

ZIOPHARM ONCOLOGY INC  
Form 10-Q  
July 30, 2010

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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 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  
(State or other jurisdiction of  
incorporation or organization)

84-1475642  
(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:  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  Smaller reporting company   
(Do not check if a smaller reporting company)

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

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The number of shares of the registrant's Common Stock, \$.001 par value, outstanding as of July 27, 2010, was 48,826,555 shares.

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## 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)

	June 30, 2010	December 31, 2009
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 73,662	\$ 48,839
Prepaid expenses and other current assets	279	354
Total current assets	73,941	49,193
Property and equipment, net	216	255
Deposits	87	46
Other non-current assets	212	242
Total assets	\$ 74,456	\$ 49,736
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,143	\$ 1,789
Accrued expenses	1,139	1,261
Deferred rent - current portion	23	45
Total current liabilities	2,305	3,095
Deferred rent	60	66
Warrant liabilities	17,373	18,471
Total liabilities	19,738	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; 48,826,555 and 41,583,528 shares issued and outstanding at June 30, 2010 and December 31, 2009, respectively	49	42
Additional paid-in capital - common stock	131,593	96,133
Additional paid-in capital - warrants issued	22,834	23,073
Deficit accumulated during the development stage	(99,758)	(91,144)
Total stockholders' equity	54,718	28,104

Total liabilities and stockholders' equity	\$	74,456	\$	49,736
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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 June 30,		For the Six Months Ended June 30,		Period from September 9, 2003 (date of inception) through June 30, 2010
	2010	2009	2010	2009	
Research contract revenue	\$ -	\$ -	\$ -	\$ -	\$ -
Operating expenses:					
Research and development, including costs of research contracts	2,222	501	4,161	2,109	63,067
General and administrative	2,894	1,692	5,524	3,415	47,699
Total operating expenses	5,116	2,193	9,685	5,524	110,766
Loss from operations	(5,116)	(2,193)	(9,685)	(5,524)	(110,766)
Other income, net	13	2	22	2	3,932
Change in fair value of warrants	14,142	(208)	1,049	(216)	7,076
Net income (loss)	\$ 9,039	\$ (2,399)	\$ (8,614)	\$ (5,738)	\$ (99,758)
Net income (loss) per share - basic	\$ 0.21	\$ (0.11)	\$ (0.21)	\$ (0.27)	
Net income (loss) per share - diluted	\$ 0.19	\$ (0.11)	\$ (0.21)	\$ (0.27)	
Weighted average common shares outstanding used to compute net income (loss) per share - basic	42,364,791	21,307,297	41,253,076	21,305,824	
Weighted average common shares outstanding used to compute net income (loss) per share - diluted	48,822,686	21,307,297	41,253,076	21,305,824	

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 Six Months Ended June 30, 2010

(unaudited)

(in thousands, except share and per share data)

	Preferred Stock		Common Stock		Stockholders' Equity			Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Additional	Additional	Deficit	
					Capital	Paid-in	Accumulated	
					Common	Capital	During the	
					Stock	Warrants	Stage	
Balance at December 31, 2009	-	\$ -	41,583,528	\$ 42	\$ 96,133	\$ 23,073	\$ (91,144)	\$ 28,104
Stock-based compensation	-	-	-	-	2,174	-	-	2,174
Exercise of employee stock options	-	-	115,334	-	176	-	-	176
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	-	-	(15,282)	-	(47)	-	-	(47)
Forfeiture of unvested restricted common stock	-	-	(11,250)	-	-	-	-	-
Issuance of common stock in a registered direct offering, net of commissions and expenses of \$2,203	-	-	7,000,000	7	32,797	-	-	32,804
Net loss	-	-	-	-	-	-	(8,614)	(8,614)
Balance at June 30, 2010	-	\$ -	48,826,555	\$ 49	\$ 131,593	\$ 22,834	\$ (99,758)	\$ 54,718

