ZIOPHARM ONCOLOGY INC
Form 10-Q
May 15, 2009

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

Form 10-Q

(Mark One)

þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2009

OR

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

Commission File Number 001-33484

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: þ No: ¨

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

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

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

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

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

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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)

	March 31, 2009	December 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.

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ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF OPERATIONS
(unaudited)

(in thousands, except share and per share data)

	For the Three Months Ended March 31,		Period from September 9, 2003 (date of inception) through March 31, 2009
	2009	2008	
Research contract revenue	$ -	$ -	$ -
Operating expenses:			
Research and development, including costs of research contracts	1,608	6,074	55,958
General and administrative	1,724	2,745	36,332
Total operating expenses	3,332	8,819	92,290
Loss from operations	(3,332)	(8,819)	(92,290)
Interest income, net	-	196	3,897
Change in fair value of warrants	(7)	-	(7)
Net loss	$ (3,339)	$ (8,623)	$ (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.

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ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)

	For the Three Months Ended March 31,		Period from September 9, 2003 (date of inception) through March 31, 2009
	2009	2008	
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.

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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.

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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			
Description	Balance as of March 31, 2009	Quoted Prices in Active Markets for Identical Assets/Liabiities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservabl Inputs (Level 3)
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.

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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, 2008 and those relative to non-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

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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 year 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).

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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.

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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	Warrants	Stage

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)

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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

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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	Weighted-Average Exercise Price	Weighted-Average Contractual Term (Years)	Aggregate 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-Average 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

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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 and more specifically on completing initial enrollment of the ongoing randomized phase II trial with 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.

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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. Ifosfamide 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 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 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 I 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.

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- 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.

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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 ® and also with Xeloda ® 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.

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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:

($ in thousands)	Three months ended March 31, 2009	2008	Change	
Research and development	$ 1,608	$ 6,074	$ (4,466)	-74%

Research and development expenses decreased by $4.5 million from the three months ended March 31, 2008 to the three months ended March 31, 2009. The decrease was primarily due to reduced manufacturing costs of $2.9 million, reduced clinical project costs of $770,000, reduced travel of $104,000 and other reductions of $138,000. Contributing to the decrease was the reduction in personnel which led to a savings of $603,000 in our salary and benefit expenses and stock based compensation expense. These reductions and savings are attributed to our cost cutting initiatives in order to extend our operations.

We expect our research and development expenses to continue to decrease as patient costs related to indibulin and darinaparsin end.

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

($ in thousands)	Three months ended March 31, 2009	2008	Change	
General and administrative	$ 1,724	$ 2,745	$ (1,021)	-37%

The decrease in general and administrative expenses of $1.0 million from the three months ended March 31, 2008 to the three months ended March 31, 2009 was primarily due to decreased headcount which lead to a decrease in our salary and benefit expenses and stock based compensation expense of $457,000. The decrease is also attributable to reductions in legal and patent costs of $239,000, travel of $128,000, consulting of $127,000 and other cost reductions of $70,000.

We expect our selling, general and administrative expenses to level off over the remainder of the year.

Other income (expense). Other income (expense) for the three months ended March 31, 2009 and 2008 was as follows:

($ in thousands)	Three months ended March 31, 2009	2008	Change	
Interest income	$ -	$ 196	$ (196)	-100%
Change in fair value of warrants	(7)	-	7	-100%
Total	$ (7)	$ 196	$ (189)	

The decrease in interest income from the three months ended March 31, 2008 compared to the three months ended March 31, 2009 was due primarily to lower cash balances during the three months ended March 31, 2009.

