

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

- QUARTERLY REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended September 30, 2008

OR

- TRANSITION REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-32353

**ZIOPHARM Oncology, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation or Organization)

**84-1475642**

(IRS Employer Identification No.)

**1180 Avenue of the Americas, 19th Floor, New York, NY**  
(Address of Principal Executive Offices)

**10036**  
(Zip Code)

**(646) 214-0700**

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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

As of October 30, 2008, there were 21,373,964 shares of the issuer's common stock, \$.001 par value per share, outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. UNAUDITED FINANCIAL STATEMENTS

**ZIOPHARM Oncology, Inc.**

(A Development Stage Enterprise)

Balance Sheets

	September 30, 2008 <u>(Unaudited)</u>	December 31, 2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,191,789	\$ 35,028,798
Prepaid expenses and other current assets	577,165	498,864
Total current assets	<u>15,768,954</u>	<u>35,527,662</u>
Property and equipment, net	589,138	746,421
Deposits	95,497	95,497
Other non-current assets	360,922	356,881
Total assets	<u>\$ 16,814,511</u>	<u>\$ 36,726,461</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,227,537	\$ 2,909,170
Accrued expenses	3,473,027	3,396,480
Total current liabilities	<u>5,700,564</u>	<u>6,305,650</u>
Deferred rent	<u>60,932</u>	<u>50,988</u>
Total liabilities	<u>5,761,496</u>	<u>6,356,638</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.001 par value; 280,000,000 shares authorized; 21,373,964 and 21,298,964 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	21,374	21,299
Preferred stock, \$0.01 par value; 30,000,000 shares authorized and no shares issued and outstanding	-	-
Additional paid-in capital	71,025,617	69,674,151
Warrants issued	20,503,894	20,503,894
Deficit accumulated during the development stage	(80,497,870)	(59,829,521)
Total stockholders' equity	<u>11,053,015</u>	<u>30,369,823</u>
Total liabilities and stockholders' equity	<u>\$ 16,814,511</u>	<u>\$ 36,726,461</u>

**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Statements of Operations

For the three and nine months ended September 30, 2008 and 2007 (unaudited) and for the period from inception (September 9, 2003) through September 30, 2008 (unaudited)

	For the three months ended September 30, 2008 (unaudited)	For the three months ended September 30, 2007 (unaudited)	For the nine months ended September 30, 2008 (unaudited)	For the nine months ended September 30, 2007 (unaudited)	For the Period from Inception (September 9, 2003) through September 30, 2008 (unaudited)
Research contract revenue	\$ -	\$ -	\$ -	\$ -	\$ -
Operating expenses and other income:					
Research and development, including costs of research contracts	3,878,987	5,568,872	14,219,623	13,342,389	51,324,017
General and administrative	1,740,466	2,293,212	6,834,696	7,131,809	33,068,990
Total operating expenses	5,619,453	7,862,084	21,054,319	20,474,198	84,393,007
Loss from operations	(5,619,453)	(7,862,084)	(21,054,319)	(20,474,198)	(84,393,007)
Interest income	74,972	538,718	385,970	1,564,945	3,895,137
Net loss	<u>\$ (5,544,481)</u>	<u>\$ (7,323,366)</u>	<u>\$ (20,668,349)</u>	<u>\$ (18,909,253)</u>	<u>\$ (80,497,870)</u>
Basic and diluted net loss per share	<u>\$ (0.26)</u>	<u>\$ (0.35)</u>	<u>\$ (0.97)</u>	<u>\$ (0.94)</u>	
Weighted average common shares outstanding used to compute basic and diluted net loss per share	<u>21,228,964</u>	<u>21,196,607</u>	<u>21,228,964</u>	<u>20,018,480</u>	

**ZIOPHARM Oncology, Inc.***(A Development Stage Enterprise)*

## Statements of Cash Flows

For the nine months ended September 30, 2008 and 2007 and for the period from inception (September 9, 2003) through September 30, 2008 (unaudited)