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 Six Months Ended June 30,		Period from September 9, 2003 (date of inception) through June 30, 2010
	2010	2009	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (8,614)	\$ (5,738)	\$ (99,758)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation and amortization	116	169	1,577
Stock-based compensation	2,174	749	11,079
Change in fair value of warrants	(1,049)	216	(7,076)
Loss on disposal of fixed assets	-	-	9
<b>Change in operating assets and liabilities:</b>			
<b>(Increase) decrease in:</b>			
Prepaid expenses and other current assets	76	174	(279)
Other noncurrent assets	30	48	(212)
Deposits	(41)	-	(87)
<b>Increase (decrease) in:</b>			
Accounts payable	(646)	(1,033)	1,143
Accrued expenses	(122)	(1,407)	1,139
Deferred rent	(28)	(13)	83
<b>Net cash used in operating activities</b>	<b>(8,104)</b>	<b>(6,835)</b>	<b>(92,382)</b>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(78)	(1)	(1,803)
Proceeds from sale of property and equipment	-	-	1
<b>Net cash used in investing activities</b>	<b>(78)</b>	<b>(1)</b>	<b>(1,802)</b>
<b>Cash flows from financing activities:</b>			
Stockholders' capital contribution	-	-	500
Proceeds from exercise of stock options	176	-	315
Payments to employees for repurchase of common stock	(47)	-	(427)
Proceeds from exercise of warrants	72	-	349
Proceeds from issuance of common stock and warrants, net	32,804	-	150,349
Proceeds from issuance of preferred stock, net	-	-	16,760
<b>Net cash provided by financing activities</b>	<b>33,005</b>	<b>-</b>	<b>167,846</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>24,823</b>	<b>(6,836)</b>	<b>73,662</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>48,839</b>	<b>11,379</b>	<b>-</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 73,662</b>	<b>\$ 4,543</b>	<b>\$ 73,662</b>
<b>Supplementary disclosure of cash flow information:</b>			
Cash paid for interest	\$ -	\$ -	\$ -

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Cash paid for income taxes	\$	-	\$	-	\$	-
Supplementary disclosure of noncash investing and financing activities:						
Warrants issued to placement agents and investors	\$	-	\$	-	\$	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 June 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 June 30, 2010, the Company's accumulated deficit was approximately \$99.8 million. The Company currently believes that it has sufficient capital to fund development and commercialization activities, principally for palifosfamide, 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

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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 six months ended June 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 June 30, 2010 are as follows:

Description	Fair Value Measurements at Reporting Date Using			
	Balance as of June 30, 2010	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liability	\$ 17,373	\$ -	\$ 17,373	\$ -

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 or disclosable subsequent events.

## 5. Net Income (Loss) per Share

Basic net earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding for the period. Diluted net earnings (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.

in thousands, except share and per share data	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2010	2009	2010	2009
<b>Basic</b>				
Net income (loss)	\$ 9,039	\$ (2,399)	\$ (8,614)	\$ (5,738)
Weighted-average common shares outstanding	42,364,791	21,307,297	41,253,076	21,305,824
Earnings per share, basic	\$ 0.21	\$ (0.11)	\$ (0.21)	\$ (0.27)
<b>Diluted</b>				
Net income (loss)	\$ 9,039	\$ (2,399)	\$ (8,614)	\$ (5,738)
Weighted-average common shares outstanding	42,364,791	21,307,297	41,253,076	21,305,824
<b>Effect of dilutive securities</b>				
Stock options	1,292,335	-	-	-
Unvested restricted common stock	1,496,334	-	-	-
Warrants	3,669,226	-	-	-
Dilutive potential common shares	6,457,895	-	-	-
Shares used in calculating diluted earnings per share	48,822,686	21,307,297	41,253,076	21,305,824
Earnings per share, diluted	\$ 0.19	\$ (0.11)	\$ (0.21)	\$ (0.27)

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 earnings (loss) per share for the three and six months ended June 30, 2010 and 2009 as the result would be antidilutive. Such potential common shares at June 30, 2010 and 2009 consist of the following:

For the Three Months Ended June 30,		For the Six Months Ended June 30,	
2010	2009	2010	2009

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Stock options	227,000	3,220,916	3,564,685	3,220,916
Unvested restricted common stock	-	483,667	1,496,334	483,667
Warrants	3,756,709	5,039,659	15,924,642	5,039,659

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies

License agreements and patents

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 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). No milestones have been reached or expensed as of June 30, 2010.

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 June 30, 2010. DEKK-Tec is entitled to receive 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 six months of 2009.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies – (continued)

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 isophosphoramidate 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 isophosphoramidate 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 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 have been reached or expensed as of June 30, 2010.

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, as well as 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.

In October 2009, the Baxter License Agreement was amended to allow the Company to manufacturer indibulin. No milestones have been reached or expensed as of June 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 June 30, 2010. The Company expensed \$120 thousand during the first six months of 2009 and 2010 for consulting services per the aforementioned agreement. No milestones have been reached or expensed as of June 30, 2010.

## 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 June 30, 2010 and December 31, 2009 were as follows:

	June 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

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. In applying the methodology, the Company concluded that certain warrants issued by the Company in May 2005 and December 2009 have terms that do not meet the criteria to be considered indexed to the Company's own stock and therefore are classified in the liability section of the Balance Sheets. 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.

