ZIOPHARM ONCOLOGY INC Form 10-Q May 15, 2009

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 March 31, 2009
 OR
 OR TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

Commission File Number 001-33484

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: b = 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
		(Do not check if a smaller reporting company)	company þ

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

The number of shares of the registrant's Common Stock, \$.001 par value, outstanding as of May 14, 2009, was 21,848,464 shares.

ZIOPHARM Oncology, Inc. (a development stage company)

Table of Contents

		Page
<u>Part I -</u>	Financial Information	
<u>Item 1.</u>	Financial Statements	
	Balance Sheets (unaudited) as of March 31, 2009 and December 31, 2008	3
	Statements of Operations (unaudited) for the three months ended March 31, 2009 and 2008 and the period from September 9, 2003 (date of inception) through March 31, 2009	4
	Statements of Cash Flows (unaudited) for the three months ended March 31, 2009 and 2008 and the period from September 9, 2003 (date of inception) through March 31, 2009	5
	Notes to Financial Statements (unaudited)	6
<u>Item 2.</u>	Management's Discussion and Analysis of Financial Condition and Results of Operations	14
<u>Item 3.</u>	Quantitative and Qualitative Disclosures about Market Risk	22
<u>Item 4.</u>	Controls and Procedures	22
<u>Part II</u>	Other Information	
<u>Item 1.</u>	Legal Proceedings	23
Item 1A.	Risk Factors	23
<u>Item 2.</u>	Unregistered Sale of Equity Securities and Use of Proceeds	35
<u>Item 3.</u>	Defaults upon Senior Securities	35
<u>Item 4.</u>	Submission of Matters to a Vote of Security Holders	35
<u>Item 5.</u>	Other Information	35
<u>Item 6.</u>	Exhibits	35
<u>SIGNATURES</u>		36

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)

	arch 31, 2009	Dec	ember 31, 2008
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 6,768	\$	11,379
Prepaid expenses and other current assets	238		327
Total current assets	7,006		11,706
Property and equipment, net	489		489
Deposits	87		87
Other non current assets	291		291
Total assets	\$ 7,873	\$	12,573
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$ 1,621	\$	2,639
Accrued expenses	2,298		3,137
Deferred rent - current portion	37		-
Total current liabilities	3,956		5,776
Deferred rent	100		58
Warrant liabilities	80		-
Total Liabilities	4,136		5,834
commitments and contingencies (note 4)			
Stockholders' equity:			
Common stock, \$.001 par value; 280,000,000 shares authorized; 21,848,464 and 21,860,464 shares issued and outstanding at March 31, 2009 and December 31, 2008,			
respectively	22		22
Preferred stock, \$0.01 par value; 30,000,000 shares authorized and no shares issued			
and outstanding	_		_
Additional paid-in capital	71,683		71,274
Warrants issued	18,865		20,504

Deficit accumulated during the development stage	(86,833)	(85,061)
Total stockholders' equity	3,737	6,739
Total liabilities and stockholders' equity	\$ 7,873	\$ 12,573

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

Table of Contents

ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF OPERATIONS (unaudited)

(in thousands, except share and per share data)

	Fc	or the Three Mon 31 2009	Inded March 2008	Period from September 9, 2003 (date of inception) through March 31, 2009
Research contract revenue	\$	-	\$ -	\$ -
Operating expenses: Research and development, including costs of research contracts General and administrative Total operating expenses Loss from operations		1,608 1,724 3,332 (3,332)	6,074 2,745 8,819 (8,819)	55,958 36,332 92,290 (92,290)
Interest income, net Change in fair value of warrants Net loss	\$	(7) (3,339)	\$ 196 - (8,623)	3,897 (7) \$ (88,400)
Basic and diluted net loss per share	\$	(0.16)	\$ (0.41)	
Weighted average common shares outstanding used to compute basic and diluted net loss per share		21,304,334	21,228,964	

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

4

Table of Contents

ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF CASH FLOWS (unaudited)

(in thousands)

