ZIOPHARM ONCOLOGY INC
Form 10-Q
August 01, 2011

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 June 30, 2011

OR

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

Commission File Number 001-33038

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes: þ 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 þ	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: þ

The number of shares of the registrant's Common Stock, $.001 par value, outstanding as of July 27, 2011, was 68,402,009 shares.

ZIOPHARM Oncology, Inc. (a development stage company)

Table of Contents

2

Part I - Financial Information

Item 1. Consolidated Financial Statements

ZIOPHARM Oncology, Inc. (a development stage company)

BALANCE SHEETS
(unaudited)

(in thousands, except share and per share data)

	June 30, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$130,282	$ 60,392
Prepaid expenses and other current assets	1,016	424
Total current assets	131,298	60,816
Property and equipment, net	549	253
Deposits	91	87
Other non-current assets	883	364
Total assets	$132,821	$ 61,520
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,784	$ 1,031
Accrued expenses	6,084	2,538
Deferred revenue - current portion	800	-
Deferred rent - current portion	23	43
Total current liabilities	8,691	3,612
Deferred revenue	3,933	-
Deferred rent	58	44
Warrant liabilities	36,011	27,311
Total liabilities	48,693	30,967
Commitments and contingencies (note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 30,000,000 shares authorized and no shares issued and outstanding	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized; 68,312,227 and 48,466,562 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively	68	48
Additional paid-in capital - common stock	243,809	131,530
Additional paid-in capital - warrants issued	13,797	22,789

Deficit accumulated during the development stage	(173,546)	(123,814)
Total stockholders' equity	84,128	30,553
Total liabilities and stockholders' equity	$132,821	$ 61,520

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

ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF OPERATIONS
(unaudited)

(in thousands, except share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,		Period from September 9, 2003 (date of inception) through
	2011	2010	2011	2010	June 30, 2011
Research contract revenue	$ 200	$ -	$ 267	$ -	$ 267
Operating expenses:					
Research and development, including costs of research contracts	9,125	2,222	33,766	4,161	105,582
General and administrative	3,923	2,894	7,275	5,524	61,086
Total operating expenses	13,048	5,116	41,041	9,685	166,668
Loss from operations	(12,848)	(5,116)	(40,774)	(9,685)	(166,401)
Other income, net	9	13	7	22	4,682
Change in fair value of warrants	2,115	14,142	(8,965)	1,049	(11,827)
Net income (loss)	$ (10,724)	$ 9,039	$ (49,732)	$ (8,614)	$ (173,546)
Net income (loss) per share - basic	$ (0.16)	$ 0.21	$ (0.78)	$ (0.21)	
Net income (loss) per share - diluted	$ (0.16)	$ 0.19	$ (0.78)	$ (0.21)	
Weighted average common shares outstanding to compute net income (loss) per share - basic	67,229,098	42,364,791	63,839,723	41,253,076	
Weighted average common shares outstanding to compute net income (loss) per share - diluted	67,229,098	48,822,686	63,839,723	41,253,076	

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

ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
For the Six Months Ended June 30, 2011
(unaudited)

(in thousands, except share and per share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital Common Stock	Additional Paid-in Capital Warrants	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2010	-	$ -	48,466,562	$ 48	$ 131,530	$ 22,789	$ (123,814)	$ 30,553
Stock-based compensation	-	-	-	-	1,314	-	-	1,314
Exercise of employee stock options	-	-	430,283	-	849	-	-	849
Exercise of warrants to purchase common stock	-	-	2,319,078	2	21,548	(8,992)	-	12,558
Issuance of restricted common stock	-	-	25,000	-	-	-	-	-
Repurchase of shares of common stock	-	-	(15,190)	-	(78)	-	-	(78)
Forfeiture of unvested restricted common stock	-	-	(16,667)	-	-	-	-	-
Issuance of common stock in a securities offering, net of commissions and expenses of $245	-	-	11,040,000	11	59,795	-	-	59,806
Issuance of common stock in a collaboration agreement, net of commissions and expenses of $86	-	-	6,063,161	7	28,851	-	-	28,858
Net loss	-	-	-	-	-	-	(49,732)	(49,732)
Balance at June 30, 2011	-	$ -	68,312,227	$ 68	$ 243,809	$ 13,797	$ (173,546)	$ 84,128

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

ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)