	For the nine months ended September 30, 2008 (unaudited)	For the nine months ended September 30, 2007 (unaudited)	For the period from inception (September 9, 2003) through September 30, 2008 (unaudited)
<b>Cash flows from operating activities:</b>			
Net loss	\$ (20,668,349)	\$ (18,909,253)	\$ (80,497,870)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation and amortization	279,355	345,890	1,021,813
Non-cash stock-based compensation	1,351,541	1,079,048	6,474,658
Loss on disposal of fixed assets	302	4,098	8,725
<b>Change in operating assets and liabilities:</b>			
<b>(Increase) decrease in:</b>			
Prepaid expenses and other current assets	(78,301)	(224,226)	(577,165)
Other noncurrent assets	(4,041)	(177,176)	(360,922)
Deposits	-	(91,630)	(95,497)
<b>Increase (decrease) in:</b>			
Accounts payable	(681,633)	861,709	2,227,537
Accrued expenses	76,547	1,269,965	3,473,027
Deferred rent	9,944	(4,765)	60,932
Net cash used in operating activities	<u>(19,714,635)</u>	<u>(15,846,340)</u>	<u>(68,264,762)</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(123,074)	(617,959)	(1,620,376)
Proceeds from sale of property and equipment	700	-	700
Decrease in short-term investments	-	1,555,164	-
Net cash provided by (used in) investing activities	<u>(122,374)</u>	<u>937,205</u>	<u>(1,619,676)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from the exercise of stock options	-	21,394	65,596
Stockholders' capital contribution	-	-	500,000
Proceeds from issuance of common stock and warrants, net	-	28,970,915	67,751,035
Proceeds from issuance of preferred stock, net	-	-	16,759,596
Net cash provided by financing activities	<u>-</u>	<u>28,992,309</u>	<u>85,076,227</u>
Net increase (decrease) in cash and cash equivalents	(19,837,009)	14,083,174	15,191,789
Cash and cash equivalents, beginning of period	35,028,798	26,855,450	-
Cash and cash equivalents, end of period	<u>\$ 15,191,789</u>	<u>\$ 40,938,624</u>	<u>\$ 15,191,789</u>
<b>Supplementary disclosure of cash flow information:</b>			
Cash paid for interest	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>
Cash paid for income taxes	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>
<b>Supplementary disclosure of noncash investing and financing activities:</b>			
Warrants issued to placement agents and investors, in connection with private placement	<u>\$ -</u>	<u>\$ 5,432,793</u>	<u>\$ 20,208,217</u>
Preferred stock conversion to common stock	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 16,759,596</u>
Warrants converted to common shares	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 17,844</u>

**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Statement of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)  
for the period from inception (September 9, 2003) through September 30, 2008 (unaudited)

	Convertible Preferred Stock and Warrants			Stockholder's Equity (Deficit)					Total Stockholders' Equity/ (Deficit)
	Series A		Warrants to Purchase Series A Convertible	Common Stock		Additional Paid- in Capital	Warrants	Deficit Accumulated During The Development Stage	
	Convertible Preferred Stock Shares	Amount	Preferred Stock Warrants	Shares	Amount				
Stockholders' contribution, September 9, 2003	-	\$ -	\$ -	250,487	\$ 250	\$ 499,750	\$ -	\$ -	\$ 500,000
Net loss	-	-	-	-	-	-	-	(160,136)	(160,136)
Balance at December 31, 2003	-	-	-	250,487	250	499,750	-	(160,136)	339,864
Issuance of common stock	-	-	-	2,254,389	2,254	4,497,746	-	-	4,500,000
Issuance of common stock for services	-	-	-	256,749	257	438,582	-	-	438,839
Fair value of options/warrants issued for nonemployee services	-	-	-	-	-	13,240	251,037	-	264,277
Net loss	-	-	-	-	-	-	-	(5,687,297)	(5,687,297)
Balance at December 31, 2004	-	-	-	2,761,625	2,761	5,449,318	251,037	(5,847,433)	(144,317)
Issuance of Series A convertible preferred stock (net of expenses of \$1,340,263 and warrant cost of \$1,682,863)	4,197,946	15,076,733	-	-	-	-	-	-	-
Fair value of warrants to purchase Series A convertible preferred stock	-	-	1,682,863	-	-	-	-	-	-
Issuance of Common stock to EasyWeb Shareholders	-	-	-	189,922	190	(190)	-	-	-
Conversion of Series A convertible preferred stock @ \$0.001 into \$0.001 common stock on September 13, 2005 at an exchange ratio of .500974	(4,197,946)	(15,076,733)	(1,682,863)	4,197,823	4,198	15,072,535	1,682,863	-	16,759,596
Issuance of common stock for options	-	-	-	98,622	99	4,716	-	-	4,815
Fair value of options/warrants issued for nonemployee services	-	-	-	-	-	54,115	44,640	-	98,755
Net loss	-	-	-	-	-	-	-	(9,516,923)	(9,516,923)
Balance at December 31, 2005	-	-	-	7,247,992	7,248	20,580,494	1,978,540	(15,364,356)	7,201,926
Issuance of common stock in private placement, net of expenses \$2,719,395	-	-	-	7,991,256	7,991	21,179,568	-	-	21,187,559
Issuance of warrants	-	-	-	-	-	-	13,092,561	-	13,092,561
Issuance of common stock for services rendered	-	-	-	25,000	25	106,225	-	-	106,250
Stock based compensation for employees	-	-	-	-	-	2,776,408	-	-	2,776,408
Issuance of common stock due to exercise of stock options	-	-	-	5,845	6	25,186	-	-	25,192
Issuance of common stock due to exercise of stock warrants	-	-	-	2,806	3	(3)	-	-	-
Net loss	-	-	-	-	-	-	-	(17,856,919)	(17,856,919)
Balance at December 31, 2006	-	-	-	15,272,899	15,273	44,667,878	15,071,101	(33,221,275)	26,532,977
Issuance of common stock in private placement, net of expenses \$1,909,090	-	-	-	5,910,049	5,910	23,532,212	-	-	23,538,122
Issuance of warrants	-	-	-	-	-	-	5,432,793	-	5,432,793
Stock-based compensation for employees	-	-	-	-	-	1,318,096	-	-	1,318,096
Stock-based compensation for non-employee	-	-	-	-	-	120,492	-	-	120,492
Issuance of common stock due to exercise of stock options	-	-	-	46,016	46	35,543	-	-	35,589
Issuance of restricted stock	-	-	-	70,000	70	(70)	-	-	-
Net loss	-	-	-	-	-	-	-	(26,608,246)	(26,608,246)
Balance at December 31, 2007	-	-	-	21,298,964	21,299	69,674,151	20,503,894	(59,829,521)	30,369,823
Stock-based compensation for employees	-	-	-	-	-	1,351,541	-	-	1,351,541
Issuance of restricted stock	-	-	-	100,000	100	(100)	-	-	-
Cancellation of restricted stock	-	-	-	(25,000)	(25)	25	-	-	-
Net loss	-	-	-	-	-	-	-	(20,668,349)	(20,668,349)
Balance at September 30, 2008 (unaudited)	-	\$ -	\$ -	21,373,964	\$ 21,374	\$ 71,025,617	\$ 20,503,894	\$ (80,497,870)	\$ 11,053,015