				Period from September 9, 2003 (date of inception)
	For the Three M		is Ended	
	Marcl	n 31,		through
	2009		2008	March 31, 2009
Cash flows from operating activities:				
Net loss	\$ (3,339)	\$	(8,623)	\$ (88,400)
Adjustments to reconcile net loss to net cash used in				
operating activities:				
Depreciation and amortization	83		89	1,213
Stock-based compensation	410		468	7,133
Change in fair value of warrants	7		-	7
Loss on disposal of fixed assets	-		-	9
Change in operating assets and liabilities:				
(Increase) decrease in:				
Prepaid expenses and other current assets	89		163	(238)
Other noncurrent assets	3		(2)	(288)
Deposits	-		-	(87)
Increase (decrease) in:				
Accounts payable	(1,018)		(261)	1,621
Accrued expenses	(839)		686	2,298
Deferred rent	(6)		8	52
Net cash used in operating activities	(4,610)		(7,472)	(76,680)
Cash flows from investing activities:				
Purchases of property and equipment	(1)		(69)	(1,630)
Proceeds from sale of property and equipment	-		-	1
Net cash used in investing activities	(1)		(69)	(1,629)
Cash flows from financing activities:				
Stockholders' capital contribution	-		-	500
Proceeds from exercise of stock options	-		-	66
Proceeds from issuance of common stock and warrants, net	-		-	67,751
Proceeds from issuance of preferred stock, net	-		-	16,760
Net cash provided by financing activities	-		-	85,077
Net increase (decrease) in cash and cash equivalents	(4,611)		(7,541)	6,768
Cash and cash equivalents, beginning of period	11,379		35,028	-
Cash and cash equivalents, end of period	\$ 6,768	\$	27,487	\$ 6,768

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, in			
connection with private placement	\$ -	\$ - \$	20,208
Preferred stock conversion to common stock	\$ -	\$ - \$	16,760
Warrants converted to common shares	\$ -	\$ - \$	18

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 treatment.

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 March 31, 2009, as defined by the Financial Accounting Standards Board ("FASB") in Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises." 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 March 31, 2009, the Company's accumulated deficit was approximately \$86.8 million. With the proceeds from its 2007 common stock offering, which was completed on February 23, 2007, the Company currently believes that it has sufficient capital to fund development and commercialization activities, principally for palifosfamide, late into the second quarter of 2010. 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 focus and direction of its research and development programs, competitive and technical advances, patent developments 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. The Company is working with placement agents to obtain additional financing. 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 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 or pursue merger or divestiture strategies. There can be no assurances that forecasted results will be achieved or that additional financing will be obtained. 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 unaudited financial statements and the notes thereto for the year ended December 31, 2008 included in the Company's Form 10-K.

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 months ended March 31, 2009 are not necessarily indicative of the results to be expected for the full fiscal year.

Table of Contents

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

2. Summary of Significant Accounting Policies

Except for the policies listed below, our significant accounting policies were identified in the Company's Form 10-K for the fiscal year ended December 31, 2008.

Warrants

On January 1, 2009, the Company adopted Emerging Issues Task Force Issue 07-05, "Determining whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock", ("EITF 07-05"). This Issue prescribes the methodology by which a company must determine whether a financial instrument is a derivative within the meaning of Statement of Financial Accounting Standard No. 133 Accounting for Derivative Instruments and Hedging Activities ("FASB No. 133"). In applying the methodology contained in EITF 07-05 and FASB No. 133 it was concluded that certain warrants issued by the Company in May 2005 have terms that do not meet the criteria to be considered indexed to the Company's own stock and therefore should be re-classified from the equity section to the liability section of the Balance Sheets. . The warrant is subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of other income (expense). Fair value is measured using the Black-Scholes valuation model.

Fair Value Measurements

Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS 157"). In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, "Effective Date of FASB Statement No. 157," which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. SFAS 157 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 under SFAS 157 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 under SFAS 157 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.

The adoption of this statement did not have a material impact on the Company's results of operations and financial condition.

