
Total	364,993	

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. [Removed and Reserved.]

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The exhibits listed in the Exhibit Index immediately preceding such exhibits are filed as part of this report and such Exhibit Index is incorporated herein by reference.

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.

/s/ Jonathan Lewis
Jonathan Lewis, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)
Dated: November 4, 2010

/s/ Richard E. Bagley
Richard E. Bagley
President, Chief Operating Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated November 4, 2010

EXHIBIT INDEX

31.1*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications pursuant to 18 U.S.C. Section 1350

* Filed herewith