## 1. BASIS OF PRESENTATION AND OPERATIONS

The financial statements included herein have been prepared by ZIOPHARM Oncology, Inc. (“ZIOPHARM” or the “Company”) without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the accompanying unaudited financial statements include all adjustments (consisting of normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows of the Company at the dates and for the periods indicated. The unaudited financial statements included herein should be read in conjunction with the audited financial statements and the notes thereto included in ZIOPHARM Oncology, Inc.’s Form 10-KSB filed on February 21, 2008 for the fiscal year ended December 31, 2007.

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

The Company has operated at a loss since its inception in 2003 and has no revenues. The Company anticipates that losses will continue for the foreseeable future. At September 30, 2008, the Company’s accumulated deficit was approximately \$80.5 million. 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 our research and development programs, competitive and technical advances, patent developments or other developments. Additional financing will be required to continue operations after we exhaust our current cash resources and to continue our long-term plans for clinical trials and new product development.

The results disclosed in the Statements of Operations for the three and nine months ended September 30, 2008 are not necessarily indicative of the results to be expected for the full year.

## 2. RECENT ACCOUNTING PRONOUNCEMENTS

In September 2006, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards 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 will issue 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. This statement became effective for the Company on January 1, 2008. Adoption of this new standard did not have a material impact on the Company’s financial position, results of operations or cash flows.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Liabilities, Including an amendment of FASB Statement No. 115* (“SFAS 159”). This statement permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 is effective as of the beginning of fiscal 2008. This statement became effective for the Company on January 1, 2008. 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 the measurement period. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 with early adoption prohibited. The Company expects that the adoption of this new standard will not have a material impact on the Company’s financial position, results of operations or cash flows.

## 2. RECENT ACCOUNTING PRONOUNCEMENTS...CONTINUED

In December 2007, the FASB issued Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of Accounting Research Bulletin No. 51* (“SFAS 160”). SFAS 160 requires a company to clearly identify and present ownership interests in subsidiaries held by parties other than the company in the consolidated financial statements within the equity section but separate from the company’s equity. It also requires the amount of consolidated net income attributable to the parent and to the noncontrolling interest be clearly identified and presented on the face of the consolidated statement of income; changes in ownership interest be accounted for similarly, as equity transactions; and when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary and the gain or loss on the deconsolidation of the subsidiary be measured at fair value. This statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. The Company expects that the adoption of this new standard will not have a material impact on the Company’s financial position, results of operations or cash flows.

In March 2008, the FASB issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities* (“SFAS 161”). SFAS No. 161 expands the disclosure requirements in SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* about an entity’s derivative instruments and hedging activities. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. We are currently evaluating the impact of SFAS No. 161, which is not expected to have a material impact on our financial statements.

In May 2008, the FASB issued Statement No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (“SFAS 162”). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of non-governmental entities that are presented in conformity with GAAP. SFAS 162 directs the GAAP hierarchy to the entity, not the independent auditors, as the entity is responsible for selecting accounting principles for financial statements that are presented in conformity with GAAP. SFAS 162 is effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to remove the GAAP hierarchy from the auditing standards. SFAS 162 is not expected to have a material impact on our financial statements.