Assets and liabilities measured at fair value on a recurring basis as of March 31, 2009 are as follows: (\$ in thousands) Fair Value Measurements at Reporting Date Using

	Balar as		in A Mar	ed Prices Active kets for entical		Signif Otł Obser	ner	Signifi Unobse	
Description	of Ma 31, 20		Assets/Lia	biities (Le 1)	evel	Inp (Lev		Inpu (Leve	
Warrant liability	\$	80	\$	-		\$	80	\$	-

The warrants were valued using a Black-Scholes valuation model. See note 5 for additional disclosure on the valuation methodology and significant assumptions.

7

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

2. Summary of Significant Accounting Policies - (continued)

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. On February 6, 2008, the FASB announced it issued a FASB Staff Position (FSP) to allow a one-year deferral of adoption of SFAS 157 for nonfinancial assets and nonfinancial liabilities that are recognized at fair value on a nonrecurring basis. SFAS 157 provides a common fair value hierarchy for companies to follow in determining fair value measurements in the preparation of financial statements and expands disclosure requirements relating to how such fair value measurements were developed. SFAS 157 clarifies the principle that fair value should be based on the assumptions that the marketplace would use when pricing an asset or liability, rather than company specific data. The Company adopted the provisions of this statement relative to financial assets and liabilities on January 1, 2009. Adoption of this new standard did not have a material impact on the Company's financial position, results of operations or cash flows.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS 141(R)"). SFAS 141(R) expands the definition of a business combination and requires the fair value of the purchase price of an acquisition, including the issuance of equity securities, to be determined on the acquisition date. SFAS 141(R) also requires that all assets, liabilities, contingent considerations, and contingencies of an acquired business be recorded at fair value at the acquisition date. In addition, SFAS 141(R) requires that acquisition costs generally be expensed as incurred, restructuring costs generally be expensed in periods subsequent to the acquisition date, changes in accounting for deferred tax asset valuation allowances be expensed after the measurement period, and acquired income tax uncertainties be expensed after t he measurement period. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 with early adoption prohibited. SFAS 141(R) is effective for the Company beginning January 1, 2009 and did not have an impact but may change accounting for business combinations on a prospective basis.

In April 2008, the FASB issued EITF 07-05, "Determining whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock", ("EITF 07-05"). EITF 07-05 provides guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in paragraph 11(a) of SFAS 133. EITF 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and early application is not permitted. Adoption of this new standard decreased equity warrants by \$1,639,000, decreased deficit accumulated during the development stage by \$1,566,000 and increased warrant liability by \$73,000. See Note 6, "Warrants" for additional disclosure.

In April 2009, the FASB issued FASB Staff Position FAS 157-4, Determining Whether a Market Is Not Active and a Transaction Is Not Distressed, or FSP FAS 157-4; FSP FAS 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS 157. FSP FAS 157-4 provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed, is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures. This standard is effective for periods ending after June 15, 2009. We are evaluating the impact that it will have on our financial statements, if any.

In April 2009 the FASB issued FASB Staff Position FAS 115-2, FAS 124-2, and EITF 99-20-2, Recognition and Presentation of Other-Than-Temporary Impairments, or FSP FAS 115-2, FAS 124-2, and EITF 99-20-2; and FSP FAS 115-2, FAS 124-2, and EITF 99-20-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. This FSP applies to debt securities. This standard is effective for periods ending after June 15, 2009. We are evaluating the impact that it will have on our financial statements, if any.

In April 2009 the FASB issued FASB Staff Position FAS 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments, or FSP FAS 107-1 and APB 28-1. FSP FAS 107-1 and APB 28-1, amends FASB Statement No. 107, Disclosures about Fair Value of Financial Instruments, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements. This FSP also amends APB Opinion No. 28, Interim Financial Reporting, to require those disclosures in all interim financial statements. This standard is effective for periods ending after June 15, 2009. We are evaluating the impact that it will have on our financial statements, if any.