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Liquidity and Capital Resources

As of March 31, 2009, we had approximately $6.8 million in cash and cash equivalents, down from $11.4 million in cash and cash equivalents as of December 31, 2008. Given the rate at we have historically used cash, the limited amount of cash for use in operations and the recent instability in the capital markets, we have taken measures to reduce our near term expenses while we seek additional financing and partnering arrangements for the development of certain drug candidates. We have reduced staffing and other personnel and project related expenses, and have focused our priorities, including changes in our clinical trial program and seeking a partner, to continue the further development of darinaparsin. If we cannot find a partner to fund the development of either one or both forms of darinaparsin, we intend to discontinue the development of darinaparsin following the completion of ongoing trials for which associated expenses are included in the current forecast. If we are able to obtain additional financing, further studies will progress with regard to indibulin. Based on our current costs, we believe that we currently have sufficient capital to fund the development programs for palifosfamide into the second quarter of 2010 (see Development Plan). Because our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the palifosfamide beyond that time or to continue development of our other product candidates. To the extent additional capital is not available when we need it, or if we cannot successfully enter into partnership agreements for the further development of our products, we may be forced to abandon some or all of our development efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to the expected costs of development and commercialization and timeframe for completion are dependent on numerous factors other than available financing, including significant unforeseen delays in the clinical trial and regulatory approval process, which could be extremely costly. In addition, our estimates assume that we will be able to enroll a sufficient number of patients in each clinical trial.

The following table summarizes our net increase (decrease) in cash and cash equivalents for the three months ended March 31, 2009 and 2008:

	Three months ended March 31,	
	2009	2008
($ in thousands)		
Net cash provided by (used in):		
Operating activities	$ (4,610)	$ (7,472)
Investing activities	(1)	(69)
Financing activities	-	-
Net increase (decrease) in cash and cash equivalents	$ (4,611)	$ (7,541)

Net cash used in operating activities was $4.6 million for the three months ended March 31, 2009 compared to $7.5 million for the three months ended March 31, 2008. The $2.9 million decrease was primarily due to a $5.3 million decrease in the net loss partially offset by changes to accounts payable, accruals and other assets and liabilities.

Net cash used in investing activities was $1,000 for the three months ended March 31, 2009 compared to net cash used in investing activities of $69,000 for the three months ended March 31, 2008. The decrease was primarily due to a reduction in spending for purchases of property and equipment.

There was no net cash provided by financing activities for the three months ended March 31, 2009 and 2008.

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Operating capital and capital expenditure requirements

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. Our actual cash requirements may vary materially from those planned because of a number of factors including:

- Changes in the focus and direction of our development programs;
- Competitive and technical advances;
- Costs associated the development of palifosfamide and indibulin and the further financing of darinaparsin development by a partner; and
- Costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights, or other developments.

In order to continue our long-term plans for clinical trials and new product development, we will need to raise additional capital to continue to fund our research and development as well as operations after we exhaust our current cash resources. We expect to finance our cash needs through the sale of equity securities and strategic collaborations or debt financings or through other sources that may be dilutive to existing stockholders. 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. Currently, we have no committed sources of additional capital. Recently, capital markets have experienced a period of unprecedented instability that we expect may severely hinder our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, or we could be required to delay, scale back or eliminate some or all our research and development programs.

Working capital as of December 31, 2008 was $5.9 million, consisting of $11.7 million in current assets and $5.8 million in current liabilities. Working capital as of March 31, 2009 was $3.0 million, consisting of $7.0 million in current assets and $4.0 million in current liabilities.

Contractual obligations

The following table summarizes our outstanding obligations as of March 31, 2009 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

($ in thousands)	Total	Less than 1 year	2 - 3 years	4 - 5 years	More than 5 years
Operating Leases	$ 927	$ 434	$ 413	$ 80	$ -

Our commitments for operating leases relate to the lease for our corporate headquarters in New York, NY and our operations center in Boston, Massachusetts.

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Off-balance sheet arrangements

During the three months ended March 31, 2009 and 2008, we did not engage in any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

In our Form 10-K for the fiscal year ended December 31, 2008, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to stock-based compensation; net operating losses and tax credit carryforwards; and impairment of long-lived assets. We reviewed our policies and determined that those policies remain our most critical accounting policies for the three months ended March 31, 2009. During the three months ended March 31, 2009, we have added an accounting policy for valuing our warrant liability. See footnotes 2 and 5 herein for additional disclosure.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is limited to our cash. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain our cash in interest-bearing bank accounts. As all of our investments are cash deposits in a global bank, it is subject to minimal interest rate risk.