On June 30, 2010, the liability-classified warrants were valued at \$17.4 million using a Black-Scholes valuation model. The change in the fair value of the warrant liability was a gain of \$14.1 million and \$1.0 million for the three and six months ended June 30, 2010 and a loss of \$208 thousand and \$216 thousand for the three and six months ended June 30, 2009, respectively, and was charged to other income (loss) in the Statements of Operations. The following assumptions were used in the Black-Scholes valuation model at June 30, 2010 and December 31, 2009:

	June 30, 2010	December 31, 2009
Risk-free interest rate	0.59-1.56%	1.37 - 2.65%
Expected life in years	1.92-4.43	2.42 - 4.92
Expected volatility	92-116%	105%
Expected dividend yield	0	0

During the first six 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 six months of 2009.



## ZIOPHARM Oncology, Inc. (a development stage company)

## NOTES TO FINANCIAL STATEMENTS (unaudited)

## 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:

(in thousands)	For the three months ended June 30,		For the six months ended June 30,	
	2010	2009	2010	2009
Research and development, including costs of research contracts	\$ 206	\$ 87	\$ 414	\$ 155
General and administrative	1,035	252	1,760	594
Stock-based employee compensation expense	\$ 1,241	\$ 339	\$ 2,174	\$ 749

The Company granted 62 thousand and 152 thousand stock options during the three and six months ended June 30, 2010 that had a weighted-average grant date fair value of \$3.68 and \$3.63 per share, respectively. During the three and six months ended June 30, 2009, the Company granted 805 thousand and 815 thousand stock options that had a weighted-average grant date fair value of \$0.53 per share for each period.

For the six months ended June 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 six months ended June 30,	
	2010	2009
Risk-free interest rate	1.93 - 2.75%	1.31-1.44%
Expected life in years	5	5
Expected volatility	89 - 90%	102-103%
Expected dividend yield	0	0

## ZIOPHARM Oncology, Inc. (a development stage company)

## NOTES TO FINANCIAL STATEMENTS (unaudited)

## 9. Stock-Based Compensation – (continued)

Stock option transactions under the Company's stock option plan for the six months ended June 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	152,000	5.14		
Exercised	115,334	1.53		
Cancelled	6,667	5.19		
Outstanding, June 30, 2010	3,564,685	\$ 2.96	7.13	\$ 3,264
Options exercisable, June 30, 2010	2,646,185	\$ 2.94	6.45	\$ 2,820
Options available for future grant	3,119,734			

A summary of the status of non-vested restricted stock for the six months ended June 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	74,583	\$ 2.70
Cancelled	11,250	\$ 4.34
Non-vested, June 30, 2010	1,496,334	\$ 2.49

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 capsule 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 (Zinapar<sup>TM</sup>, ZIO-101), palifosfamide (Zymafos<sup>TM</sup>, ZIO-201), and indibulin (Zybulin<sup>TM</sup>, ZIO-301), our primary focus has been and remains on palifosfamide development and now more specifically on completing the recently initiated palifosfamide pivotal Phase III trial as announced subsequent to the quarter in July to support registration in combination with doxorubicin in the front -line setting of soft tissue sarcoma.

- ZIO-101 or darinaparsin (Zinapar<sup>TM</sup>) 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<sup>®</sup>] or "ATO") has been approved in the United States and 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 darinaarsin and provided support for the development of an oral capsule form of the drug, and established synergy of darinaarsin 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 capsule 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 in the same setting.

- ZIO-201 or palifosfamide (Zymafos™), 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 licensed 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 of palifosfamide with doxorubicin well tolerated in the Phase I trial and evidencing activity, 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 a Special Protocol Assessment (SPA) process. Although the Company elected to engage in the SPA process, the Company 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 preparing 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 capsule form of palifosfamide is entering Phase I study while additional preclinical work continues in pediatric cancer.

- ZIO-301 or indibulin (Zybulin™), 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 Ixempra™ 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 capsule 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 Tarceva™ and Xeloda™, respectively. Favorable activity and safety profile of oral indibulin with oral Xeloda™ 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.



## 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 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 18 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 \$29.5 on research and development expenses and approximately \$6.8 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 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 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 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 as the first step for a pivotal trial in the same setting. The Phase I trial with an oral form of darinaparsin is again ongoing. The Company is actively seeking partners and other 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.

Intravenous palifosfamide, the proprietary stabilized form of isophosphoramidate 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. IV palifosfamide will also be studied in SCLC while 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 capsule 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™ and also with Xeloda™ have been conducted. At the 2009 ASCO Annual Meeting, the Company presented favorable preliminary activity and safety data of oral indibulin with oral Xeloda™. 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 six months ended June 30, 2010 compared to three and six months ended June 30, 2009

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

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

	Three months ended June 30,			Six months ended June 30,
2010	2009	Change	2010	