3. 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. The Company's potential dilutive shares, which include outstanding common stock options, unvested restricted stock and warrants have not been included in the computation of diluted net loss per share for any of the periods presented as the result would be antidilutive. Such potential common shares at March 31, 2009 and 2008 consist of the following:

	March 31,			
	2009	2008		
Stock options	2,581,256	2,834,666		
Unvested restricted stock	541,167	170,000		
Warrants	5,039,659	5,039,659		
	8,162,082	8,044,325		

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

4. 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 US 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.

In October 2004, the Company received a notice of allowance for US Patent Application No. 10/337969, entitled "S-dimethylarsino-thiosuccinic acid S-dimethylarsino-2-thiobenzoic acid S-(simethylarsino) glutathione as treatments for cancer." The patent application claims both therapeutic uses and pharmaceutical compositions containing a novel class of organic arsenicals, including darinaparsin, for the treatment of cancer. In February 2006, we announced that a second organic arsenic case has been issued under U.S. Patent No. 6995188. This patent provides further coverage of cancer treatment using organic arsenic, including darinaparsin, in combination with other agents or therapies. On July 29, 2008, an additional organic arsenic patent was issued under U.S. Patent No. 7,405,314, providing further coverage of cancer treatment using organic arsenic, including higher purity darinaparsin. Currently there are corresponding foreign applications relating to darinaparsin in various foreign countries.

As partial consideration for the license rights obtained, the Company made an upfront payment of \$125 thousand and granted the Licensors 250,487 (500,000 pre-Merger) shares of our common stock. The Company recorded expense for the \$125 thousand upfront payment and recognized research and development expense of \$426 thousand in connection with the issuance of the 250,487 shares of common stock in the year ended December 31, 2004. In addition, the Company issued options to purchase an additional 50.222 (100.250 pre-Merger) shares outside the 2003 Stock Option Plan for \$0.002 per share following the successful completion of certain clinical milestones. Upon the filing of an Investigation New Drug Application ("IND") for darinaparsin in 2005, 12,555 (25,063 pre-Merger) shares vested and the Company recognized compensation expense of \$54 thousand. Upon the completion of dosing of the last patient for both phase I clinical trials in 2007, 25,111 (50,125 pre-Merger) shares vested and the Company recognized expense of \$120 thousand. The remaining 12,556 (25,062 pre-Merger) 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") for darinaparsin). The options were subject to accounting pursuant to EITF 96-18, and therefore were valued at the date which the milestones are achieved. In addition, the Licensors are entitled to receive certain milestone payments (the "Anderson Milestones"), including \$100,000 that was paid upon the commencement of phase I clinical trial for which the Company recognized the expense in the year ended December 31, 2005 and \$250 thousand upon the dosing of the first patient in the Registrant-sponsored phase II clinical trial for darinaparsin which was recognized in the vear ended December 31, 2006. 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 \$4.9 million. In addition, the Licensors

are entitled to receive royalty payments on sales from a licensed product should such a product be approved for commercial sale and sales of a licensed product be effected in the United States, Canada, the European Union or Japan. The Licensors also will be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. For the years ended December 31, 2007 and 2006, the Company expensed \$100 thousand for payments made to the Licensors to conduct scientific research. The Company has the exclusive right to all intellectual property rights resulting from such research pursuant to the terms of the license agreement. These sponsored research agreements and any related extensions expired in February 2008 with no payments being made in 2008 or the first quarter of 2009.

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).

Table of Contents

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

4. 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 a \$50 thousand up-front payment in the year ended December 31, 2004.

In consideration for the license rights, DEKK-Tec is entitled to receive milestone payments upon the occurrence of certain achievements of certain milestones, in varying amounts which on a cumulative basis may total \$3,900,000. Of the aggregate milestone payments, most of the total amount will be creditable against future royalty payments, as referenced below. During the year ended December 31, 2006, the Company recorded a charge of \$100 thousand for achieving phase II milestones. Additionally in 2004, the Company issued DEKK-Tec an option to purchase 27,616 shares of our common stock for \$0.02 per share. The options were subject to accounting pursuant to EITF 96-18, and therefore are valued at the date which the milestones are achieved. Upon the execution of the license agreement, 6,904 shares vested and were exercised in the fiscal year ended December 31, 2005 and resulted in a recorded charge of \$12 thousand to research and development expense. The remaining options will vest upon certain milestone events, culminating with final FDA approval of the first NDA submitted by the Company (or by our sublicensee) for palifosfamide. DEKK-Tec is entitled to receive royalty payments on the sales of palifosfamide should it be approved for commercial sale. There were no payments during the first quarter of 2009.