## 3. STOCK-BASED COMPENSATION AND STOCK OPTION PLAN

### *Stock-based Compensation Expense*

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R) (“SFAS 123R”) Share-Based Payment, using the modified prospective method, which results in the provision of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award using the Black Scholes Model and is recognized as expense over the service period. Previously, the Company had followed Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employee*, and related interpretations which resulted in account for employee share options at their intrinsic value in the financial statements.

The Company recognized the full impact of its share-based payment plans in the statements of operations for the three and nine months ended September 30, 2008 and 2007 under SFAS 123R and did not capitalize any such costs on the balance sheets. The following table presents share-based compensation expense included in the Company’s statement of operations:

	<u>Three months</u> <u>ended September 30, 2008</u>	<u>Three months</u> <u>ended September 30, 2007</u>	<u>Nine months</u> <u>ended September 30, 2008</u>	<u>Nine months</u> <u>ended September 30, 2007</u>
Research and development, including costs of research contracts	\$ 115,472	\$ 139,696	\$ 500,440	\$ 511,954
General and administrative	265,488	203,601	851,101	567,094
Share based compensation expense before tax	380,960	343,297	1,351,541	1,079,048
Income tax benefit	-	-	-	-
Net compensation expense	<u>\$ 380,960</u>	<u>\$ 343,297</u>	<u>\$ 1,351,541</u>	<u>\$ 1,079,048</u>



### 3. STOCK-BASED COMPENSATION AND STOCK OPTION PLAN...CONTINUED

#### Stock Option Plan

The Company has adopted the 2003 Stock Option Plan (the "Plan"), under which the Company had reserved the issuance of 1,252,436 shares of its Common Stock. The Plan was approved by the Company's stockholders on December 21, 2004. On April 25, 2007 and April 26, 2006, the dates of the Company's annual stockholders meetings, the Company's stockholders approved amendments to the Plan increasing the total shares reserved by 2,000,000 and 750,000 shares, respectively, for a total of 4,002,436 shares. As of September 30, 2008 there were 2,751,670 shares that are issuable under the Plan upon exercise of outstanding options to purchase common stock and an additional 145,000 shares of restricted stock had been issued under the Plan.

#### Stock Options

As of September 30, 2008, the Company had issued to employees outstanding options to purchase up to 2,271,246 shares of the Company's common stock. In addition, the Company has issued to directors options to purchase up to 480,174 shares of the Company's common stock, as well as options to a consultant in connection with services rendered to purchase up to 250 shares of the Company's common stock.

Currently, stock options are granted with an exercise price equal to the closing market price of the Company's common stock on the day before the date of grant. Stock options to employees generally vest ratably over three years and have contractual terms of ten years. Stock options to directors generally vest ratably over two or three years and have contractual terms of ten years. Stock options are valued using the Black-Scholes option valuation method and compensation is recognized based on such fair value over the period of vesting on a straight-line basis. The Company has also reserved an aggregate of 45,823 additional shares for issuance under options granted outside of the Plan.

During the three and nine months ended September 30, 2008, the Company granted 11,000 and 172,000 options, respectively. Also during the three and nine months ended September 30, 2008, the Company cancelled 139,830 and 217,330 options, respectively, while no options were exercised, under the 2003 Stock Option plan, in this period. During the three and nine months ended September 30, 2007, the Company granted 25,500 and 454,750 options, respectively. During the three and nine months ended September 30, 2007, the Company cancelled 40,940 and 129,181 options, respectively, while 12,555 options were exercised, under the 2003 Stock Option plan, in this period. Proceeds from the third quarter 2007 exercise amounted to \$21,394 and the intrinsic value of these options amounted to \$21,220. During the nine months September 30, 2007, the Company entered into a termination agreement with an employee which accelerated the vesting of an employee's previously granted options. The Company recorded a charge of \$41,663 in the nine months ended September 30, 2007 as a result of the acceleration. These accelerated options have expired without exercise and the Company cancelled the options in the nine-month period ending September 30, 2007.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. Assumptions regarding volatility, expected term, dividend yield and risk-free interest rate are required for the Black-Scholes model. Volatility and expected term assumptions are based on comparable Company's historical experience. The risk-free interest rate is based on a U.S. treasury note with a maturity similar to the option award's expected life. The assumptions used to value options granted during the three and nine months ended September 30, 2008 are as follows, volatility of 94 - 96%, expected life of approximately 5 years, a dividend yield of 0%, and a risk-free interest rate of 2.48 - 3.49%.