Item 4. Controls and Procedures

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

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

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Part II - Other Information

Item 1. Legal Proceedings

Not applicable.

Item 1A. Risk Factors

The following important factors could cause our actual business and financial results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or elsewhere by management from time to time. The risk factors in this report have been revised to incorporate changes to our risk factors from those included in our annual report on Form 10-K for the year ended December 31, 2008. The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission.

RISKS RELATED TO OUR BUSINESS

We may not be able to raise sufficient capital to continue clinical testing our product candidates.

If we do not succeed in raising additional funds on acceptable terms or if we cannot successfully enter into partnership agreements for the further development of our products, we will be unable to continue our planned preclinical and clinical trials or obtain approval for any of our product candidates from the FDA or other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. In the event that we are unable to continue as a going concern, we may be forced to cease operations altogether or may elect or be required to seek protection from our creditors by filing a voluntary petition in bankruptcy or may be subject to an involuntary petition in bankruptcy.

We believe we have sufficient capital to continue enrolling patients in our ongoing randomized phase II trial for palifosfamide as we are currently seeking a partner to fund the development of darinaparsin and we complete our current trials with indibulin. Further work with indibulin is ongoing preclinically and will be further extended clinically if we are able to obtain sufficient additional capital. If we are unable to obtain sufficient additional capital, the program will be placed on hold. If we cannot find a partner to fund the development of darinaparsin, we intend to discontinue its development following the completion of ongoing trials. We are currently devoting a significant portion of our resources to the development of palifosfamide. Accordingly, the resources that we are devoting to the development of indibulin and darinaparsin have significantly diminished. As a result, further progress with the development of darinaparsin and indibulin, if any, may be significantly delayed and may depend on the success of our ongoing clinical trials involving palifosfamide.

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

We have never generated revenue and have incurred significant net losses in each year since our inception. For the three months ended March 31, 2009, we had a net loss of $3.3 million and we had incurred approximately $86.8 million of cumulative net losses since our inception in 2003. We expect to continue to incur significant operating and capital expenditures. Although we have taken near-term cost cutting measures aimed at preserving capital while we pursue sources of potential additional financing, further development of our product candidates will likely require substantial increases in our expenses in the future as we:

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

Even if we succeed in developing and commercializing one or more of our product candidates, for which success is not assured, we may not be able to generate significant revenues. If we do generate significant revenues, we may never achieve or maintain profitability. Our failure to achieve or maintain profitability could negatively impact the trading price of our common stock.

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If we are not able to successfully develop and commercialize our product candidates, we may not generate sufficient revenues to continue our business operations.

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

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

As of March 31, 2009, we had incurred approximately $86.8 million of cumulative net losses and had approximately $6.8 million of cash, cash equivalents, and short-term investments. Currently and anticipating additional reductions in expense with no additional capital, we anticipate we will have sufficient cash to fund our operations, principally related to the development of palifosfamide, late into the second quarter of 2010. However, changes may occur that would consume our existing capital prior to that time, including the progress of our research and development efforts, changes in governmental regulation, and acquisitions of additional product candidates.

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

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

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

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

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

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

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

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

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

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

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

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We may not be able to successfully manage our growth.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

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

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

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

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

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

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

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

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

We have received “Orphan Drug” status for palifosfamide in both the United States and Europe and we are hopeful that we may be able to obtain “Fast Track” and/or Orphan Drug status from the FDA for our product candidates. Fast Track allows the FDA to facilitate development and expedite review of drugs that treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Fast Track status does not apply to a

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

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

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

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

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

- Perceptions by members of the health care community, including physicians, regarding the safety and effectiveness of our drugs;
- Cost-effectiveness of our products relative to competing products;
- Availability of reimbursement for our products from government or other healthcare payers; and
- Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

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

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

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

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

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

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

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

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

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

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

RISKS RELATED TO OUR ABILITY TO COMMERCIALIZE OUR PRODUCT CANDIDATES

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

We currently have no marketing, sales, or distribution capabilities. If and when we become reasonably certain that we will be able to commercialize our current or future products, we anticipate allocating resources to the marketing, sales and distribution of our proposed products in North America; however, we cannot assure that we will be able to market, sell, and distribute our products successfully. Our future success also may depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities and to encourage the collaborator’s strategic interest in the products under development, and such collaborator’s ability to successfully market and sell any such products. Although we intend to pursue certain collaborative arrangements regarding the sale and marketing of our

products, there are no assurances that we will be able to establish or maintain collaborative arrangements or, if we are able to do so, whether we would be able to conduct our own sales efforts. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.

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

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

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

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

- Developing drugs;
- Undertaking preclinical testing and human clinical trials;
- Obtaining FDA and other regulatory approvals of drugs;
- Formulating and manufacturing drugs; and
- Launching, marketing, and selling drugs.

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

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

- Perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
- Pharmacological benefit and cost-effectiveness of our products relative to competing products;
- Availability of reimbursement for our products from government or other healthcare payors;

- Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- The price at which we sell our products.

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

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

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

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

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

There also likely will continue to be legislative and regulatory proposals that could bring about significant changes in the healthcare industry. We cannot predict what form those changes might take or the impact on our business of any legislation or regulations that may be adopted in the future. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

- The degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;

- If and when patents will be issued;

- Whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or

- Whether we will need to initiate litigation or administrative proceedings that may be costly whether we win or lose.

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

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

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

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

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

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

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

OTHER RISKS RELATED TO OUR COMPANY

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

As a public reporting company, we are subject to the Sarbanes-Oxley Act of 2002, as well as to the information and reporting requirements of the Securities Exchange Act of 1934, as amended, and other federal securities laws. As a result, we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs associated with our public company reporting requirements and corporate governance requirements. As an example of public reporting company requirements, we evaluate the effectiveness of disclosure controls and procedures and of our internal control over financing reporting in order to allow management to report on such controls. Pursuant to Sarbanes-Oxley, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting, as of December 31, 2009, in our Annual Report on Form 10-K for the fiscal year ending December 31, 2009. While management has not currently identified any material weaknesses in our internal control over financial reporting, there can be no assurance that our systems will be deemed effective when our independent registered public accounting firm reviews the systems during 2009 and tests transactions. In addition, any updates to our finance and accounting systems, procedures and controls, which may be required as a result of our ongoing analysis of internal controls, or results of testing by our independent auditor, may require significant time and expense.

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

There is not now, and there may not ever be an active market for shares of our common stock.

In general, there has been limited trading activity in shares of the Company's common stock. The small trading volume may make it more difficult for our stockholders to sell their shares as and when they choose. Furthermore, small trading volumes generally depress market prices. As a result, you may not always be able to resell shares of our common stock publicly at the time and prices that you feel are fair or appropriate.

Our common stock could be delisted from The NASDAQ Capital Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is listed on The NASDAQ Capital Market. The listing standards of The NASDAQ Capital Market provide, among other things, that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days. In light of current market conditions, The Nasdaq Stock Market has suspended this listing requirement until July 20, 2009. Recently our stock has traded below $1.00, and if we fail to comply with the listing standards applicable to issuers listed on The NASDAQ Capital Market, our common stock may be delisted absent further suspension of the trading price requirements. The delisting of our common stock would significantly affect the ability of investors to trade our securities and would significantly negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from The NASDAQ Capital Market could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

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

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to

increase the number of outstanding shares and hinder a takeover attempt, and limit who may call a special meeting of stockholders. In addition, Section 203 of the Delaware General Corporation Law, which prohibits business combinations between us and one or more significant stockholders unless specified conditions are met, may discourage, delay or prevent a third party from acquiring us.

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

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

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

Not applicable.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Submission of Matters to a Vote of the Security Holders

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

/s/ Jonathan Lewis
Jonathan Lewis, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)
Dated: May 14, 2009

/s/ Richard E. Bagley
Richard E. Bagley
President and Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: May 14, 2009

EXHIBIT INDEX

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

* Filed herewith