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 (the "SRI Option").

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 "SRI Research Program"). The option agreement was exercised on February 13, 2007 and annual payments of \$25 thousand were made in the years ended December 31, 2008 and 2007 for maintenance of this option agreement. There were no payments during the first quarter of 2009.

License Agreement with Baxter Healthcare Corporation

On November 3, 2006, the Company signed a definitive Asset Purchase Agreement (for indibulin) and License Agreement (to Baxter's proprietary nanosuspension technology) with affiliates of Baxter Healthcare Corporation. Indibulin is a novel anti-cancer agent that binds to tubulin, one of the essential proteins for chromosomal segregation, and targets mitosis like the taxanes and vinca alkaloids. It is available as both an oral and a proprietary nanosuspension intravenous form. Molecules that target mitosis and inhibit cell division (antimitotic agents) are a major focus of cancer research and they are among the most widely used anti-cancer drugs in oncology

today. Among the more well known antimitotic drugs are the taxanes (paclitaxel, docetaxel) and the vinca alkaloids (vincristine, vinblastine). The terms of the agreement include an upfront cash payment of approximately \$1.1 million, which has been expensed as purchased research and development in the year ended December 31, 2006. In addition, \$15 thousand was paid for annual patent and license maintenance fee and \$100 thousand was paid for existing inventory during 2006. During the year ended December 31, 2007, the Company recorded an expense of \$625 thousand related to the achievement of a milestone for the successful US IND application for indibulin and also paid an additional \$15 thousand for the annual patent and license maintenance fee. In 2008, the Company paid \$15 thousand for the annual patent and license maintenance fee. In addition to the upfront costs, there will be additional milestone payments that could amount to approximately \$8 million in the aggregate and royalties on net sales. The purchase price includes the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories. There were no payments during the first quarter of 2009.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

4. Commitments and Contingencies – (continued)

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. The initial term is one year and may be renewed or extended. The Company shall pay Harmon Hill \$20 thousand per month for the consulting services. In addition the Company agrees 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. A 1% award of royalties received from a sublicensee will be given to Harmon Hill in any event that the Specified Drug is sublicensed. During the year ended December 31, 2008, the Company paid and expensed \$180 thousand for consulting services per aforementioned contract. No milestones have been reached or accrued during the three months ended March 31, 2009 or the year ended December 31, 2008.

5. Warrants

On January 1, 2009, the Company adopted Emerging Issues Task Force Issue 07-05, "Determining whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock", ("EITF 07-05"). This Issue prescribes the methodology by which a company must determine whether a financial instrument is a derivative within the meaning of Statement of Financial Accounting Standard No. 133 Accounting for Derivative Instruments and Hedging Activities ("FASB No. 133"). In applying the methodology contained in EITF 07-05 and FASB No. 133 it was concluded that certain warrants issued by the Company in May 2005 have terms that do not meet the criteria to be considered indexed to the Company's own stock and therefore should be re-classified from the equity section to the liability section of the Balance Sheets.