Stock option activity under the Plan for the nine-month period ended September 30, 2008 was as follows:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2008	2,797,000	\$ 3.81		
Granted	172,000	2.63		
Exercised	—	—		
Cancelled	217,330	4.37		
Outstanding, September 30, 2008	<u>2,751,670</u>	<u>\$ 3.69</u>	<u>7.79</u>	<u>\$ 436,531</u>
Options exercisable, September 30, 2008	<u>1,553,279</u>	<u>\$ 3.70</u>	<u>6.92</u>	<u>\$ 432,531</u>

Stock options granted in the three and nine months ended September 30 had weighted-average grant date fair values of \$1.01 and \$1.93 in 2008 and \$3.31 and \$3.55 in 2007, respectively. At September 30, 2008, total unrecognized compensation costs related to non-vested stock options outstanding amounted to \$2,090,698. The cost is expected to be recognized over a weighted-average period of 1.40 years.

### 3. STOCK-BASED COMPENSATION AND STOCK OPTION PLAN...CONTINUED

#### *Restricted Stock*

During the nine months ended September 30, 2008, 100,000 shares of restricted stock were issued to an employee which vest in equal annual installments over a three-year period. During the year ended December 31, 2007, the Company issued 70,000 shares of restricted stock to several employees that will vest entirely on December 1, 2008. During the three and nine months ended September 30, 2008, \$59,814 and \$207,201 of compensation expense was recognized. A summary of the status of non-vested restricted stock as of September 30, 2008 is as follows:

	<b>Restricted Stock</b>	<b>Weighted- Average Grant Date Fair Value</b>
Non-vested at January 1, 2008	70,000	\$ 2.73
Granted	100,000	3.25
Vested	—	—
Canceled	25,000	2.73
Non-vested at September 30, 2008	<u>145,000</u>	<u>\$ 3.09</u>

As of September 30, 2008, there was \$270,848 of total unrecognized stock-based compensation expense related to non-vested restricted stock arrangements granted under the 2003 Plan. The expense is expected to be recognized over a weighted-average period of 1.47 years.

#### 4. INCOME TAXES

The Company adopted Financial Interpretation Number 48, "Accounting for Uncertain Tax Positions" on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." FIN 48 prescribes a recognition threshold and measurement of a tax position taken or expected to be taken in a tax return. The Company did not establish any additional reserves for uncertain tax liabilities upon adoption of FIN 48. No adjustment to the Company's uncertain tax positions has been made in the three and nine months ending September 30, 2008.

The Company has not recognized any interest and penalties in the statement of operations because of the Company's net operating losses and tax credits that are available to be carried forward. When necessary, the Company will account for interest and penalties related to uncertain tax positions as part of its provision for federal and state income taxes. The Company does not expect the amounts of unrecognized benefits will change significantly within the next twelve months.

The Company is currently open to audit under the statute of limitations by the Internal Revenue Service and state jurisdictions for the years ended December 31, 1999 through the current period.

## Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS

### Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains statements that are not historical, but are forward-looking in nature, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. In particular, the "Management's Discussion and Analysis" section in Part I, Item 2 of this Quarterly Report include forward-looking statements that reflect our current views with respect to future events and financial performance. We use words such as we "expect," "anticipate," "believe," and "intend" and similar expressions to identify forward-looking statements. A number of important factors could, individually or in the aggregate, cause actual results to differ materially from those expressed or implied in any forward-looking statements. Such factors include, but are not limited to, our ability to successfully develop or commercialize our product candidates, our ability to obtain additional financing, our ability to develop and maintain customer relationships, regulatory developments relating to and the general success of our products, and our ability to protect our proprietary technology. Other risks are described under the section entitled "Risk Factors" in our Current Report on Form 10-KSB filed on February 21, 2008.

### **Overview:**

ZIOPHARM Oncology, Inc. is a biopharmaceutical company that is seeking to develop a diverse, risk-sensitive portfolio of in-licensed cancer drugs that address unmet medical needs. Our principal focus is on the licensing and development of proprietary small molecule drug candidates which can be administered by intravenous ("IV") and oral dosing and which can offer enhanced patient benefit as compared to related, but mechanistically different, cancer therapeutics on the market and in development. We believe this strategy will result in lower risk and expedited drug development programs with lower costs of production. We expect to commercialize our products through partnerships with other companies with the requisite financial resources to bring these products through clinical trials to commercialization. Currently, we are in Phase I and/or II studies for three product candidates known as darinaparsin ("ZIO-101"), palifosfamide ("ZIO-201") and indibulin ("ZIO-301"):

- Darinaparsin is an organic arsenic compound covered by issued patents and pending patent applications in the U.S. and in foreign countries. A form of commercially available inorganic arsenic (arsenic trioxide [Trisenox<sup>®</sup>]; "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 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. In ongoing *in vitro* studies, the activity of darinaparsin against B-cell, T-cell, and NK-cell Non-Hodgkin's Lymphoma cell lines is being investigated. 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, provided support for the development of an oral form of the drug, and established synergy of darinaparsin in combination with other approved anti-cancer agents.

Phase I testing of the intravenous 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 has recently initiated two Phase I studies with an oral 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 discontinue the development program for darinaparsin.