	For the Six Months Ended June 30,		Period from September 9, 2003 (date of inception) through
	2011	2010	June 30, 2011
Cash flows from operating activities:			
Net loss	$ (49,732)	$ (8,614)	$ (173,546)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	95	116	1,744
Stock-based compensation	1,314	2,174	13,855
Change in fair value of warrants	8,965	(1,049)	11,827
Common stock issued in exchange for in-process research and development	17,457	-	17,457
Loss on disposal of fixed assets	-	-	9
Change in operating assets and liabilities:			
(Increase) decrease in:			
Prepaid expenses and other current assets	(592)	76	(1,016)
Other noncurrent assets	(519)	30	(883)
Deposits	(4)	(41)	(91)
Increase (decrease) in:			
Accounts payable	753	(646)	1,784
Accrued expenses	3,546	(122)	6,084
Deferred revenue	4,733	-	4,733
Deferred rent	(5)	(28)	81
Net cash used in operating activities	(13,989)	(8,104)	(117,962)
Cash flows from investing activities:			
Purchases of property and equipment	(392)	(78)	(2,303)
Proceeds from sale of property and equipment	-	-	1
Net cash used in investing activities	(392)	(78)	(2,302)
Cash flows from financing activities:			
Stockholders' capital contribution	-	-	500
Proceeds from exercise of stock options	849	176	1,212
Payments to employees for repurchase of common stock	(78)	(47)	(2,126)
Proceeds from exercise of warrants	12,293	72	12,644
Proceeds from issuance of common stock and warrants, net	71,207	32,804	221,556
Proceeds from issuance of preferred stock, net	-	-	16,760
Net cash provided by financing activities	84,271	33,005	250,546
Net increase (decrease) in cash and cash equivalents	69,890	24,823	130,282
Cash and cash equivalents, beginning of period	60,392	48,839	-
Cash and cash equivalents, end of period	$ 130,282	$ 73,662	$ 130,282

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	$ -	$ -	$ 47,276
Preferred stock conversion to common stock	$ -	$ -	$ 16,760
Exercise of equity-classified warrants to common shares	$ 8,992	$ 239	$ 9,249
Exercise of liability-classified warrants to common shares	$ 265	$ 49	$ 314

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

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS
(unaudited)

1. Business

Overview

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

The Company has had limited operations to date and its activities have consisted primarily of raising capital and conducting research and development. Accordingly, the Company is considered to be in the development stage at June 30, 2011. The Company's fiscal year ends on December 31.

The Company has operated at a loss since its inception in 2003 and has minimal revenues. The Company anticipates that losses will continue for the foreseeable future. At June 30, 2011, the Company's accumulated deficit was approximately $173.5 million. The Company currently believes that it has sufficient capital to fund development and commercialization activities into early 2013. The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be realized by the Company, or if realized, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company's working capital requirements until it achieves profitable operations.

Basis of Presentation

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.

It is management's opinion that the accompanying unaudited interim financial statements reflect all adjustments (which are normal and recurring) that are necessary for a fair statement of the results for the interim periods. The unaudited interim financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2010 included in the Company's Form 10-K for such fiscal year.

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

The results disclosed in the Statements of Operations for the three and six months ended June 30, 2011 are not necessarily indicative of the results to be expected for the full fiscal year.

Use of Estimates

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.

Subsequent Events

The Company evaluated all events or transactions that occurred after the balance sheet date through the date these financial statements were available to be issued. During this period, the Company did not have any material recognizable subsequent events and two disclosable events. Subsequent to June 30, 2011, the Company entered into a new lease for its corporate headquarters in New York, New York. The terms of the lease now extend to January 2019, with total payments over the lease of approximately $2.9 million. Also subsequent to June 30, 2011, the collaboration agreement with Harmon Hill, LLC was extended through April 8, 2012.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

2. Summary of Significant Accounting Policies

Other than the policy below, our significant accounting policies were identified in the Company's Form 10-K for the fiscal year ended December 31, 2010.

Revenue Recognition

The Company receives revenue from a collaboration agreement (see Note 3). Under the terms of the collaboration agreement, the Company may receive non-refundable, upfront license fees, funding of research and development efforts, milestone payments if specified objectives are achieved and/or profit-sharing or royalties on product sales. Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner. The consideration received is then allocated among the separate units based on their respective fair values and the applicable revenue recognition criteria are applied to each of the separate units.

Revenue from non-refundable, upfront license fees is reported as research and development revenue and is recognized on a straight-line basis over the contracted or estimated period of performance, which is typically the development term. Research and development funding is earned over the period of effort. The Company currently estimates this period to be 75 months, which could be adjusted in the future.

Milestone payments are recognized as research and development revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone and (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payment is deferred and recognized as revenue over the estimated remaining period of performance under the contract as the Company completes its performance obligations.

3. Collaborations and Alliances

On March 7, 2011, the Company entered into a License and Collaboration Agreement with Solasia Pharma K.K. ("Solasia").

Pursuant to the License and Collaboration Agreement (the "Agreement"), the Company granted Solasia an exclusive license to develop and commercialize darinaparsin (Zinapar™ or ZIO-101) in both intravenous and oral forms and related organic arsenic molecules, in all indications for human use in a pan-Asian/Pacific territory comprised of Japan, China, Hong Kong, Macau, Republic of Korea, Taiwan, Singapore, Australia, New Zealand, Malaysia, Indonesia, Philippines and Thailand.

As consideration for the license, the Company received an upfront payment of $5 million to be used exclusively for further clinical development of darinaparsin outside of the pan-Asian/Pacific territory, and will be entitled to receive additional payments of up to $32.5 million in development-based milestones and up to $53.5 million in sales-based milestones. The Company will also be entitled to receive double digit royalty payments from Solasia based upon on net sales of licensed products in the applicable territories, once commercialized, and a percentage of sublicense revenues generated by Solasia.

The Agreement provides that Solasia will be responsible for the development and commercialization of darinaparsin in the pan-Asian/Pacific territory.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

4. Fair Value Measurements

The Company accounts for fair value measurements of its financial assets and liabilities and non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value on a recurring basis. The accounting standard defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

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

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

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

Assets and liabilities measured at fair value on a recurring basis as of June 30, 2011 and December 31, 2010 are as follows:

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	Balance as of June 30, 2011	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 130,072	$ 130,072	$ -	$ -
Warrant liability	$ 36,011	$ -	$ 36,011	$ -

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

4. Fair Value Measurements – (continued)

($ in thousands)	Fair Value Measurements at Reporting Date Using			
Description	Balance as of December 31, 2010	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 59,219	$ 59,219	$ -	$ -
Warrant liability	$ 27,311	$ -	$ 27,311	$ -

The warrants were valued using a Black-Scholes valuation model. See Note 8 for additional disclosures on the valuation methodology and significant assumptions.

5. Earnings (Loss) per Share

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
in thousands, except share and per share data	2011	2010	2011	2010
Basic				
Net income (loss)	$ (10,724)	$ 9,039	$ (49,732)	$ (8,614)
Weighted-average common shares outstanding	67,229,098	42,364,791	63,839,723	41,253,076
Earnings (loss) per share, basic	$ (0.16)	$ 0.21	$ (0.78)	$ (0.21)
Diluted				
Net income (loss)	$ (10,724)	$ 9,039	$ (49,732)	$ (8,614)
Weighted-average common shares outstanding	67,229,098	42,364,791	63,839,723	41,253,076
Effect of dilutive securities				
Stock options	-	1,292,335	-	-
Unvested restricted common stock	-	1,496,334	-	-
Warrants	-	3,669,226	-	-
Dilutive potential common shares	-	6,457,895	-	-
Shares used in calculating diluted earnings (loss) per share	67,229,098	48,822,686	63,839,723	41,253,076
Earnings (loss) per share, diluted	$ (0.16)	$ 0.19	$ (0.78)	$ (0.21)

10

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

5. Earnings (Loss) per Share – (continued)

Certain shares related to some of the Company's outstanding common stock options, unvested restricted stock and warrants, have not been included in the computation of diluted earnings (loss) per share for the three and six months ended June 30, 2011 and 2010 as the result would be anti-dilutive. Such potential common shares at June 30, 2011 and 2010 consist of the following:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2011	2010	2011	2010
Stock options	4,790,552	227,000	4,790,552	3,567,685
Unvested restricted common stock	248,752	-	248,752	1,496,334
Warrants	13,252,346	3,756,709	13,252,346	15,924,642
	18,291,650	3,983,709	18,291,650	20,988,661

6. Commitments and Contingencies

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

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

As partial consideration for the license rights obtained, the Company made an upfront payment in 2004 of $125 thousand and granted the Licensors 250,487 shares of the Company’s common stock. In addition, the Company issued options to purchase an additional 50,222 shares outside the 2003 Stock Option Plan for $0.002 per share following the successful completion of certain clinical milestones, which vested with respect to 12,555 shares upon the filing of an Investigation New Drug application (“IND”) for darinaparsin in 2005 and vested with respect to another 25,111 shares upon the completion of dosing of the last patient for both Phase 1 clinical trials in 2007. The Company recorded $120 thousand of stock based compensation expense related to the vesting in 2007. The remaining 12,556 shares will vest upon enrollment of the first patient in a multi-center pivotal clinical trial i.e. a human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of an approvable New Drug Application (“NDA”). In addition, the Licensors are entitled to receive certain milestone payments, including $100 thousand that was paid in 2005 upon the commencement of Phase 1 clinical trial and $250 thousand that was paid in 2006 upon the dosing of the first patient in the Registrant-sponsored Phase 2 clinical trial for darinaparsin. The Company may be required to make additional payments upon achievement of certain other milestones in varying amounts which on a cumulative basis could total up to an additional $4.5 million. In addition, the Licensors are entitled to receive single digit percentage royalty payments on sales from a licensed product and will also be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. In addition, the Company also paid the Licensors $100 thousand in 2006 and 2007 to conduct scientific research with the Company obtaining

exclusive right to all resulting intellectual property rights. The sponsored research agreements governing this research and any related extensions expired in February 2008 with no payments being made subsequent to that date.

The license agreement also contains other provisions customary and common in similar agreements within the industry, such as the right to sublicense the Company rights under the agreement. However, if the Company sublicenses its rights prior to the commencement of a pivotal study i.e. a human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of an approvable NDA, the Licensors will be entitled to receive a share of the payments received by the Company in exchange for the sublicense (subject to certain exceptions). The term of the license agreement extends until the expiration of all claims under patents and patent applications associated with the licensed technology, subject to earlier termination in the event of defaults by the Company or the Licensors under the license agreement, or if the Company becomes bankrupt or insolvent. No milestones under the license agreement were reached or expensed during the years ended December 31, 2008, 2009 or 2010 or during the six months ended June 30, 2011.

ZIOPHARM Oncology, Inc. (a development stage company)