In May 2005, the Company issued 419,786 placement warrants for services performed, 11,083 of which were subsequently exercised. The remaining 408,703 warrants were originally valued at \$1,639,000. These warrants have a provision for price protection should common stock or warrants be subsequently issued at less than the warrants' exercise price of \$4.75 per share. This provision was triggered in 2006 when stock was sold at \$4.63 per share in a PIPE financing. Accordingly, the warrants were re-priced at \$4.69. The application of FASB No. 133 requires that the warrants be valued at each financial reporting period and the resulting gain or loss be recorded as other income (expense) in the Statements of Operations. Using a Black-Scholes model, the warrants were valued at \$73,000 on January 1, 2009, when EITF 07-05 was adopted. The reclassification attributed to the adoption of EITF 07-05 had the following cumulative effect on the Balance Sheets:

Liabilities Stockholders' Equity Deficit Accumulated During the Development Warrants Stage

Edgar Filing: ZIOPHARM ONCOLOGY INC - Form 10-Q

As reported on December 31, 2008	\$ - \$	20,504	\$ (85,061)
Re-classification	73	(1,639)	1,566
Balance on January 1, 2009	\$ 73 \$	18,865	\$ (83,495)

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

5. Warrants – (continued)

On March 31, 2009, the warrants were valued at \$80,000 using a Black-Scholes valuation model. The change in the fair value of the warrant liability of \$7,000, was charged to other income (loss) in the Statements of Operations. The following assumptions were used at January 1, 2009 and March 31, 2009:

	January 1, 2009	March 31, 2009
Risk-free interest rate	1.55%	1.67%
Expected life in years	3.42	3.17
Expected volatility	102%	103%
Expected dividend yield	0	0

6. Stock-Based Compensation

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

	For the three months ended March 31,			
(in thousands)	2009		2008	
Research and development, including				
costs of research contracts	\$	69	\$	180
General and administrative		341		288
Share based employee compensation				
expense before tax		410		468
Income tax benefit		-		-
Net share based employee				
compensation expense	\$	410	\$	468

During the three months ended March 31, 2009, the Company granted 10,000 stock options at an exercise price of \$0.80 per share. The weighted-average grant date fair value was \$0.60 per share.

For the three months ended March 31, 2009 and 2008, 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 three months ended March 31,			
	2009	2008			
Risk-free interest rate	1.44%	2.48 - 2.98%			

Expected life in years	5	5
Expected volatility	102%	95 - 96%
Expected dividend yield	0	0

Table of Contents

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Stock-Based Compensation – (continued)

Transactions under the stock option plan for the three months ended March 31, 2009 are as follows:

(in thousands, except share and per share data)	Number of Shares	rage	Weighted- Average Contractual Term (Years)	ggregate Intristic Value
Outstanding, December 31, 2008	2,738,089	\$ 3.43		
Granted	10,000	\$ 0.80		
Exercised	-			
Cancelled	166,833	\$ 2.12		
Outstanding, March 31, 2009	2,581,256	\$ 3.50	7.09	\$ 148
Options exercisable, March 31, 2009	1,772,142		6.93	\$ 148
Options available for future grant	754,561			

A summary of the status of non-vested restricted stock for the three months ended March 31, 2009 is as follows:

	Number of Shares	Weighted-Avera Grant Date Fair Value	
Outstanding, December 31, 2008	586,500	\$	1.15
Granted	-		
Vested	(33,333)	\$	2.73
Cancelled	(12,000)	\$	0.83
Outstanding, March 31, 2009	541,167	\$	1.19

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 can be administered by intravenous ("IV") and/or oral capsule forms of administration. 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 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. The Company 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 and/or II studies for three product candidates identified as darinaparsin (ZinaparTM, ZIO-101), palifosfamide (ZymafosTM, ZIO-201), and indibulin (ZybulinTM, ZIO-301), the Company's current focus is on palifosfamide to support a registration trial for palifosfamide in combination with doxorubicin in the front- and second-line setting of soft tissue sarcoma. We anticipate the initiation of such a trial as early as the first half of 2010.

•ZIO-101, or darinaparsin 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 ®]; "ATO") has been approved in the United States and the European Union for the treatment of acute promyelocytic leukemia ("APL"), a precancerous condition. 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 inorganic arsenic, particularly with regard to cardiac toxicity. In vitro testing of darinaparsin using the National Cancer Institute's human cancer cell panel detected

activity against a series of tumor cell lines including lung, colon, brain, melanoma, ovarian, and kidney cancer. Moderate activity was detected against breast and prostate cancer. 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. Preliminary 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 capsule form of the drug, and established synergy of darinaparsin in combination with other approved anti-cancer agents.