Palifosfamide, or isophosphoramide mustard ("IPM"), 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. FDA. Preclinical studies have shown that palifosfamide has activity against leukemia and solid tumors. These studies also indicate that palifosfamide may have a better safety profile than ifosfamide or cyclophosphamide because it does not appear to produce known toxic metabolites, 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, encouraging results have been obtained with palifosfamide in combination with doxorubicin, an agent approved to treat sarcoma.

Following Phase I 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 that has been recently substituted 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 reports of 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 study of palifosfamide in combination with doxorubicin in patients with 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 (enrollment completed, study ongoing), 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 soft tissue sarcoma. Data from this trial are expected to shape a Phase III trial in the same setting. The Company is also developing an oral form of palifosfamide to be studied clinically following completion of additional preclinical studies and with further data from the IV trials. Importantly, Orphan Drug Designation for palifosfamide has been obtained in both the United States and the European Union for the treatment of soft tissue sarcomas.

## Overview...Continued

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<sup>®</sup>, Abraxane<sup>®</sup>), docetaxel (Taxotere<sup>®</sup>), and the *Vinca* alkaloid family members, vincristine and vinorelbine. 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 formulation of indibulin creates significant commercial opportunity because no oral 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/II combination studies have been initiated with Tarceva<sup>®</sup> and Xeloda<sup>®</sup>. Preclinical work to explore dose dense and metronomic dosing in the clinical setting are progressing.

Although we intend to continue with clinical development of darinaparsin for lymphoma in conjunction with a partner, palifosfamide for soft tissue sarcoma, and 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 and are difficult to accurately predict. 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.

## Plan of Operation

Our plan of operation for the next twelve months is highly focused on completing the randomized Phase II trial for palifosfamide, partnering darinaarsin, and further establishing safety and drug activity with indibulin. We expect our principal expenditures during those 12 months to include:

- Clinical trial expenses, including the costs incurred with respect to the conduct of clinical trials for palifosfamide and indibulin;
- Fees and milestone payments required under the license agreements relating to our existing product candidates;
- Costs related to the scale-up and the manufacture of palifosfamide 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.

With the planned development of palifosfamide and indibulin, with the intention of partnering further development of darinaarsin following completion of ongoing studies, and with other adjustments in our project and personnel expenses, including a recent workforce reduction of eight positions, we expect to spend, during the next twelve months, approximately \$1.1 million on preclinical and regulatory expenses, \$7.2 million on clinical expenses (including clinical trials and milestone payments that we expect to be triggered under the license agreements relating to our product candidates), approximately \$2.8 million on manufacturing costs, approximately \$400,000 on facilities, rent, and other facilities-related costs, and approximately \$3.4 million on general corporate and working capital. With our current cash position, adjustments in staffing, aggressive cash management strategy and amortization of upfront payments, we believe that we currently have sufficient capital that will support operations very early into the first quarter of 2010.

### **Product Candidate Development and Clinical Trials**

*Intravenous darinaarsin*, organic arsenic, has been or is being tested in patients with advanced myeloma, other hematological malignancies, and liver cancer. Three separate Phase II trials are 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 formulation of darinaarsin are ongoing in solid tumors and have been also expanded to include non-Hodgkin's lymphoma patients. The Company is 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.

*Intravenous palifosfamide*, the proprietary form of isophosphoramidate 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 and with the dose 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 soft tissue sarcoma. An oral formulation has also been developed preclinically and, following further IV study results and additional preclinical study, a Phase I is expected to initiate. Importantly, 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.

*Indibulin*, a novel anti-cancer agent that targets mitosis by inhibiting tubulin polymerization, is administered as an oral 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. The Phase I portion of a Phase I/II trial in combination with Tarceva<sup>®</sup> and also with Xeloda<sup>®</sup> have been initiated. Preclinical studies under the direction of Dr. Larry Norton to support clinical study of dose dense and metronomic dosing are well underway.

## Results of Operations for the three and nine months ended September 30, 2008 versus September 30, 2007

*Revenues.* We had no revenues for either of the three and nine-month periods ended September 30, 2008 and 2007.

*Research and development expenses.* For the three-month period ended September 30, 2008, research and development expenses decreased by \$1,689,885, or 30.3%, to \$3,878,987 from \$5,568,872 in the three-month period ended September 30, 2007. Decreased research and development expenses in the current period are primarily attributable to a decrease in clinical trial, regulatory and related activities in the current quarter. For the nine-month period ended September 30, 2008, research and development expenses increased by \$877,234, or 6.6%, to \$14,219,623 from \$13,342,389 in the nine-month period ended September 30, 2007. Increased research and development expenses in the current year period are primarily attributable to an increase of approximately \$792,000 in manufacturing related costs, an increase of approximately \$612,000 in payroll and employee related costs, and an increase of approximately \$250,000 for consulting and related services. These increases were slightly offset by the decrease of \$625,000 in milestone payments and by an approximately \$360,000 decrease in the cost of clinical trials, regulatory, and preclinical related expenses and during the nine months ended September 30, 2008 compared with the same period of 2007.