Phase I testing of the intravenous form of darinaparsin in solid tumors and hematological cancers has been completed. The Company has reported clinical activity and, importantly, a safety profile from these studies as predicted by preclinical results. The Company is nearing completion of Phase II studies in advanced myeloma, in certain other hematological cancers, and primary liver cancer. In addition, the Company is completing two Phase I studies with an oral capsule form of darinaparsin. Preliminary favorable results from the trial with IV-administered darinaparsin in hematologic cancers have been reported. Initial study results indicate efficacy and a favorable safety profile in various types of blood cancers. In the ongoing Phase I trials, preliminary reported data in solid tumors indicate the oral form is active and well tolerated. The Company is actively seeking a partner or partners, or other sources of funding, to progress both the IV and oral programs into phase II study in particular sub-types of non-Hodgkin's lymphoma. If we cannot find a partner to fund the development of either one or both forms of darinaparsin, we would intend to complete the ongoing studies which are included in the Company's current estimate of expenses and then place the development program for darinaparsin on hold.

•ZIO-201, or palifosfamide, is 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. Like cyclophosphamide and ifosfamide, palifosfamide is an alkylating agent. The Company believes 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. If osfamide has been shown to be effective at high doses in the treatment of sarcoma and lymphoma, either by itself or in combination with other anticancer agents. Ifosfamide is approved by the U.S. Food and Drug Administration ("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 U.S. Food and Drug Administration. 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 ifosfamideand/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 a Phase I dose escalation study, Phase II testing of the intravenous form of palifosfamide as a single agent to treat advanced sarcoma has been completed. 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. With an earlier form of palifosfamide, which has been substituted in the clinic with a new form, kidney toxicity (Fanconi's Syndrome) and acute renal failure were reported primarily at doses significantly higher than the dose currently used in clinical trials. In clinical study to date with the new form, there have been no definitive reports of drug related kidney toxicity and palifosfamide has been otherwise well tolerated. The Company reported clinical activity of palifosfamide when used alone in the Phase II study addressing advanced sarcoma. Following review of the preclinical combination studies, clinical data, and discussion with sarcoma experts, the Company initiated a Phase I dose escalation study of palifosfamide in combination with doxorubicin in patients with metastatic or unresectable soft tissue sarcoma. In light of the reported favorable phase II clinical activity data and with the combination of palifosfamide with doxorubicin well tolerated in the phase II trial and evidencing activity, the Company has initiated a Phase II randomized controlled trial to compare doxorubicin plus palifosfamide to doxorubicin alone in patients with front and second-line metastatic or unresectable soft tissue sarcoma. Data from the

initial patients in this trial are expected to shape a registration trial in the same setting which is expected to initiate as early as the first half of 2010. The Company is also developing an oral capsule form of palifosfamide to be studied clinically following further data from the IV trials and partnering or other sources of funding and is considering other phase II trials in other solid tumors as funding becomes available. Orphan Drug Designation for palifosfamide has been obtained in both the United States and the European Union for the treatment of soft tissue sarcomas.

•ZIO-301, or indibulin, is a novel, orally available small molecular-weight inhibitor of tubulin polymerization that was acquired from Baxter Healthcare 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 ongoing 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 paclitaxel or related compounds are currently on the market in the United States.

Indibulin has completed a Phase I trial in Europe and two additional Phase I trials are nearing completion in the U.S. in patients with advanced solid tumors. The Company has reported signs of 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 have been enrolled with Tarceva® and Xeloda® and are reaching completion. Preclinical work with consultant Dr. Larry Norton is continuing to explore dose scheduling for the clinical setting. With the data from the phase I single agent and combination studies showing activity and with a dose limiting toxicity not yet reached, the Company has decided to continue the indibulin development program with a focus on Dr. Norton's dose scheduling findings and, subject to the availability of additional funding, with dose escalation to maximum tolerated dose using a schedule selected from the preclinical work.