*General and administrative expenses.* For the three-month period ended September 30, 2008, general and administrative expenses decreased by \$552,746, or 24.1%, to \$1,740,466 from \$2,293,212 in the three-month period ended September 30, 2007. The decrease is primarily attributable to a decrease of approximately \$182,000 in investor relations and financial consulting costs, a decrease of approximately \$141,000 in payroll and related expenses and a decrease of approximately \$138,000 in recruiting expenses. These decreases were slightly offset by an increase of approximately \$63,000 in stock compensation expense related to stock options and restricted stock. For nine-month period ended September 30, 2008, general and administrative expenses decreased by \$297,113, or 4.2%, to \$6,834,696 from \$7,131,809 in the nine-month period ended September 30, 2007. The decrease is primarily attributed to a decrease of approximately \$622,000 in investor relations and financial consulting costs. This decrease is slightly offset by an approximate increase of approximately \$326,000 in payroll, stock compensation and related expenses related.

*Other income (expense).* Other income decreased by \$463,746, or 86.1%, to \$74,972 in the three-month period ended September 30, 2008 from \$538,718 recorded in the three-month period ended September 30, 2007. Other income decreased by \$1,178,975 or 75.3% to \$385,970 in the nine-month period ended September 30, 2008 from \$1,564,945 recorded in the nine-month period ended September 30, 2007. Other income during the three and nine-month periods ended September 30, 2008 and 2007, respectively, was comprised of interest income. The decrease in both periods is due to a lower average cash balance and the drop in the return from our investments, primarily in U.S. treasuries and money market funds as compared to the previous period.

*Net income (loss).* For the reasons described above, the net loss decreased by \$1,778,885, or 24.3%, to \$5,544,481 in the three month period ended September 30, 2008 from \$7,323,366 for the same period of 2007. The net loss increased \$1,759,096, or 9.3%, to \$20,668,349 in the nine month period ended September 30, 2008 from \$18,909,253 for the same period of 2007.

### Liquidity and Capital Resources

As of September 30, 2008, we had approximately \$15.2 million in cash and cash equivalents. We have reduced staff, including a recent workforce reduction of eight positions and other personnel and project related expenses and 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. We believe we currently have sufficient capital to fund the development programs for palifosfamide, and indibulin very early into the first quarter of 2010 (see Plan of Operations). Because our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the 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 Company anticipates that losses will continue for the foreseeable future. At September 30, 2008, the Company's accumulated deficit was approximately \$80.5 million. The Company has incurred significant losses from operations and has an accumulated deficit that raises substantial doubt about the Company's ability to continue as a going concern. 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. 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. 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.

Since inception, our primary source of funding for our operations has been the private sale of our securities. During the nine months ended September 30, 2007, we received gross proceeds of approximately \$30.9 million (\$28,970,915 net of cash issuance costs) as a result of a sale of an aggregate of 5,910,049 shares of the Company's common stock at a price of \$5.225 per share in a private placement (the "2007 Offering"). In addition to these shares, the Company also issued to each investor a five-year warrant to purchase, at an exercise price of \$5.75 per share, an additional number of shares of common stock equal to 20 percent of the shares purchased by such investor in the 2007 Offering. In the aggregate, these warrants entitle investors to purchase an additional 1,182,015 shares of common stock. The Company engaged Paramount BioCapital, Inc., Oppenheimer & Co. Inc., and Griffin Securities, Inc. (together, the "2007 Placement Agents") as placement agents in connection with the 2007 Offering. In consideration for their services, the Company paid the 2007 Placement Agents aggregate cash commissions of \$1,630,800 and issued 5-year warrants to the 2007 Placement Agents and their designees to purchase an aggregate of 156,058 shares of the Company's common stock at an exercise price of \$5.75 per share. In connection with the 2007 Offering, the Company also made cash payments of \$222,000 and issued 5-year warrants to purchase 21,244 shares of the Company's common stock, at an exercise price of \$5.75 per share, to a financial consultant pursuant to the non-circumvention provision of a prior agency agreement. The Company estimated the fair value of the warrants issued in the 2007 offering at \$4,724,169 using the Black-Scholes model, using an assumed risk-free rate of 4.71% and an expected life of 5 years, volatility of 93% and a dividend yield of 0%. The total gross proceeds resulting from the 2007 Offering was approximately \$30.9 million, before deducting selling commissions and expenses.

During the year ended December 31, 2006, we received gross proceeds of approximately \$37 million (\$34,280,121 net of cash issuance costs) as a result of the sale of an aggregate of 7,991,256 shares of common stock, at a price of \$4.63 per share, in a private placement (the "2006 Offering") that was completed on May 3, 2006. In addition to these shares, the Company also issued to each investor a five-year warrant to purchase, at an exercise price of \$5.56 per share, an additional number of shares of common stock equal to 30 percent of the shares purchased by such investor in the 2006 Offering. In the aggregate, these warrants entitle investors to purchase an additional 2,397,392 shares of common stock. The Company engaged Paramount BioCapital, Inc. and Griffin Securities, Inc. (the "Placement Agents") as co-placement agents in connection with the 2006 Offering. In consideration for their services, the Company paid the Placement Agents and certain selected dealers engaged by the Placement Agents aggregate cash commissions of \$2,589,966 and issued 7-year warrants to the Placement Agents and their designees to purchase an aggregate of 799,126 shares at an exercise price of \$5.09 per share. The Company also agreed to reimburse the Placement Agents for their accountable expenses incurred in connection with the 2006 Offering.

During the year ended December 31, 2005, we received \$4,815 proceeds from the exercise of stock options and gross proceeds of approximately \$18.1 million (\$16.8 net of issuance costs) as a result of the sale by ZIOPHARM, Inc. of Series A Convertible Preferred Stock in a private placement transaction. During the twelve months ended December 31, 2004, we received proceeds of approximately \$4.5 million as a result of the sale by ZIOPHARM, Inc. of common stock in a private placement transaction.

At September 30, 2008, working capital was approximately \$10.1 million, compared to working capital of approximately \$29.2 million at December 31, 2007. The decrease in working capital reflects the use of funds for operations.

Capital expenditures were approximately \$123,000 for the nine months ended September 30, 2008. We anticipate capital expenditures of approximately \$150,000 for the fiscal year ended December 31, 2008.

The Company's significant lease obligation payable for the twelve months ended September 30:

	Payments due by Period					2013 and thereafter
	Total	2009	2010	2011	2012	
Operating leases	\$ 1,184,362	\$ 471,026	\$ 350,804	\$ 186,188	\$ 176,344	—

## Critical Accounting Policies and Significant Estimates

The preparation of financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to accounting for stock-based compensation and research and development activities. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under difference assumptions or conditions.

## Research and Development

Research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for preclinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution and organizational affairs and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our research and development costs as they are incurred. General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development and general legal activities.

## Stock-based compensation

Our results include non-cash compensation expense as a result of the issuance of stock option and warrants grants. On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R) ("SFAS 123R") Share-Based Payment, using the modified prospective method, which results in the provision of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award using the Black Scholes Model and is recognized as expense over the service period. Previously, the Company had followed Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations which resulted in account for employee share options at their intrinsic value in the financial statements. The Company's most critical estimates consist of accounting for stock-based compensation.

## Off-Balance Sheet Arrangements

We do not have any “off-balance sheet agreements,” as that term is defined by SEC regulation.

### **Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

Our exposure to market risk is confined to our cash and cash equivalents. We have attempted to minimize risk by investing in low-risk treasury security funds and to a very limited extent, money market funds, with no security having an effective duration longer than 90 days. We are subject to risk due to general market conditions, which may adversely impact the carrying value of our treasury securities. To date, we have experienced no material loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurances that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial markets. If the market interest rate decreases by 100 basis points or 1%, the fair value of our cash and cash equivalents portfolio would have minimal to no impact on the carrying value of our portfolio. We did not hold any derivative instruments as of September 30, 2008, and we have never held such instruments in the past.

### **Item 4. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, a control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Based on their evaluation as of September 30, 2008, our Chief Executive Officer and Chief Financial Officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) are effective to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities and Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

During the quarter ended September 30, 2008, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**

### **Item 1. Legal Proceedings**

No response required.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

No response required.

### **Item 3. Defaults Upon Senior Securities.**

No response required.

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

No response required.

**Item 5. Other Information**

No response required.

**Item 6. EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
31.1	Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**SIGNATURES**

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ZIOPHARM ONCOLOGY, INC.**

Date: October 30, 2008

By: /s/ Jonathan Lewis  
Jonathan Lewis, M.D., Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

Date: October 30, 2008

By: /s/ Richard Bagley  
Richard Bagley  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
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32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.



CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Jonathan Lewis, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ZIOPHARM Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 30, 2008

/s/ Jonathan Lewis

Jonathan Lewis, M.D., Ph.D.  
Principal Executive Officer

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CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Richard Bagley, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ZIOPHARM Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 30, 2008

*/s/ Richard E. Bagley*

Richard E. Bagley  
Principal Financial Officer

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ZIOPHARM Oncology, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Lewis, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

*/s/ Jonathan Lewis*

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Jonathan Lewis, M.D., Ph.D.

Principal Executive Officer

October 30, 2008

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ZIOPHARM Oncology, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Lewis, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

*/s/ Richard E. Bagley*

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Richard E. Bagley  
Principal Financial Officer  
October 30, 2008

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