Although we intend to continue with clinical development of darinaparsin for lymphoma in conjunction with a partner, of palifosfamide for soft tissue sarcoma, and of indibulin for solid tumors, 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 is focused on completing the first 50 patients in the randomized Phase II trial for palifosfamide, partnering darinaparsin, and further establishing dose scheduling and maximum tolerated dose with indibulin. We expect our principal expenditures during those 12 months to be predominately for

palifosfamide and include:

•

- Clinical trial expenses for palifosfamide;
- Clinical trial expenses, including the close down and data collection expenses for darinaparsin and indibulin;
 - Rent for our facilities; and
 - General corporate and working capital, including general and administrative expenses.

We intend 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.

16

With the planned development of palifosfamide and continued collection of indibulin data, with the intention of partnering further development of darinaparsin following completion of ongoing studies, and with other adjustments in our project and personnel expenses, including a recent workforce reduction of four positions in February 2009 and other loss of personnel, following the initial patient enrollment and assuming no additional capital from financing or partnering, we expect to incur the following expenses during the next twelve months: approximately \$1.6 million on preclinical and regulatory expenses; approximately \$3.1 million on clinical expenses (including clinical trials that we expect to be triggered under the license agreements relating to our product candidates); approximately \$1.4 million on manufacturing expenses; approximately \$0.7 million on facilities, rent, and other facilities-related expenses; and approximately \$3.7 million on general corporate and administrative expenses. With our current cash position, adjustments in staffing and aggressive cash management strategy, we believe that we currently have sufficient capital that will support our current operations strategy into the second quarter of 2010. 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.

Product Candidate Development and Clinical Trials

Intravenous darinaparsin, organic arsenic, has been or is being tested in patients with advanced myeloma, other hematological malignancies, and liver cancer. Two separate Phase II trials have been completed with a third nearing completion. Recently reported positive results in patients with lymphoma have led to the expansion of the hematological trial focusing on non-Hodgkin's lymphoma. The Phase I trials with an oral form of darinaparsin are completed in solid tumors and have been also expanded to include non-Hodgkin's lymphoma patients. The Company is in actively seeking partners and other sources of funding for continuing the development program of both the IV and oral forms in certain sub-types of non-Hodgkin's lymphoma. If funding or partnering is not accomplished, the project will be placed on hold.

Intravenous palifosfamide, the proprietary form of isophosphoramide mustard, is being developed presently to treat soft tissue sarcoma. A Phase II trial in advanced sarcoma has been completed. A Phase I trial in combination with doxorubicin is fully enrolled with treatment still ongoing and with the combination well tolerated, evidencing activity, and with the dose combination established for further study. The Company has initiated a randomized controlled 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 intends to treat initial patients to develop a registration trial to initiate as early as the first half of 2010. An oral formulation has also been developed preclinically and, following further IV study results, additional funding or partnering, a phase I is expected to initiate. Other trials in solid tumors are under consideration pending further funding. 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 resources allow.

Indibulin, a novel anti-cancer agent that targets mitosis by inhibiting tubulin polymerization, is administered as an oral capsule formulation. Indibulin has completed a Phase I trial in Europe and two additional Phase I trials are nearing completion in the United States with preliminary results reported for all three trials. Phase I trials of indibulin in combination with Tarceva (a) and also with Xeloda (b) have been initiated and are completing. Preclinical studies under the direction of Dr. Larry Norton to support clinical study of dose dense and metronomic dosing are well underway. Pending further results from the Norton preclinical work and subject to available funding, the Company intends to further study indibulin with an identified schedule and to determine maximum tolerated dose prior to formal

phase II testing in a selected solid tumor. If further funding is not available, the project will be placed on hold.

Financial Overview

Overview of Results of Operations

Three months ended March 31, 2009 compared to three months ended March 31, 2008

Revenue. We had no revenues for the three months ended March 31, 2009 and 2008.

Research and development expenses. Research and development expenses during the three months ended March 31, 2009 and 2008 were as follows: