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, 2012
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, 20th 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 29, 2012, was 79,567,946 shares.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are based on our current beliefs and expectations. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “project,” “target,” “will” and other words and terms of similar meaning. Reference is made in particular to forward-looking statements regarding:

- the anticipated amount, timing and accounting of deferred revenues, milestone and other payments under licensing, collaboration or acquisition agreements, tax positions and contingencies, research and development costs and other expenses, and amortization of intangible assets;
- our expectations regarding the application of certain accounting pronouncements and their effect on our disclosures;
- the protection afforded by our patent rights;
- our assessment of the potential impact on our future revenues of healthcare reform legislation in the United States;
- the timing and impact of measures worldwide designed to reduce healthcare costs;
- the impact of the deterioration of the credit and economic conditions in certain countries in Europe;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the sufficiency of our cash, investments and cash flows from operations and our expected uses of cash;
- the costs and timing of the development and commercialization of our pipeline products and services;
- additional planned regulatory filings for and commercialization of Palifosfamide;
- contract manufacturing activity;

These forward-looking statements involve risks and uncertainties, including those that are described in the “*Risk Factors*” section of this report and elsewhere within this report that could cause actual results to differ materially from those reflected in such statements. You should not place undue reliance on these statements. Forward-looking statements speak only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statements.

NOTE REGARDING COMPANY REFERENCES

Throughout this report, “ZIOPHARM,” the “Company,” “we,” “us” and “our” refer to ZIOPHARM Oncology, Inc .

NOTE REGARDING TRADEMARKS

Our registered trademarks include Zymafos and Zinapar. Our trademarks include Zybulin. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

ZIOPHARM Oncology, Inc. (a development stage company)

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Part I - Financial Information

Item 1. Consolidated Financial Statements

ZIOPHARM Oncology, Inc. (a development stage company)

BALANCE SHEETS
(unaudited)

(in thousands, except share and per share data)

	June 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 110,391	$ 104,713
Collaboration receivable	-	79
Prepaid expenses and other current assets	9,051	1,313
Total current assets	119,442	106,105
Property and equipment, net	1,982	1,141
Deposits	132	91
Other non-current assets	824	771
Total assets	$ 122,380	$ 108,108
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,470	$ 1,727
Accrued expenses	15,502	10,821
Deferred revenue - current portion	800	800
Deferred rent - current portion	4	15
Total current liabilities	17,776	13,363
Deferred revenue	3,133	3,533
Deferred rent	363	180
Warrant liabilities	25,472	19,425
Total liabilities	46,744	36,501
Commitments and contingencies (note 7)		
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; 79,625,290 and 69,206,044 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	80	69
Additional paid-in capital - common stock	304,219	246,519
Additional paid-in capital - warrants issued	7,012	12,611
Deficit accumulated during the development stage	(235,675)	(187,592)
Total stockholders' equity	75,636	71,607
Total liabilities and stockholders' equity	$ 122,380	$ 108,108

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
	2012	2011	2012	2011	June 30, 2012
Research contract revenue	$ 200	$ 200	$ 400	$ 267	$ 1,067
Operating expenses:					
Research and development, including costs of research contracts	18,264	9,125	32,249	33,766	161,148
General and administrative	4,902	3,923	9,750	7,275	78,545
Total operating expenses	23,166	13,048	41,999	41,041	239,693
Loss from operations	(22,966)	(12,848)	(41,599)	(40,774)	(238,626)
Other income, net	3	9	(23)	7	4,691
Change in fair value of warrants	(650)	2,115	(6,461)	(8,965)	(1,740)
Net income (loss)	$ (23,613)	$ (10,724)	$ (48,083)	$ (49,732)	$ (235,675)
Net income (loss) per share - basic	$ (0.30)	$ (0.16)	$ (0.62)	$ (0.78)	
Net income (loss) per share - diluted	$ (0.30)	$ (0.16)	$ (0.62)	$ (0.78)	
Weighted average common shares outstanding to compute net income (loss) per share - basic	78,514,718	67,229,098	77,067,424	63,839,723	
Weighted average common shares outstanding to compute net income (loss) per share - diluted	78,514,718	67,229,098	77,067,424	63,839,723	

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

ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENT OF STOCKHOLDERS' EQUITY
For the Six Months Ended June 30, 2012
(unaudited)

(in thousands, except share and per share data)

	Stockholders' Equity							
	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, 2011	-	$ -	69,206,044	$ 69	$ 246,519	$ 12,611	$ (187,592)	$ 71,607
Stock-based compensation	-	-	-	-	2,290	-	-	2,290
Exercise of employee stock options	-	-	8,300	-	30	-	-	30
Exercise of warrants to purchase common stock	-	-	192,603	-	788	(166)	-	622
Issuance of restricted common stock	-	-	170,302	-	-	-	-	-
Forfeiture of unvested restricted common stock	-	-	(66,360)	-	-	-	-	-
Expired warrants	-	-	-	-	5,433	(5,433)	-	-
Issuance of common stock in a securities offering, net of commission and expenses of $3,426	-	-	10,114,401	11	49,159	-	-	49,170
Net loss	-	-	-	-	-	-	(48,083)	(48,083)
Balance at June 30, 2012	-	$ -	79,625,290	$ 80	$ 304,219	$ 7,012	$ (235,675)	$ 75,636

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,		(date of inception) through
	2012	2011	June 30, 2012
Cash flows from operating activities:			
Net loss	$ (48,083)	$ (49,732)	$ (235,675)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	265	95	2,181
Stock-based compensation	2,290	1,314	17,591
Change in fair value of warrants	6,461	8,965	1,740
Loss on disposal of fixed assets	-	-	9
Common stock issued in exchange for in-process research and development	-	17,457	17,457
Change in operating assets and liabilities:			
(Increase) decrease in:			
Collaboration receivable	79	-	-
Prepaid expenses and other current assets	(7,738)	(592)	(9,051)
Other noncurrent assets	(53)	(519)	(824)
Deposits	(41)	(4)	(132)
Increase (decrease) in:			
Accounts payable	(258)	753	1,469
Accrued expenses	4,681	3,546	15,502
Deferred revenue	(400)	4,733	3,933
Deferred rent	172	(5)	367
Net cash used in operating activities	(42,625)	(13,989)	(185,433)
Cash flows from investing activities:			
Purchases of property and equipment	(1,107)	(392)	(4,174)
Proceeds from sale of property and equipment	-	-	1
Net cash used in investing activities	(1,107)	(392)	(4,173)
Cash flows from financing activities:			
Stockholders' capital contribution	-	-	500
Proceeds from exercise of stock options	30	849	1,373
Payments to employees for repurchase of common stock	-	(78)	(2,321)
Proceeds from exercise of warrants	210	12,293	12,959
Proceeds from issuance of common stock and warrants, net	49,170	71,207	270,726
Proceeds from issuance of preferred stock, net	-	-	16,760
Net cash provided by financing activities	49,410	84,271	299,997
Net increase (decrease) in cash and cash equivalents	5,678	69,890	110,391
Cash and cash equivalents, beginning of period	104,713	60,392	-
Cash and cash equivalents, end of period	$ 110,391	$ 130,282	$ 110,391
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	$ 166	$ 8,992	$ 9,490
Exercise of liability-classified warrants to common shares	$ 412	$ 265	$ 764

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's operations to date 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, 2012. 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, 2012, the Company's accumulated deficit was approximately $235.7 million. The Company currently believes that it has sufficient capital to fund development and commercialization activities into the second half of 2013. The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or to 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 in the United States 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, 2011 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 generally accepted accounting principles in the United States.

The results disclosed in the Statements of Operations for the three and six months ended June 30, 2012 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 accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although the Company regularly assesses these estimates, actual results could differ from those estimates. Changes in estimates are recorded in the period in which they become known.

1. Business - (continued)

The Company's most significant estimates and judgments used in the preparation of its financial statements are:

- Clinical trial expenses;
- Fair value measurements for stock based compensation and warrants; and
- Income taxes.

Subsequent Events

The Company evaluated all events and transactions that occurred after the balance sheet date through the date of this filing. Except as disclosed below, the Company did not have any other material subsequent events that impacted its financial statements or disclosures.

On July 16, 2012, the Company announced that it has restructured its management team and will also be closing its Germantown, MD office. As a result of this action, the Company expects to record a restructuring charge, consisting primarily of severance and health benefit continuation costs, of approximately $1.1 million in the third quarter of 2012.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies were identified in the Company's Form 10-K for the fiscal year ended December 31, 2011.

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 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 $5.0 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 net sales of licensed products in the applicable territories, once commercialized, and a percentage of sublicense revenues generated by Solasia.

The upfront payment for 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.

Under the Agreement, the Company provides Solasia with drug product to conduct clinical trials. These transfers are accounted for as a reduction of research and development costs and an increase in collaboration receivables.

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

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, 2012 and December 31, 2011 are as follows:

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	Balance as of June 30, 2012	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 109,455	$ 109,455	$ -	$ -
Warrant liability	$ 25,472	$ -	$ 25,472	$ -

4. Fair Value Measurements – (continued)

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	Balance as of December 31, 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	$ 103,736	$ 103,736	$ -	$ -
Warrant liability	$ 19,425	$ -	$ 19,425	$ -

The cash equivalents represent deposits in a short term U.S. treasury money market mutual fund quoted in an active market and classified as a Level I asset. The Company's Level II financial liabilities consist of long-term investor and placement agent warrants issued in connection with its December 2009 public offering. The warrants were valued using Binomial/Monte Carlo valuation models. See Note 8 for additional disclosures on the valuation methodology and significant assumptions.

5. Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding for the period. The Company's potential dilutive shares, which include outstanding common stock options, unvested restricted stock and warrants, have not been included in the computation of diluted net loss per share for any of the periods presented as the result would be antidilutive. Such potential shares of common stock at June 30, 2012 and 2011 consist of the following:

	For the Six Months Ended June 30,	
	2012	2011
Stock options	5,397,154	4,790,552
Unvested restricted common stock	1,029,848	248,752
Warrants	11,268,678	13,252,346
	17,695,680	18,291,650

6. Related Party Transactions

On January 6, 2011, the Company entered into an Exclusive Channel Partner Agreement (the "Channel Agreement") with Intrexon Corporation (see Note 7 for additional disclosure relating to the Channel Agreement). During the six months ended June 30, 2012, the Company paid Intrexon approximately $10.7 million, of which $2.5 million was for services already incurred and the remaining $8.2 million expected to be incurred within a year. This amount has been included as part of prepaid expenses and other current assets on the accompanying balance sheet as of June 30, 2012. The Company does not owe any amounts to Intrexon that have not already been accrued for as of June 30, 2012.

On January 25, 2012, Intrexon purchased 1,923,075 shares of common stock in the Company's public offering (see Note 9).

7. 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 Company-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, 2009, 2010, 2011 or for the six months ended June 30, 2012.

7. Commitments and Contingencies – (continued)

License Agreement with DEKK-Tec, Inc.

On October 15, 2004, the Company entered into a license agreement with DEKK-Tec, Inc., pursuant to which it was granted an exclusive, worldwide license for palifosfamide. As part of the signing of license agreement with DEKK-Tec, the Company expensed an upfront $50 thousand payment to DEKK-Tec in 2004.

In consideration for the license rights, DEKK-Tec is entitled to receive payments upon achieving certain milestones in varying amounts, which on a cumulative basis may total $4.0 million. Of the aggregate milestone payments, most will be creditable against future royalty payments as referenced below. The Company expensed a $100 thousand milestone payment upon achieving Phase 2 milestones during the year ended December 31, 2006. Additionally, in 2004 the Company issued DEKK-Tec an option to purchase 27,616 shares of the Company's common stock for $0.02 per share. Upon the execution of the license agreement, 6,904 shares vested and were subsequently exercised in 2005 and the remaining options will vest upon certain milestone events, culminating with final FDA approval of the first NDA submitted by the Company (or by its sublicensee) for palifosfamide. DEKK-Tec is entitled to receive single-digit percentage royalty payments on the sales of palifosfamide should it be approved for commercial sale. On March 16, 2010, the Company expensed a $100 thousand milestone payment upon receiving a United States Patent for palifosfamide. In December 2010, the Company expensed a $300 thousand milestone payment and vested 6,904 stock options upon achieving Phase 3 milestones. These options were subsequently exercised in 2011. The Company's obligation to pay royalties will terminate on a country-by-country basis upon the expiration of all valid claims of patents in such country covering licensed product, subject to earlier termination in the event of defaults by the parties under the license agreement. No milestones under the license agreement were reached or expensed during the years ended December 31, 2009, 2011 or for the six months ended June 30, 2012.

Option Agreement with Southern Research Institute ("SRI")

On December 22, 2004, the Company entered into an Option Agreement with SRI (the "Option Agreement"), pursuant to which the Company was granted an exclusive option to obtain an exclusive license to SRI's interest in certain intellectual property, including exclusive rights related to certain isophosphoramide mustard analogs.

Also on December 22, 2004, the Company entered into a Research Agreement with SRI pursuant to which the Company agreed to spend a sum not to exceed $200 thousand between the execution of the agreement and December 21, 2006, including a $25 thousand payment that was made simultaneously with the execution of the agreement, to fund research and development work by SRI in the field of isophosphoramide mustard analogs. The Option Agreement was exercised on February 13, 2007. Under the license agreement entered into upon exercise of the option, the Company is required to remit minimum annual royalty payments of $25 thousand until the first commercial sale of a licensed product. These payments were made for the years ended December 31, 2008, 2009, 2010 and 2011. The Company may be required to make payments upon achievement of certain milestones in varying amounts which on a cumulative basis could total up to $775,000. In addition, SRI will be entitled to receive single digit percentage royalty payments on the sales of a licensed product in any country until all licensed patents rights in that country which are utilized in the product have expired. No milestones under the license agreement were reached or expensed during the years ended December 31, 2009, 2010, 2011 or for the six months ended June 30, 2012.

7. Commitments and Contingencies – (continued)

License Agreement with Baxter Healthcare Corporation

On November 3, 2006, the Company entered into a definitive Asset Purchase Agreement for indibulin and a License Agreement to proprietary nanosuspension technology with affiliates of Baxter Healthcare S.A. The purchase included the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories. The terms of the Asset Purchase Agreement included an upfront cash payment of approximately $1.1 million and an additional $100 thousand payment for existing inventory, both of which were expensed in 2006. In addition to the upfront costs, the Asset Purchase Agreement includes additional diligence and milestone payments that could amount to approximately $8 million in the aggregate and royalties on net sales of products covered by a valid claim of a patent for the life of the patent on a country-by-country basis. The Company expensed a $625 thousand milestone payment upon the successful U.S. IND application for indibulin in 2007. The License Agreement requires payment of a $15 thousand annual patent and license prosecution/maintenance fee through the expiration of the last of the licensed patents, which is expected to expire in 2025, and single-digit royalties on net sales of licensed products covered by a valid claim of a patent for the life of the patent on a country-by-country basis. The term of the license agreement extends until the expiration of the last to expire of the patents covering the licensed products, subject to earlier termination in the event of defaults by the parties under the license agreement.

In October 2009, the Baxter License Agreement was amended to allow the Company to manufacturer indibulin. No milestones under the license agreement were reached or expensed during the years ended December 31, 2009, 2010, 2011 or for the six months ended June 30, 2012.

Exclusive Channel Partner Agreement with Intrexon Corporation

On January 6, 2011, we entered into the Channel Agreement, with Intrexon that governs a “channel partnering” arrangement in which we use Intrexon’s technology directed towards *in vivo* expression of effectors in connection with the development of ZIN-CTI-001 and ZIN-ATI-001 and generally to research, develop and commercialize products, in each case in which DNA is administered to humans for expression of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer, which we collectively refer to as the Cancer Program. The Channel Agreement establishes committees comprised of representatives of us and Intrexon that govern activities related to the Cancer Program in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts and intellectual property.

The Channel Agreement grants us a worldwide license to use patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of products involving DNA administered to humans for expression of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer (collectively the “ZIOPHARM Products”). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of ZIOPHARM Products, and otherwise is non-exclusive. Subject to limited exceptions, we may not sublicense the rights described without Intrexon’s written consent.

Under the Channel Agreement, and subject to certain exceptions, we are responsible for, among other things, the performance of the Cancer Program, including development, commercialization and certain aspects of manufacturing of ZIOPHARM Products. Intrexon is responsible for the costs of establishing manufacturing capabilities and facilities for the bulk manufacture of products developed under the Cancer Program, certain other aspects of manufacturing and costs of discovery-stage research with respect to platform improvements and costs of filing, prosecution and maintenance of Intrexon’s patents.

Subject to certain expense allocations and other offsets provided in the Channel Agreement, we will pay Intrexon on a quarterly basis 50% of net profits derived in that quarter from the sale of ZIOPHARM Products, calculated on a ZIOPHARM Product-by- ZIOPHARM Product basis. We have likewise agreed to pay Intrexon on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement. In addition, in partial consideration for each party’s execution and delivery of the Channel Agreement, we entered into a Stock Purchase Agreement with Intrexon.

7. Commitments and Contingencies – (continued)

During the first 24 months of the agreement, either we or Intrexon may terminate the Channel Agreement in the event of a material breach by the other and Intrexon may terminate the Channel Agreement under certain circumstances if we assign our rights under the Channel Agreement without Intrexon's consent. Following the first 24 months of the agreement, Intrexon may also terminate the Channel Agreement if we fail to use diligent efforts to develop and commercialize ZIOPHARM Products or if we elect not to pursue the development of a Cancer Program identified by Intrexon that is a "Superior Therapy" as defined in the Channel Agreement. Also following the first 24 months of the agreement, we may voluntarily terminate the Channel Agreement upon 90 days written notice to Intrexon.

Upon termination of the Channel Agreement, we may continue to develop and commercialize any ZIOPHARM Product that, at the time of termination:

- is being commercialized by us;
- has received regulatory approval;
- is a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- is the subject of at least an ongoing Phase 2 clinical trial (in the case of a termination by Intrexon due to an uncured breach or a voluntary termination by us), or an ongoing Phase 1 clinical trial in the field (in the case of a termination by us due to an uncured breach or a termination by Intrexon following an unconsented assignment by us or our election not to pursue development of a Superior Therapy).

Our obligation to pay 50% of net profits or revenue described above with respect to these "retained" products will survive termination of the Channel Agreement.

Collaboration Agreement with Harmon Hill, LLC

On April 8, 2008, the Company signed a collaboration agreement for Harmon Hill, LLC ("Harmon Hill") to provide consulting and other services for the development and commercialization of oncology therapeutics by ZIOPHARM. Under the agreement the Company has agreed to pay Harmon Hill $20 thousand per month for the consulting services and has further agreed to pay Harmon Hill (a) $500 thousand upon the first patient dosing of the Specified Drug in a pivotal trial, which trial uses a dosing regime introduced by Harmon Hill; and (b) provided that the Specified Drug receives regulatory approval from the FDA, the European Medicines Agency or another regulatory agency for the marketing of the Specified Drug, a 1% royalty of the Company's net sales will be awarded to Harmon Hill. If the Specified Drug is sublicensed to a third party, the agreement entitles Harmon Hill to 1% award of royalties or other payments received from a sublicense. The agreement expired on May 8, 2012 and is currently being renegotiated through November 8, 2012. The Company expensed $240 thousand during each of the years ended December 31, 2009, 2010 and 2011 and $120 thousand for the six months ended June 30, 2012 for consulting services per the aforementioned agreement. No milestones under the license agreement were reached or expensed during the years ended December 31, 2009, 2010, 2011 or for the six months ended June 30, 2012.

Collaboration Agreement with Solasia Pharma K.K.

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

Pursuant to the License and Collaboration Agreement, we granted Solasia an exclusive license to develop and commercialize darinaparsin in both IV 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.

7. Commitments and Contingencies – (continued)

As consideration for the license, we received an upfront payment of $5.0 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. We will also be entitled to receive double-digit royalty payments from Solasia based upon net sales of licensed products in the applicable territories, once commercialized, and a percentage of sublicense revenues generated by Solasia.

The upfront payment for research and development funding is earned over the period of effort. We currently estimate this period to be 75 months, which could be adjusted in the future.

Under the License and Collaboration Agreement, we provide Solasia with drug product to conduct clinical trials. These transfers are accounted for as a reduction of research and development costs and an increase in collaboration receivables.

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

CRO Services Agreement with PPD Development, L.P.

The Company and PPD Development, L.P. ("PPD") are parties to a master clinical research organization services agreement dated January 29, 2010, a related work order dated June 25, 2010 and a related work order dated April 8, 2011 under which PPD provides clinical research organization ("CRO") services in support of the Company's clinical trials. PPD is entitled to cumulative payments of up to $18.3 million under these arrangements, which is payable by the Company in varying amounts upon PPD achieving specified milestones. During the year ended December 31, 2010, the Company expensed $1.8 million upon contract execution and $1.1 million upon a clinical study commencement of enrollment in North America. During the year ended December 31, 2011, additional milestones related to commencing enrollment in Europe, Latin America and Asia, along with enrollment based milestones, were met and the Company recorded an aggregate $4.0 million expense. During the six months ended June 30, 2012, two enrollment related milestones were met and the Company recorded an expense of $2.6 million.

CRO Services Agreement with Pharmaceutical Research Associates, Inc.

The Company and Pharmaceutical Research Associates, Inc. (“PRA”) are parties to a master clinical research organization services agreement dated December 13, 2011 under which PRA provides CRO services in support of the Company's clinical trials. PRA is entitled to cumulative payments of up to $19.7 million under these arrangements, which is payable by the Company in varying amounts upon PRA achieving specified milestones. During the year ended December 31, 2011, the Company expensed $0.5 million upon execution of a letter of intent. During the six months ended June 30, 2012, the Company expensed $0.4 million upon execution of extensions of the foregoing letter of intent, $0.7 million upon work order execution and $1.0 million upon initial clinical study enrollment in the United States.

8. Warrants

The Company has issued both warrants that are accounted for as liabilities and warrants that are accounted for as equity instruments. The number of warrants outstanding at June 30, 2012 and December 31, 2011 were as follows:

	June 30, 2012	December 31, 2011
Liability-classified warrants	8,050,709	8,424,905
Equity-classified warrants	3,217,969	4,692,359
Total warrants	11,268,678	13,117,264

8. Warrants – (continued)

Liability-Classified Warrants

In May 2005, the Company issued 419,786 warrants to placement agents for services performed in connection with a 2005 private placement (the "2005 Warrants") which were originally valued at $1.6 million. Subject to certain exceptions, the 2005 Warrants provide for anti-dilution protection should common stock or common stock equivalents be subsequently issued at a price less than the exercise price of the 2005 Warrants then in effect, which was initially $4.75 per share. This provision was triggered when the Company sold stock in a 2006 private placement at $4.63 per share. Accordingly, the 2005 Warrants were re-priced at $4.69. The provision was triggered a second time upon completion of a 2009 private placement in which the Company sold stock at $1.825 per share and issued common stock purchase warrants with an exercise price of $2.04, and the 2005 Warrants were re-priced at $4.25. The provision was triggered again when the Company sold stock in a December 2009 public offering at $3.10 per share and the 2005 Warrants were re-priced at $3.93. During the first six months of 2012, 373,617 warrants were exercised and 579 expired on May 31, 2012.

Also, in connection with its December 2009 public securities offering, the Company issued warrants to purchase an aggregate of 8,206,520 shares of common stock (including the investor warrants and 464,520 warrants issued to the underwriters for the offering) (the "2009 Warrants"). The 2009 Warrants issued to investors were exercisable immediately and the warrants issued to underwriters became exercisable six months after the date of issuance. The 2009 Warrants have an exercise price of $4.02 per share and have a five-year term. The fair value of the 2009 Warrants was estimated at $22.9 million using a Black-Scholes model with the following assumptions: expected volatility of 105%, risk free interest rate of 2.14%, expected life of five years and no dividends.

The Company assessed whether the 2005 Warrants and the 2009 Warrants require accounting as derivatives. The Company determined that these warrants were not indexed to the Company's own stock in accordance with accounting standards codification Topic 815, *Derivatives and Hedging*. As such, the Company has concluded these warrants did not meet the scope exception for determining whether the instruments require accounting as derivatives and were classified as liabilities.

In December 2011, the Company changed from using a Black-Scholes pricing model to estimate the value of the liability-classified warrants to a Binomial/Monte Carlo pricing model. The following assumptions were used in the Binomial/Monte Carlo valuation model at June 30, 2012 and the Black-Scholes valuation model at June 30, 2011:

	June 30, 2012	June 30, 2011
Risk-free interest rate	0.37%	0.18 - 1.01%
Expected life in years	2.44	0.92 - 3.43
Expected volatility	70%	45 - 97%
Expected dividend yield	0	0
Steps per year	12	N/A

The change in the fair value of the warrant liability resulted in losses of $0.6 million and $6.4 million for the three and six months ended June 30, 2012, respectively. The change in the fair value of the warrant liability resulted in a gain of $2.1 million for the three months ended June 30, 2011 and a loss of $9.0 million for the six months ended June 30, 2011. The change in the fair value of the warrant liability was charged to other income (expense) in the Statements of Operations.

8. Warrants – (continued)

During the first six months of 2012, warrant exercises were as follows:

(in thousands, except share data)	Equity Warrants	Liability Warrants	Common Stock Issued	Liability Reclassed to Equity	Cash Received
Cash exercises	102,744	-	102,744	$ -	$ 210
Cashless exercises	12,329	373,617	89,859	412	-
	115,073	373,617	192,603	$ 412	$ 210

During the first six months of 2011, warrant exercises were as follows:

(in thousands, except share data)	Equity Warrants	Liability Warrants	Common Stock Issued	Liability Reclassed to Equity	Cash Received
Cash exercises	2,259,770	-	2,259,770	$ -	$ 12,293
Cashless exercises	39,832	144,905	59,308	265	-
	2,299,602	144,905	2,319,078	$ 265	$ 12,293

During the six months ended June 30, 2012, 1,359,317 warrants issued on February 23, 2007, exercisable at $5.75, expired unexercised on February 23, 2012 and 579 warrants issued on May 31, 2005, exercisable at $3.93, expired unexercised on May 31, 2012.

9. Common Stock

On January 20, 2012, the Company entered into an underwriting agreement with J. P. Morgan Securities LLC, as representative of the several underwriters named therein, relating to the issuance and sale of 9,650,000 shares of our common stock. The price to the public in the offering was $5.20 per share, and the underwriters agreed to purchase the shares from the Company pursuant to the underwriting agreement at a purchase price of $4.888 per share. Under the terms of the underwriting agreement, the Company also granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,447,500 shares of common stock at a purchase price of $4.888 per share. The offering was made pursuant to the Company's effective registration statement on Form S-3 (Registration Statement No. 333-177793) previously filed with the SEC, and a prospectus supplement thereunder. The underwriters purchased the 9,650,000 shares on January 25, 2012 and purchased an additional 464,401 shares on January 31, 2012 pursuant to the partial exercise of their option to purchase additional shares, resulting in our issuing a total of 10,114,401 shares. The net proceeds from the offering were approximately $49.2 million after deducting underwriting discounts and offering expenses payable by the Company.

10. Stock-Based Compensation

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

	For the three months ended June 30,		For the six months ended June 30,	
(in thousands)	**2012**	**2011**	**2012**	**2011**
Research and development	$ 426	$ 166	$ 942	$ 276
General and administrative	652	446	1,348	1,038
Stock-based employee compensation expense	$ 1,078	$ 612	$ 2,290	$ 1,314

The Company granted 361,900 and 425,400 stock options during the three and six months ended June 30, 2012 that had a weighted-average grant date fair value of $3.51 and $3.48 per share, respectively. The Company granted 516,000 and 1,063,900 stock options during the three and six months ended June 30, 2011 that had a weighted-average grant date fair value of $4.69 and $4.33 per share, respectively.

At June 30, 2012, total unrecognized compensation costs related to unvested stock options outstanding amounted to $10.3 million. The cost is expected to be recognized over a weighted-average period of 1.59 years.

10. Stock-Based Compensation – (continued)

For the three months ended June 30, 2012 and 2011, the fair value of stock options was estimated on the date of grant using a Black-Scholes option valuation model with the following assumptions:

	For the three months ended June 30,	
	2012	**2011**
Risk-free interest rate	0.93 - 1.10%	1.83 - 2.61%
Expected life in years	6	5.77 - 6
Expected volatility	83.36 - 83.52%	84.4 - 87.4%
Expected dividend yield	0	0

Stock option activity under the Company's stock option plan for the six months ended June 30, 2012 is as follows:

(in thousands, except share and per share data)	**Number of Shares**	**Weighted-Average Exercise Price**	**Weighted-Average Contractual Term (Years)**	**Aggregate Intrinsic Value**
Outstanding, December 31, 2011	5,138,486	$ 4.08		
Granted	425,400	4.96		
Exercised	(8,300)	3.61		
Cancelled	(158,432)	5.90		
Outstanding, June 30, 2012	5,397,154	$ 4.10	7.19	$ 10,320
Vested and unvested expected to vest at June 30, 2012	5,340,550	$ 4.10	7.19	$ 10,212
Options exercisable, June 30, 2012	3,124,387	$ 3.40	5.28	$ 8,137
Options exercisable, December 31, 2011	2,911,186	$ 3.21	5.52	$ 4,232
Options available for future grant	3,678,000			

A summary of the status of unvested restricted stock for the six months ended June 30, 2012 is as follows:

	Number of Shares	**Weighted-Average Grant Date Fair Value**
Non-vested, December 31, 2011	950,906	$ 4.34
Granted	170,302	4.51
Vested	(25,000)	5.21
Cancelled	(66,360)	4.41
Non-vested, June 30, 2012	1,029,848	$ 4.34

At June 30, 2012, total unrecognized compensation costs related to unvested restricted stock outstanding amounted to $6.4 million. The cost is expected to be recognized over a weighted-average period of 1.76 years.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward Looking Statements

This quarterly report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In particular, statements contained in this Form 10-Q, including but not limited to, statements regarding our future results of operations and financial position, business strategy and plan prospects, projected revenue or costs and objectives of management for future research, development or operations, are forward-looking statements. These statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as "may," "will," "should," "expects," "plans," "anticipates," "intends," "targets," "projects," "contemplates," "believes," "seeks," "goals," "estimates," "predicts," "potential" and "continue" or similar words. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 1A. "Risk Factors" and elsewhere herein. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

Business Overview

ZIOPHARM Oncology, Inc. is a biopharmaceutical company that seeks to develop and commercialize a diverse portfolio of cancer drugs that can address unmet medical needs through the licensing and development of proprietary small molecule drug candidates and novel DNA-based biotherapeutics. Our small molecule drug candidates are related to cancer therapeutics already on the market or in development and that can be administered by intravenous, or IV, and/or oral dosing. Our small molecule clinical programs include palifosfamide (ZIO-201), indibulin (ZIO-301) and darinaparsin (ZIO-101). We are also pursuing the development of novel DNA-based biotherapeutics in the field of cancer, using a synthetic biology platform, pursuant to a partnering arrangement with Intrexon Corporation, or Intrexon. Under the arrangement, we obtained rights to Intrexon's effector platform for use in the field of oncology, which includes two existing clinical stage product candidates, ZIN-CTI-001 (or DC-RTS-IL-12 + AL) and ZIN-ATI-001 (or Ad-RTS-IL-12 + AL). We plan to leverage Intrexon's synthetic biology platform to develop products to stimulate key pathways used by the body's immune system to inhibit the growth and metastasis of cancers, adding significantly to our small molecule drug development portfolio and utilizing our capabilities to translate science to the patient setting. More detailed descriptions of palifosfamide, indibulin, darinaparsin, ZIN-CTI-001 and ZIN-ATI-001, and our clinical development plans for each, are set forth below. More detailed descriptions of these product candidates and our clinical development plans for each are also set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and in other reports that we file from time to time with the Securities and Exchange Commission.

Product Candidates

Palifosfamide, ZIO-201

General. Palifosfamide is a novel bi-functional DNA alkylating agent which is not metabolized by ALDH, nor a substrate for mutli-drug resistance pathways. Therefore, it is likely to have activity, and be effective, in multiple drug tumors using typical resistance pathways. Also in preclinical cancer models, palifosfamide was shown to be orally active and synergistic results have been obtained with palifosfamide in combination with doxorubicin, an agent approved to treat sarcoma.

Further preclinical studies have shown that, in animal and laboratory models, palifosfamide evidences activity against leukemia and solid tumors. These studies also indicate that palifosfamide may have a better safety profile than other in-class agents, in part because it does not appear to produce certain toxic metabolites. One such agent that is commonly used, ifosfamide, produces the toxic metabolites 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. Because of its distinct pharmaceutical composition, activity and tolerability profile, we believe palifosfamide may be a new, more effective and well tolerated agent to treat cancer.

Lead Indications for palifosfamide: Soft Tissue Sarcoma. Sarcomas are cancers of the bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue. There are more than 50 histological or tissue types of soft tissue sarcomas, or STS, but with considerable homogeneity when the disease is metastatic. The prognosis for patients with soft tissue sarcoma depends on several factors, including the patient’s age, size of the primary tumor, histological grade, and stage of the tumor. Factors associated with a poorer prognosis include being older than 60 years of age, having tumors larger than five centimeters, and having tumors of high-grade histology. While small, low-grade tumors are usually curable by surgery alone, the higher-grade or larger sarcomas are associated with higher local treatment failure rates and increased metastatic potential.

Intravenous palifosfamide may be a useful agent that, either alone or in combination with other agents and doxorubicin, in particular, may deliver enhanced therapeutic activity with fewer side effects of the type that have been associated with agents such as ifosfamide. In the United States, ifosfamide is often included in combination regimens for the treatment of sarcomas, testicular cancers, head and neck cancer, certain types of non-Hodgkin’s lymphomas, and other solid tumors including small-cell lung cancer, or SCLC, although ifosfamide is formally approved by FDA only for the treatment of testicular cancer. Doxorubicin, approved decades ago, is the only FDA-approved treatment for sarcoma. We believe that palifosfamide in combination with doxorubicin may be more effective than doxorubicin alone or in combination with minimal impact on the safety profile and better Quality of Life (QoL).

Small-Cell Lung Cancer. SCLC is almost exclusively associated with smoking. Similar to sarcoma, standard of care for SCLC, which is etoposide and platinum therapy, has changed little in decades. Published studies of ifosfamide in combination with standard of care have evidenced enhanced efficacy but also with enhanced side effects, providing for an unfavorable benefit to risk association. We believe that combining palifosfamide with standard of care could offer enhanced efficacy with an appropriate balance of benefit to toxicity.

Other Indications. Palifosfamide may be useful to treat many other solid tumors, such as breast cancer, and for the treatment of pediatric cancer and hematological malignancies. With an investigational new drug application, or IND, for the oral form of palifosfamide now approved by FDA and clinical study under development, oral palifosfamide could also offer not only a significant advancement to current therapies but also greater patient access and convenience.

Lead Indications for palifosfamide: STS and SCLC, Significant Unmet Medical Need. Both first-line metastatic STS and SCLC represent significant unmet medical needs with standard of care considerably dated. We believe approximately 100,000 patients worldwide are initially diagnosed with STS every year. For patients diagnosed with STS, primary care is surgery, sometimes with radiation therapy. Many patients enter a period of remission that is unpredictable and can even represent a "cure." Metastatic STS arises when the disease is either first diagnosed in the advanced setting or has and spread re-occurred and surgery is no longer an option. Chemotherapy is the standard of care for first-line metastatic STS and doxorubicin is the only first-line therapy approved in the United States for its treatment. We believe the annual projection in the United States for first-line metastatic STS treatment is approximately 9,000 patients. While data sources for Europe are limited, we estimate, based on epidemiology, an annual projection in Europe for first-line metastatic STS treatment of approximately 14,000 patients, for a combined U.S. and European estimate of 23,000 patients annually. Orphan Drug Designation for palifosfamide has been obtained in both the United States and the European Union for the treatment of STS. For SCLC, the estimated U.S. annual incidence is 30,000 – 35,000 patients and 200,000 patients worldwide. Approximately 80% - 90% of patients have extensive disease, the population for the planned pivotal trial. Platinum and etoposide are standard of care in the first-line setting. A formal retrospective mortality study also suggests that the SCLC population in China is substantial and projected from the study to be greater than 150,000 patients and growing.

Clinical Development Plan for Palifosfamide. Following Phase 1 study with IV administration, we completed Phase 2 testing of palifosfamide as a single agent to treat advanced sarcoma. In both Phase 1 and Phase 2 testing, palifosfamide has been administered without the "uroprotectant" mesna, as is required with ifosfamide, and the toxicities associated with other ifosfamide metabolites, acrolein and chloroacetaldehyde, have not been observed. We reported clinical activity of palifosfamide when used alone in the Phase 2 study addressing advanced sarcoma. Following review of preclinical combination studies, we initiated a Phase 1 dose escalation study of palifosfamide in combination with doxorubicin, primarily in patients with STS. We reported favorable results and safety profile from this study at the 2009 annual meeting of the American Society of Clinical Oncology, or ASCO.

In light of reported favorable Phase 2 single agent clinical activity data and with the combination being well tolerated in the Phase 1 trial, we initiated a Phase 2 randomized controlled trial in the second half of 2008, which we refer to as PICASSO, to compare doxorubicin plus palifosfamide to doxorubicin alone in patients with front- and second-line metastatic or unresectable STS. The study generated positive top-line interim data in 2009. Upon successfully reaching a pre-specified efficacy milestone and following safety and efficacy data review by our Data Committee, sarcoma experts, and our Medical Advisory Board, we elected to suspend enrollment in the trial in October 2009. We subsequently presented further positive interim data from the trial at the 15th Annual Connective Tissue Oncology Society meeting held in November 2009 and again at the 2010 ASCO annual meeting in June 2010, where the presentation was selected for "Best of ASCO." As presented at ASCO in February 2012, the Phase 2 PICASSO trial randomized a total of 67 patients with 66 treated and 62 eligible for evaluation. The study was designed to show a difference in progression free survival ("PFS") between doxorubicin in combination with palifosfamide versus doxorubicin alone. An analysis of the evaluable data reported a hazard ratio of 0.43 (p=0.019). Safety data were similar between the two groups in the study. The most common grade 3-4 events were neutropenia and elevated creatinine, both observed with similar frequency between treatment groups. Subsequently in February 2012, we announced the preliminary overall survival data from the PICASSO trial; the hazard ratio for overall survival was 0.78 favoring the palifosfamide group (with a 2-year survival rate of 40% compared to 30%).

In July 2010, we announced the initiation of a worldwide registration trial on a protocol design developed through a FDA End-of-Phase 2 meeting and the Special Protocol Assessment, or SPA, process. Although we did engage in the SPA process, we, with guidance from the FDA, elected to initiate the trial without having obtained SPA agreement from the FDA. The Phase 3 trial is in first-line metastatic STS, entitled PICASSO 3, and is an international, randomized, double-blinded, placebo-controlled trial with a targeted enrollment of 424 patients. The study completed enrollment in June 2012 and we now expect data from this trial to be reported in the fourth quarter of 2012.

The study is designed to evaluate the safety and efficacy of palifosfamide administered with doxorubicin compared with doxorubicin administered with placebo, with no cross-over between the arms. Progression-free survival is the primary endpoint for accelerated approval, with overall survival as the primary endpoint for full approval. PICASSO 3 has no interim efficacy analysis, while the trial is monitored by an Independent Data Monitoring Committee, or IDMC, of outside, independent experts for safety and futility. The IDMC has met on four occasions to review all available study data and in all instances has recommended trial continuation. Orphan Drug Designation for palifosfamide has been obtained in both the United States and the European Union for the treatment of STS.

A Phase 1 trial has completed accrual with palifosfamide in combination with etoposide and carboplatin and data to date have determined appropriate dosing for initiating a potentially pivotal, adaptive Phase 3 trial in first-line, extensive SCLC. In June 2012, the Company initiated an international, multi-center, open-label, adaptive, randomized study of palifosfamide in combination with carboplatin and etoposide (PaCE) chemotherapy versus carboplatin and etoposide (CE) alone in chemotherapy naïve patients with extensive-stage small cell lung cancer (MATISSE). The MATISSE study is designed to enroll up to 548 patients. The trial's primary endpoint is overall survival. Secondary endpoints include progression-free survival, objective response rate and quality of life. MATISSE will be conducted at centers in North America, Europe, Australia and Asia.

The study's adaptive design includes a prospectively planned opportunity for modification of the study protocol by adjusting one or more specified components of the design in order to maintain adequate power. Evaluation of the study's powering will be conducted by an IDMC at a single, pre-planned interim analysis, scheduled to occur following 125 events. At the interim analysis, the IDMC will review all efficacy and safety data and decide whether to: 1) halt the study for efficacy or futility, 2) continue the study to its planned enrollment of 548 patients, 3) decrease sample size, or 4) increase event size.

Additionally, an oral capsule form of palifosfamide has been the subject of preclinical studies necessary for an Investigational New Drug, or IND, application to support commencing Phase 1 study, presently under development.

DNA-based biotherapeutics (synthetic biology) ZIN-CTI-001 (or DC-RTS-IL-12 + AL) and ZIN-ATI-001 (or Ad-RTS-IL-12 + AL)

General. On January 6, 2011, we entered into an Exclusive Channel Partner Agreement with Intrexon pursuant to which we plan to supplement our small molecule drug development efforts by pursuing the development and commercialization of novel DNA-based biotherapeutics in the field of cancer treatment using Intrexon's RheoSwitch® and UltraVector® synthetic biology technologies. The channel partnering arrangement contemplates our using Intrexon's technology directed towards *in vivo* expression of effectors in connection with the development of ZIN-CTI-001 and ZIN-ATI-001 and generally to research, develop and commercialize products, in each case in which DNA is administered to humans for expression of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer. ZIN-CTI-001 (or DC-RTS-IL-12) and ZIN-ATI-001 (or Ad-RTS-IL-12) are the two existing clinical-stage products currently in development under this channel partnering arrangement. Under the arrangement, Intrexon assigned to us all regulatory filings and approvals relating to the two product candidates and we assumed sponsorship of the ongoing clinical trials of ZIN-CTI-001.

Clinical Development Plan for DNA-based biotherapeutics. The Company completed enrollment in a Phase 1b dose escalation study of ZIN-CTI-001 in Q2 2012 in the United States. ZIN-CTI-001 employs intratumoral injection of modified dendritic cells from each patient and oral dosing of an activator ligand to turn on *in vivo* expression of interleukin-12, or IL-12. ZIN-CTI-001, through the RheoSwitch Therapeutic System®, or RTS®, controls the timing and level of transgene expression. The RTS® technology functions as a "gene switch" for the regulated expression of human IL-12 in the patients' dendritic cells which are transduced with a replication deficient adenoviral vector carrying the IL-12 gene under the control of the RTS®, and in Phase 1 study, injected intratumorally for the treatment of patients with stage III or IV melanoma. The binding of the small molecule activator to the fusion proteins of RTS® is intended to regulate the timing and level of IL-12 expression. In the absence of the activator ligand, the level of IL-12 is below detectable levels.

The activator ligand has been the subject of a number of preclinical, safety and pharmacology studies under FDA and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guidelines. Preclinical studies in the B16 mouse melanoma model consistently induced regression of established melanoma lesions, both in those directly injected and those elsewhere in the animal. Preclinical studies have shown DC-RTS-IL-12, in combination with an activator ligand, to have strong activity against a broad array of cancers, including brain, colon, renal and pancreatic cancers and melanoma.

A Phase 1a clinical study of the activator ligand was conducted in 65 healthy volunteers, with the two most common side-effects being dysgeusia (impairment of taste) and throat irritation. A subsequent Phase 1b trial, which is ongoing in patients with advanced melanoma, has been amended to study efficacy and immunological and biological effects in addition to safety with cohort-based dose escalation of the activator ligand during repeated treatment cycles. Initial positive clinical results from the Phase 1b trial were presented at the June 2011 ASCO annual meeting. The trial enrolled ten patients (median age 61) with unresectable stage III or IV melanoma. Among eight evaluable patients, partial or complete regression of injected and some uninjected lesions was observed by computed axial tomography, or CT, scans in three patients, with one patient having a RECIST PR of >11 months and three patients demonstrating stable disease by RECIST, for an overall disease control rate of 50%. Treatment was generally well tolerated, adverse events were mild to moderate, with one to two patients each experiencing nausea, vomiting, anorexia, arthralgia, fever or chills. One severe adverse event was reported 18 hours after treatment onset with 60 mg AL + ZIN-CTI-001, and included diarrhea, followed by hypotension and reversible acute renal failure, which completely resolved.

Clinical study of ZIN-ATI-001, essentially ZIN-CTI-001 without dendritic cells, is in an ongoing Phase 1b study for metastatic melanoma. The Phase 1b study is evaluating safety in addition to immunological and biological effects and efficacy of the therapeutic candidate in patients with melanoma. Enrollment in the Phase 1b study is ongoing and is expected to complete in 2012.

We expect to advance ZIN-ATI-001 into a Phase 2 study for melanoma in 2012. The Company will also continue to focus on additional disease indications where there are significant unmet medical needs.

Furthermore, we are evaluating additional potential preclinical candidates and continuing discovery efforts aimed at identifying other potential product candidates under our Channel Agreement with Intrexon.

Indibulin, ZIO-301

General. Indibulin is a novel, orally available small molecular-weight inhibitor of tubulin polymerization that we acquired from Baxter Healthcare in 2006, and is the subject of numerous patents worldwide, including those in 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 anti-cancer drugs target tubulin, such as the taxane family members, paclitaxel (Taxol®), docetaxel (Taxotere®), the vinca alkaloid family members, vincristine and vinorelbine, and new classes of tubulin inhibitors including the epothilones. This broad 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 as no neurotoxicity has been observed at therapeutic doses in rodents and in the Phase 1 trials. Indibulin has also demonstrated synergy with approved anti-cancer agents in preclinical studies. The availability of an oral formulation with the expected convenience of once daily dosing we believe is a significant commercial opportunity.

Indibulin has a different pharmacological profile from other tubulin inhibitors currently on the market as it binds to a unique site on tubulin and is active in multi-drug-resistant (MDR-1, MRP-1) and taxane-resistant tumors. Indibulin binding causes destabilization of microtubules *in vitro*, an effect similar to that of the vinca alkaloid family or colchicine, but opposite to that of paclitaxel and related drugs and different from the epothilones.

Testing of indibulin for *in vitro* growth inhibitory activity against a panel of human and rodent tumor-derived cell lines revealed that the drug candidate is active in a broad spectrum of cell lines derived from different organs. *In vivo*, indibulin is active in a number of xenograft and rodent tumor models. Its unique pharmacodynamic properties demonstrated in preclinical studies, as well as an excellent safety profile observed to date in ongoing Phase 1 studies, warranted further evaluation in the clinic.

Clinical Development Plan for Indibulin. Phase 1 study as a single agent in patients with a variety of advanced solid tumors has been completed. We have reported clinical activity at well-tolerated doses using a continuous dosing scheme without the development of clinically relevant peripheral neuropathy. Following encouraging preclinical results obtained with indibulin in combination with other chemotherapies, two Phase 1 combination studies were initiated with Tarceva™ and Xeloda™, respectively. The favorable activity and safety profile of oral indibulin with oral Xeloda™ was reported at ASCO's annual meeting in May 2009. In all studies, a maximum tolerated dose, or MTD, has not been established.

Preclinical work established a dosing schedule to maximize activity while managing toxicity and that regimen, five days on drug and nine days off, is now in Phase 1 study in late stage metastatic breast cancer. In light of not establishing an MTD and the need to administer many capsules several times a day, we have recently modified the dosage form to achieve once a day dosing which continues in the Phase 1 trial with the 5 and 9 schedule.

Darinaparsin, ZIO-101

General. Darinaparsin is an anti-mitochondrial (organic arsenic) compound covered by issued patents and pending patent applications in the United States and in foreign countries. A form of commercially available inorganic arsenic (arsenic trioxide [Trisenox®], or ATO) has been approved in the United States, the European Union and Japan for the treatment of acute promyelocytic leukemia, a precancerous condition. In the United States, ATO is on the compendia listing for the therapy of multiple myeloma, and has been studied for the treatment of various other cancers. Nevertheless, ATO has been shown to be toxic to the heart, liver, and brain, which limits its use as an anti-cancer agent. ATO carries a "black box" warning for electrocardiogram abnormalities since arsenic trioxide has been shown to cause QT interval prolongation and complete atrioventricular block. QT prolongation can lead to a *torsade de pointes*-type ventricular arrhythmia, which can be fatal. Inorganic arsenic has also been shown to cause cancer of the skin and lung in humans. The toxicity of arsenic is generally correlated to its accumulation in organs and tissues. Our preclinical and clinical studies to date have demonstrated that darinaparsin is considerably less toxic than ATO, particularly with regard to cardiac toxicity.

In vitro testing of darinaparsin using the National Cancer Institute's human cancer cell panel demonstrated activity against a series of tumor cell lines including lung, colon, brain, melanoma, ovarian, and kidney cancer. Moderate activity was shown against breast and prostate cancer tumor cell lines. In addition to solid tumors, *in vitro* testing in both the National Cancer Institute's cancer cell panel and *in vivo* testing in a leukemia animal model demonstrated substantial activity against hematological cancers (cancers of the blood and blood-forming tissues) such as leukemia, lymphoma, myelodysplastic syndromes, and multiple myeloma. Results indicate significant activity against the HuT 78 cutaneous T-cell lymphoma, the NK-G2MI natural killer-cell NHL, KARPAS-299 T-cell NHL, SU-DHL-8 B-cell NHL, SU-DHL-10 B-cell NHL and SU-DHL-16 B-cell NHL cell lines. Preclinical studies have also established anti-angiogenic properties of darinaparsin, providing support for the development of an oral form of the drug, and established synergy of darinaparsin in combination with other approved anti-cancer agents.

Potential Lead Indication: Lymphoma. Three Phase 2 IV studies of darinaparsin evaluating hematological malignancies, myeloma and liver cancer, have been completed and data from these trials has been reported, the most promising being in lymphomas and particularly in peripheral T-cell lymphoma.

Clinical Development Plan for darinaparsin: Phase 1 testing of the IV form of darinaparsin in solid tumors and hematological cancers was completed and we reported clinical activity and a safety profile from these studies as predicted by preclinical results. We subsequently completed Phase 2 studies in advanced myeloma, primary liver cancer and in certain other hematological cancers. At the May 2009 annual meeting of ASCO, we reported favorable results from the IV trial in lymphoma, particularly peripheral T-cell lymphoma, or PTCL. A Phase 1 trial in solid tumors with an oral form of darinaparsin has completed enrollment. We have obtained Orphan Drug Designation for darinaparsin in the United States and Europe for the treatment of PTCL and have entered into a licensing agreement with Solasia for the Asia/Pacific territory with the present IV darinaparsin clinical priority a focus on advancing PTCL study in that region. Further clinical studies are currently ongoing with Solasia.

Development Plans

We are currently pursuing several clinical programs for our small molecule and DNA-based biotherapeutic candidates, which include:

- palifosfamide (ZIO-201) — completing our Phase 3 pivotal trial in first-line metastatic STS, entitled PICASSO 3, and continuing enrollment in our Phase 3 trial in SCLC, entitled MATISSE.
- ZIN-CTI-001 — completing a Phase 1b trial in patients with metastatic melanoma.
- ZIN-ATI-001 — completing a Phase 1b trial in patients with late-stage melanoma and advancing into a Phase 2 trial.
- indibulin (ZIO-301) — completing a Phase 1 trial in patients with metastatic breast cancer.
- darinaparsin (ZIO-101) — completing an ongoing Phase 1 study and determining future study with the oral form and working with Solasia with IV administration in PTCL in the licensed territory.

We are also evaluating additional potential preclinical candidates and continuing discovery efforts aimed at identifying other potential product candidates under our channel partnership with Intrexon.

Our current plans involve using our principal internal financial resources to develop palifosfamide and to extend the DNA-based biotherapeutic program, with the intention of ultimately partnering or otherwise raising additional resources to support further development activities for all of our product candidates. Based on these plans, we expect to incur the following expenses during the next twelve months: approximately $82.9 million on research and development expenses and approximately $24.0 million on general corporate and administrative expenses. This forecast of expenses is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses over the next twelve months could vary materially and adversely as a result of a number of factors, including the factors discussed in the ‘‘Risk Factors’’ section of this report and the uncertainties applicable to our forecast for the overall sufficiency of our capital resources, which are discussed under “—Liquidity and Capital Resources” below. We have based our estimates on assumptions that may prove to be wrong, and our expenses could prove to be significantly higher than we currently anticipate.

Furthermore, the successful development of our product candidates is highly uncertain. Product development costs and timelines can vary significantly for each product candidate, are difficult to accurately predict, and will require us to obtain additional funding, either alone or in connection with partnering arrangements. Various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of each product. The lengthy process of seeking approval and the subsequent compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially, adversely affect our business. To date, we have not received approval for the sale of any product candidates in any market and, therefore, have not generated any revenues from our product candidates.

Financial Overview

Overview of Results of Operations

Three and six months ended June 30, 2012 compared to three and six months ended June 30, 2011

Revenue. Revenue during the three and six months ended June 30, 2012 and 2011 were as follows:

($ in thousands)	Three months ended June 30, 2012	Three months ended June 30, 2011	Change		Six months ended June 30, 2012	Six months ended June 30, 2011	Change	
Collaboration revenue	$ 200	$ 200	$ -	0%	$ 400	$ 267	$ 133	50%

Revenue for the three months ended June 30, 2012 was the same as the three months ended June 30, 2011.

Revenue for the six months ended June 30, 2012 increased by $133 thousand from the six months ended June 30, 2011. The increase is due to our entry into the collaboration agreement on March 7, 2011, resulting in a partial period under the agreement during the first six months of 2011. We are recognizing the research and development funding revenue over the estimated period of performance (75 months).

Research and development expenses. Research and development expenses during the three and six months ended June 30, 2012 and 2011 were as follows:

($ in thousands)	Three months ended June 30, 2012	Three months ended June 30, 2011	Change		Six months ended June 30, 2012	Six months ended June 30, 2011	Change	
Research and development	$ 18,264	$ 9,125	$ 9,139	100%	$ 32,249	$ 33,766	$ (1,517)	-4%

Research and development expenses for the three months ended June 30, 2012 increased by $9.1 million from the three months ended June 30, 2011. The increase was due primarily to increased trial costs of $4.0 million related primarily to the Phase 3 palifosfamide study in STS and the Phase 3 palifosfamide study in SCLC, increased preclinical trials of $2.1 million, increased manufacturing activity of $1.2 million, increased salary and employee-related costs of $1.1 million, and other costs of $0.7 million.

Research and development expenses for the six months ended June 30, 2012 decreased by $1.5 million from the six months ended June 30, 2011. The decrease was primarily due to the payment in the first six months of 2011 of a one-time $17.5 million non-cash expense related to our Channel Agreement, including our associated license of Intrexon technology, partially offset by increases in trial costs of $7.0 million related primarily to the Phase 3 palifosfamide study in STS and the Phase 3 palifosfamide study in SCLC, preclinical trial costs of $3.1 million, salary and employee-related costs of $2.7 million, manufacturing activity costs of $1.5 million, other costs of $0.6 million, and a one-time expense of $0.7 million relating to a new safety database.

We expect our research and development expenses to increase, as compared to prior periods, as we continue our Phase 3 palifosfamide trials and other studies for palifosfamide, DNA therapeutics, indibulin and darinaparsin.

Our research and development expense consists primarily of salaries and related expenses for personnel, costs of contract manufacturing services, costs of facilities and equipment, fees paid to professional service providers in conjunction with our clinical trials, fees paid to research organizations in conjunction with preclinical animal studies, costs of materials used in research and development, consulting, license and milestone payments and sponsored research fees paid to third parties.

We have not accumulated and tracked our internal historical research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources are allocated across several projects, and many of our costs are directed to broadly applicable research endeavors. As a result, we cannot state the costs incurred for each of our oncology programs on a program-by-program basis.

In 2012, our clinical projects have consisted primarily of two Phase 3 projects for our lead product candidate palifosfamide. The expenses for our Phase 3 palifosfamide study in STS incurred by us to third parties were $9.9 million for the six months ended June 30, 2012 and $30.2 million from the project inception in July 2010 through June 30, 2012. The expenses for our Phase 3 palifosfamide study in SCLC incurred by us to third parties were $3.9 million for the six months ended June 30, 2012 and $3.9 million from the project inception in December 2011 through June 30, 2012.

Our future research and development expenses in support of our current and future programs will be subject to numerous uncertainties in timing and cost to completion. We test potential products in numerous preclinical studies for safety, toxicology and efficacy. We may conduct multiple clinical trials for each product. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products or indications. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product. It is not unusual for preclinical and clinical development of each of these types of products to require the expenditure of substantial resources.

We estimate that clinical trials of the type generally needed to secure new drug approval are typically completed over the following timelines:

Clinical Phase	Estimated Completion Period
Phase 1	1 - 2 years
Phase 2	2 - 3 years
Phase 3	2 - 4 years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others, the following:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patents;
- the number of patients that ultimately participate in the trials;
- the duration of patient follow-up to ensure the absence of long-term product-related adverse events; and
- the efficacy and safety profile of the product.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our programs or when and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our programs in a timely manner or our failure to enter into appropriate collaborative agreements could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time-to-time in order to continue with our product development strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

General and administrative expenses. General and administrative expenses during the three and six months ended June 30, 2012 and 2011 were as follows:

($ in thousands)	Three months ended June 30, 2012	Three months ended June 30, 2011	Change		Six months ended June 30, 2012	Six months ended June 30, 2011	Change	
General and administrative	$ 4,902	$ 3,923	$ 979	25%	$ 9,750	$ 7,275	$ 2,475	34%

General and administrative expenses for the three months ended June 30, 2012 increased by $1.0 million from the three months ended June 30, 2011. The increase was primarily due to increases in salary and employee-related costs of $0.6 million, non-employee contracted costs of $0.1 million and other costs of $0.3 million.

General and administrative expenses for the six months ended June 30, 2012 increased by $2.5 million from the six months ended June 30, 2011. The increase was primarily due to increases in salary and employee-related costs of $1.2 million, non-employee contracted costs of $0.9 million and other costs of $0.4 million.

We expect our general and administrative expenses to increase moderately to support increased activity in clinical studies.

Other income (expense). Other income (expense) for the three and six months ended June 30, 2012 and 2011 were as follows:

($ in thousands)	Three months ended June 30, 2012	Three months ended June 30, 2011	Change		Six months ended June 30, 2012	Six months ended June 30, 2011	Change	
Other income, net	$ 3	$ 9	$ (6)	-67%	$ (23)	$ 7	$ (30)	-429%
Change in fair value of warrants	(650)	2,115	(2,765)	-131%	(6,461)	(8,965)	2,504	-28%
Total	$ (647)	$ 2,124	$ (2,771)		$ (6,484)	$ (8,958)	$ 2,474	

The increase in total other income (expense) of $2.8 million from the three months ended June 30, 2012 compared to the three months ended June 30, 2011 was due primarily to decreased non-cash expense recorded from the change in the fair value of liability-classified warrants.

The decrease in total other income (expense) of $2.5 million from the six months ended June 30, 2012 compared to the six months ended June 30, 2011 was due primarily to decreased non-cash expense recorded from the change in the fair value of liability-classified warrants. Additional changes are attributable to increased state tax payments.

Liquidity and Capital Resources

As of June 30, 2012, we had approximately $110.4 million in cash and cash equivalents, compared to $104.7 million in cash and cash equivalents as of December 31, 2011. We anticipate that our cash resources will be sufficient to fund our operations into the second half of 2013. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our research and development efforts and changes in governmental regulation. Actual costs may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. We have estimated the sufficiency of our cash resources based in part on the trial design for our PICASSO 3 pivotal trial for first-line metastatic STS and our adaptive Phase 3 trial for first-line SCLC for IV palifosfamide and our current timing expectations for enrollment of the studies, which may change based on the progression of enrollment. We also assumed responsibility for the advancement of two product candidates in the clinic under our exclusive channel partnership with Intrexon, and we expect that the costs associated with these and additional product candidates will increase the level of our overall research and development expenses significantly going forward.

Although all human clinical trials are expensive and difficult to design and implement, we believe that due to complexity, costs associated with clinical trials for DNA-based biotherapeutic products are greater than the corresponding costs associated with clinical trials for small molecule candidates. In addition to increased research and development costs, we have added, and will continue to add, headcount to support our exclusive channel partnership endeavors, which will add to our general and administrative expenses going forward.

In addition to these factors, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we will be unable to proceed with development of some or all of our product candidates on expected timelines and will be forced to prioritize among them.

We expect that we will need additional financing to support our long-term plans for clinical trials and new product development. We expect to finance our cash needs through the sale of equity securities, strategic collaborations and/or debt financings, or through other sources that may be dilutive to existing stockholders. There can be no assurance that we will be able to obtain funding from any of these sources or, if obtained, what the terms of such funding(s) may be, or that any amount that we are able to obtain will be adequate to support our working capital requirements until we achieve profitable operations. We have no current committed sources of additional capital. Recently, capital markets have experienced a period of instability that may severely hinder our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. If we are unable to raise additional funds when needed, we may not be able to 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.

The following table summarizes our net increase (decrease) in cash and cash equivalents for the six months ended June 30, 2012 and 2011:

	Six months ended June 30,	
	2012	**2011**
($ in thousands)		
Net cash provided by (used in):		
Operating activities	$ (42,625)	$ (13,989)
Investing activities	(1,107)	(392)
Financing activities	49,410	84,271
Net increase in cash and cash equivalents	$ 5,678	$ 69,890

Net cash used in operating activities was $42.6 million for the six months ended June 30, 2012 compared to $14.0 million for the six months ended June 30, 2011. The $28.6 million increase was due to an increase in prepaid expenses and other current assets attributable to a related party prepayment (see Note 6), as well as an increase in the net loss from operations, caused by increased research and development activities, excluding non-cash expenses of the change in fair value of warrants, stock-based compensation, and in process research and development.

Net cash used in investing activities was $1.1 million for the six months ended June 30, 2012 compared to $0.4 million for the six months ended June 30, 2011. The increase was due to build out of additional space in the Boston office including leasehold improvements and furniture and fixtures along with software additions.

Net cash provided by financing activities was $49.4 million for the six months ended June 30, 2012 compared to $84.3 million for the six months ended June 30, 2011. The change is primarily attributable to a $49.2 million financing that occurred during the first six months of 2012 versus a $71.2 million financing and warrant exercises of $12.3 million that occurred during the first six months of 2011.

Operating capital and capital expenditure requirements

We anticipate that losses will continue for the foreseeable future. At June 30, 2012, our accumulated deficit was approximately $235.7 million. Our actual cash requirements may vary materially from those planned because of a number of factors including:

- Changes in the focus, direction and pace of our development programs;
- Competitive and technical advances;
- Internal costs associated with the development of palifosfamide and indibulin and our ability to secure further financing for darinaparsin development from a partner;
- Costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights, or other developments; and
- Other matters identified under Part II – Item 1A. “Risk Factors” below.

Working capital as of June 30, 2012 was $101.6 million, consisting of $119.4 million in current assets and $17.8 million in current liabilities. Working capital as of December 31, 2011 was $92.7 million, consisting of $106.1 million in current assets and $13.4 million in current liabilities.

Contractual obligations

The following table summarizes our outstanding obligations as of June 30, 2012 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

($ in thousands)	Total	Less than 1 year	2 - 3 years	4 - 5 years	More than 5 years
Operating leases	$ 6,073	$ 1,096	$ 2,432	$ 1,866	$ 679
Royalty and license fees	1,650	275	550	550	275
Contract milestone payments	25,579	15,454	10,125	-	-
Total	$ 33,302	$ 16,825	$ 13,107	$ 2,416	$ 954

Our commitments for operating leases relate to the lease for our corporate headquarters in New York, New York, our operations center in Boston, Massachusetts and office space in Germantown, Maryland. Our commitments for royalty and license fees relate to our patent agreement with Baxter Healthcare Corporation and our royalty agreements with Southern Research Institute and Baxter Healthcare Corporation requiring minimum royalty payments. The contract milestone payments relate to our CRO agreements with PPD Development, L.P and Pharmaceutical Research Associates, Inc. The timing of the remaining contract milestone payments are dependent upon factors that are beyond our control, including our ability to recruit patients, the outcome of future clinical trials and any requirements imposed on our clinical trials by regulatory agencies. However, for the purpose of the above table, we have assumed that the payment of the milestones will occur within five years of June 30, 2012. On July 16, 2012, we decided to close our Germanton, Maryland office (see Subsequent Events). Our operating lease commitment for the Germantown, Maryland office included in the above table is $50 thousand – less than 1 year and $39 thousand – 2-3 years.

Off-balance sheet arrangements

During the three and six months ended June 30, 2012 and 2011, we did not engage in any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to stock-based compensation; net operating losses and tax credit carryforwards; and impairment of long-lived assets. We reviewed our policies and determined that those policies remain our most critical accounting policies for the six months ended June 30, 2012.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is limited to our cash. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain our cash in interest-bearing bank accounts in global banks, U.S. treasuries and other government-backed investments, which are subject to minimal interest rate risk.

Item 4. Controls and Procedures

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

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

Part II - Other Information

Item 1. Legal Proceedings

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors.

While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of June 30, 2012, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

The following important factors could cause our actual business and financial results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or elsewhere by management from time to time. The risk factors in this report have been revised to incorporate changes to our risk factors from those included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, which may be material, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the Securities and Exchange Commission.

RISKS RELATED TO OUR BUSINESS

We will require additional financial resources in order to continue ongoing development of our product candidates; if we are unable to obtain these additional resources, we may be forced to delay or discontinue clinical testing of our product candidates.

We have not generated significant revenue and have incurred significant net losses in each year since our inception. For the six months ended June 30, 2012, we had a net loss of $48.1 million, and, as of June 30, 2012, we have incurred approximately $235.7 million of cumulative net losses since our inception in 2003. We expect to continue to incur significant operating expenditures. Further development of our product candidates, including product candidates that we may develop under our channel partnering arrangement with Intrexon, will likely require substantial increases in our expenses as we:

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

We continue to seek additional financial resources to fund the further development of our product candidates. If we are unable to obtain sufficient additional capital, one or more of these programs could be placed on hold. Because we are currently devoting a significant portion of our resources to the development of palifosfamide and to synthetic biology, further progress with the development of our other candidates may be significantly delayed and may depend on the success of our ongoing clinical trial involving palifosfamide.

We have no current committed sources of additional capital. We do not know whether additional financing will be available on terms favorable or acceptable to us when needed, if at all. Our business is highly cash-intensive and our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing and achieve profitable operations, as to which no assurances can be given. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for the further development of our products, we will be required to delay, reduce or eliminate planned preclinical and clinical trials and may be forced to terminate the approval process for our product candidates from the FDA or other regulatory authorities. In addition, we could be forced to discontinue product development, forego attractive business opportunities or pursue merger or divestiture strategies. In the event we are unable to obtain additional financing, we may be forced to cease operations altogether.

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

As of June 30, 2012, we had incurred approximately $235.7 million of cumulative net losses and had approximately $110.4 million of cash and cash equivalents. We anticipate that our cash resources will be sufficient to fund our operations into the second half of 2013. However, changes may occur that would consume our existing capital prior to that time, including expansion of the scope, and/or slower than expected progress of, our research and development efforts and changes in governmental regulation. Actual costs may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. We have estimated the sufficiency of our cash resources based in part on the trial design for our PICASSO 3 pivotal trial and our adaptive Phase 3 trial in first-line SCLC for IV palifosfamide and our current timing expectations for enrollment of the studies, which may change based on the progression of enrollment. We have also assumed responsibility for the advancement of two product candidates in the clinic under our exclusive channel partnership with Intrexon and we expect that the costs associated with these and additional product candidates will increase the level of our overall research and development expenses significantly going forward. Although our forecasts for expenses and the sufficiency of our capital resources takes into account our plans to develop the Intrexon products, we assumed development responsibility for these products on January 6, 2011 and the actual costs associated therewith may be significantly in excess of forecasted amounts.

In addition to above factors, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we will be unable to proceed with development of some or all of our product candidates on expected timelines and will be forced to prioritize among them.

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

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

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

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

- Unforeseen safety issues;
- Determination of dosing issues;
- Lack of effectiveness during clinical trials;
- Slower than expected rates of patient recruitment and enrollment;
- Inability to monitor patients adequately during or after treatment;
- Inability or unwillingness of medical investigators to follow our clinical protocols; and
- Regulatory determinations to temporarily or permanently cease enrollment for other reasons not related to patient safety.

We commenced the PICASSO 3 pivotal trial for IV palifosfamide early in the third quarter of 2010 in a small number of sites in the United States as we pursued site review board clearance for trial conduct in the anticipated 150 or more sites expected worldwide. Site opening is a complex and time-consuming process, often requiring six months to complete outside of the United States. PICASSO 3 has a targeted enrollment of 424 patients. We experienced slower than anticipated enrollment in the trial at start-up due in part to the timing of site openings and regulatory approvals. While enrollment is complicated by a number of factors outside of our control, we completed full enrollment in June 2012. The outcome in progression-free survival, the study's primary endpoint for accelerated approval, is anticipated in the fourth quarter of 2012. As an orphan designated indication, the patient population available for participation in the PICASSO 3 trial is generally limited. If we cannot meet our forecasted enrollment, or the trial is delayed for other reasons, the delay will postpone our receipt of results from the trial and, consequently, our ability to submit a corresponding NDA with FDA for regulatory approval in accordance with our plans. See also "Risk Factors—*Our product candidates are in various stages of clinical trials, which are very expensive and time-consuming. We cannot be certain when we will be able to file an NDA or BLA with the FDA and any failure or delay in completing clinical trials for our product candidates could harm our business*."

We have received "Orphan Drug" status for palifosfamide for treatment of soft tissue sarcomas and darinaparsin for treatment of peripheral T-cell lymphoma in both the United States and Europe, and we may be able to receive additional Orphan Drug status from the FDA, Europe and certain other countries for other product candidates. Orphan Drug status promotes the development of products that demonstrate the promise for the diagnosis and treatment of one disease or condition affecting fewer than 200,000 patients in the United States and affords certain financial and market protection benefits to successful applicants. There is no guarantee that any of our other product candidates will be granted Orphan Drug status by the FDA or that, even if such product candidate is granted such status, the product candidate's clinical development and regulatory approval process will not be delayed or will be successful.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submission or in the conduct of these trials.

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

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

The technology on which our Channel Agreement with Intrexon Corporation is based in part on early stage technology in the field of human oncologic therapeutics.

Our Channel Agreement with Intrexon contemplates our using Intrexon's advanced transgene engineering platform for the controlled and precise cellular production of anti-cancer effectors. The *in vivo* effector platform in which we have acquired rights represents early-stage technology in the field of human oncologic biotherapeutics, with ZIN-CTI-001 which has completed a Phase 1b study and ZIN-ATI-001 currently in a Phase 1b study, both in melanoma. Although we plan to leverage Intrexon's synthetic biology platform for additional products targeting key pathways used by cancers to grow and metastasize, we may not be successful in developing and commercializing these products for a variety of reasons. The risk factors set forth herein that apply to our small molecule drug candidates, which are in various stages of development, also apply to product candidates that we seek to develop under our Channel Agreement with Intrexon.

We will incur additional expenses in connection with our Channel Agreement with Intrexon Corporation.

The *in vivo* effector platform, in which we have acquired rights for cancer from Intrexon, includes two existing product candidates, with DC-RTS-IL-12 and Ad-RTS-IL-12. Upon entry into the Channel Agreement with Intrexon, we assumed responsibility for the clinical development of these product candidates, which we expect will increase the level of our overall research and development expenses significantly going forward. Although all human clinical trials are expensive and difficult to design and implement, we believe that due to complexity, costs associated with clinical trials for synthetic biology products are greater than the corresponding costs associated with clinical trials for small molecule candidates. In addition to increased research and development costs, we have added, and continue to add, headcount in part to support our Channel Agreement endeavors, which will add to our general and administrative expenses going forward.

Although our forecasts for expenses and the sufficiency of our capital resources takes into account our plans to develop the Intrexon products, we assumed development responsibility for these products on January 6, 2011 and the actual costs associated therewith may be significantly in excess of forecasted amounts. In addition to the amount and timing of expenses related to the clinical trials, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates and costs of filing, prosecuting, defending and enforcing our intellectual property rights. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we will be unable to proceed with development of some or all of our product candidates on expected timelines and will be forced to prioritize among them.

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

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

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

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

Because we currently neither have nor intend to establish internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and academic and other researchers to sell or license us their product candidates and technology.

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

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

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

We may not be able to successfully manage our growth.

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

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

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

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

We are highly dependent on Dr. Jonathan Lewis, our Chief Executive Officer, Dr. Hagop Youssoufian, our President of Research & Development and Chief Medical Officer, Caesar J. Belbel, our Executive Vice President and Chief Legal Officer, Jason A. Amello, our Executive Vice President and Chief Financial Officer and our principal scientific, regulatory, and medical advisors. Dr. Lewis', Dr. Youssoufian's, Mr. Belbel's and Mr. Amello's employment are governed by written employment agreements. The employment agreement with Dr. Lewis provides for terms that expire in January 2013. Drs. Lewis and Youssoufian, and Messrs. Belbel and Amello may terminate their employment with us at any time, subject, however, to certain non-compete and non-solicitation covenants. The loss of the technical knowledge and management and industry expertise of Drs. Lewis and Youssoufian and Messrs. Belbel and Amello, or any of our other key personnel, could result in delays in product development, loss of customers and sales, and diversion of management resources, which could adversely affect our operating results. We do not carry "key person" life insurance policies on any of our officers or key employees.

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

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

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

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

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

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

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

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

We may not be able to obtain the approvals necessary to commercialize our product candidates, or any product candidate that we may acquire or develop in the future for commercial sale. We will need FDA approval to commercialize our product candidates in the United States and approvals from regulatory authorities in foreign jurisdictions equivalent to the FDA to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA or biologic license application, or BLA, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity, and novelty of the product candidate, and will require substantial resources for research, development, and testing. We cannot predict whether our research, development, and clinical approaches will result in drugs that the FDA will consider safe for humans and effective for their intended uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

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

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

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

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

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

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

Even if our clinical trials are completed as planned, we cannot be certain that their results will support approval of our product candidates. The FDA normally expects two randomized, well-controlled Phase 3 pivotal studies in support of approval of an NDA or BLA. Our PICASSO 3 trial, even if successful, may not be sufficient to support approval and we may be required to conduct additional pivotal trials of palifosfamide in metastatic soft tissue sarcoma in order to obtain NDA approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be certain that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for the indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our NDAs or BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve small patient populations. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

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

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

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

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

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

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

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

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

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

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

RISKS RELATED TO OUR ABILITY TO COMMERCIALIZE OUR PRODUCT CANDIDATES

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

We currently have no marketing, sales, or distribution capabilities. If and when we become reasonably certain that we will be able to commercialize our current or future products, we anticipate allocating resources to the marketing, sales and distribution of our proposed products in North America and in certain other countries; however, we cannot assure that we will be able to market, sell, and distribute our products successfully. Our future success also may depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities and to encourage the collaborator's strategic interest in the products under development, and such collaborator's ability to successfully market and sell any such products. Although we intend to pursue certain collaborative arrangements regarding the sale and marketing of certain of our products, there are no assurances that we will be able to establish or maintain collaborative arrangements or, if we are able to do so, whether we would be able to conduct our own sales efforts. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.

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

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

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

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

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

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

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

- Perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
- Pharmacological benefit and cost-effectiveness of our products relative to competing products;
- Availability of reimbursement for our products from government or other healthcare payors;
- Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- The price at which we sell our products.

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

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

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

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

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

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably.

We cannot predict the impact on our business of any legislation or regulations that may be adopted in the future. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

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

Our ability to use net operating loss carryforwards to reduce future tax payments may be limited or restricted.

We have generated significant net operating loss carryforwards, or NOLs, as a result of our incurrence of losses since inception. We generally are able to carry NOLs forward to reduce taxable income in future years. However, our ability to utilize the NOLs is subject to the rules of Section 382 of the Internal Revenue Code. Section 382 generally restricts the use of NOLs after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 and the U.S. Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over a three-year rolling period. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carry forwards. This annual limitation is generally equal to the product of the value of the corporation's stock on the date of the ownership change, multiplied by the long-term tax-exempt rate published monthly by the Internal Revenue Service. Any unused annual limitation may be carried over to later years until the applicable expiration date for the respective NOL carry forwards. We may have experienced an "ownership change" within the meaning of Section 382 in the past. As a result, our NOLs may be subject to limitations and we may be required to pay taxes earlier and in larger amounts than would be the case if our NOLs were freely usable.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

To date, we have exclusive rights to certain U.S. and foreign intellectual property with respect to our small molecule product candidates and with respect to the Intrexon technology, including the existing Intrexon product candidates. Under our Channel Agreement with Intrexon, Intrexon has the sole right to conduct and control the filings, prosecution and maintenance of the patents and patent applications licensed to us. Although under the agreement Intrexon has agreed to consider in good faith and consult with us regarding any comments we may have regarding these patents and patent applications, we cannot guarantee that our comments will be solicited or followed. Without direct control of the channel program patents and patent applications, we are dependent on Intrexon to keep us advised of prosecution, particularly in foreign jurisdictions where prosecution information may not be publicly available. We anticipate that we and Intrexon will file additional patent applications both in the United States and in other countries. However, we cannot predict or guarantee:

- The degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- If and when patents will be issued;
- Whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- Whether we will need to initiate litigation or administrative proceedings that may be costly whether we win or lose.

Changes in patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, resulting in a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. Depending on decisions by the U.S. Patent and Trademark Office, which is developing regulations and procedures to implement the Leahy-Smith Act, and federal courts, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Certain technologies utilized in our research and development programs are already in the public domain. Moreover, a number of our competitors have developed technologies, filed patent applications or obtained patents on technologies, compositions and methods of use that are related to our business and may cover or conflict with our owned or licensed patent applications, technologies or product candidates. Such conflicts could limit the scope of the patents that we may be able to obtain or may result in the rejection of claims in our patent applications. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications. In addition, our own earlier filed patents and applications or those of Intrexon may limit the scope of later patents we obtain or may result in the rejection of claims in our later filed patent applications. If third parties filed patent applications or obtained patents on technologies, compositions and methods of use that are related to our business and that cover or conflict with our owned or licensed patent applications, technologies or product candidates, we may be required to challenge such protection, terminate or modify our programs impacted by such protection or obtain licenses from such third parties, which might not be available on acceptable terms, or at all.

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

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

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

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Patents do not protect its owner from a claim of infringement of another owner's patent. Therefore, our patent position cannot and does not provide any assurance that we are not infringing the patent rights of another.

The patent landscape in the field of novel DNA biotherapeutics, which we are pursuing under our exclusive channel partnership with Intrexon, is particularly complex. We are aware of numerous U.S. and foreign patents and pending patent applications of third parties that cover compositions, methods of use and methods of manufacture of novel DNA biotherapeutics, including biotherapeutics involving the *in vivo* expression of human IL-12. In addition, there may be patents and patent applications in the field of which we are not aware. The technology we license from Intrexon is early-stage technology and we are just beginning the process of designing and developing products using this technology. Although we will seek to avoid pursuing the development of products that may infringe any patent claims that we believe to be valid and enforceable, we may fail to do so. Moreover, given the breadth and number of claims in patents and pending patent applications in the field of novel DNA biotherapeutics and the complexities and uncertainties associated with them, third parties may allege that we are infringing upon patent claims even if we do not believe such claims to be valid and enforceable.

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

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

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

If we breach any of the agreements under which we license rights to products or technology from others, we could lose license rights that are material to our business or be subject to claims by our licensors.

We license rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we have exclusively licensed patents and patent applications under our agreement with Intrexon. Under these agreements, we are subject to a range of commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations.

Any failure by us to comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration. On termination we may be required to license to the licensor any related intellectual property that we developed.

In addition, in certain cases, the rights licensed to us are rights of a third party licensed to our licensor. In such instances, if our licensors do not comply with their obligations under such licenses, our rights under our license agreements with our licensor may be adversely affected.

OTHER RISKS RELATED TO OUR COMPANY

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

As a public reporting company, we are subject to the Sarbanes-Oxley Act of 2002, as well as to the information and reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and other federal securities laws. As a result, we incur significant legal, accounting, and other expenses that we would not incur as a private company, including costs associated with our public company reporting requirements and corporate governance requirements. As an example of public reporting company requirements, we evaluate the effectiveness of disclosure controls and procedures and of our internal control over financing reporting in order to allow management to report on such controls. Sarbanes-Oxley generally requires that a public reporting company's independent registered public accounting firm attest to the effectiveness of the company's internal control over financial reporting as of the end of each fiscal year in the company's annual report on Form 10-K. In addition, any updates to our finance and accounting systems, procedures and controls, which may be required as a result of our ongoing analysis of internal controls, or results of testing by our independent auditor, may require significant time and expense. As a company with limited accounting resources, a significant amount of management's time and attention has been and will continue to be diverted from our business to ensure compliance with these regulatory requirements. This diversion of management's time and attention may have a material adverse effect on our business, financial condition and results of operations.

Management is working to continuously monitor and improve internal controls and has set in place controls to mitigate the potential segregation of duties risk. In the event significant deficiencies or material weaknesses are indentified in our internal control over financial reporting that we cannot remediate in a timely manner, or if we are unable to receive a positive attestation from our independent registered public accounting firm with respect to our internal controls over financial reporting, investors and others may lose confidence in the reliability of our financial statements and the trading price of our common stock and ability to obtain any necessary equity or debt financing could suffer. In addition, in the event that our independent registered public accounting firm is unable to rely on our internal controls over financial reporting in connection with its audit of our financial statements, and in the further event that it is unable to devise alternative procedures in order to satisfy itself as to the material accuracy of our financial statements and related disclosures, we may be unable to file our periodic reports with the SEC. This would likely have an adverse affect on the trading price of our common stock and our ability to secure any necessary additional equity or debt financing, and could result in the delisting of our common stock from the NASDAQ Capital Market, which would severely limit the liquidity of our common stock.

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

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt, and limit who may call a special meeting of stockholders. In addition, Section 203 of the Delaware General Corporation Law generally prohibits a publicly-held Delaware corporation from engaging in a business combination with a party that owns at least 15% of its common stock unless the business combination is approved by the company's board of directors before the person acquires the 15% ownership stake or later by its board of directors and two-thirds of its stockholders. In connection with our January 2011 issuance of shares of common stock to Intrexon in a private placement transaction, our board of directors waived the Section 203 prohibition with respect to a future business combination with Intrexon. However, the Stock Purchase Agreement governing such issuance contains a standstill provision that generally prohibits Intrexon from seeking, initiating, offering or proposing to effect such a transaction with our inviting them to do so. Section 203 and this standstill provision could have the effect of delaying, deferring or preventing a change in control that our stockholders might consider to be in their best interests.

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

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

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

None.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

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

SIGNATURES

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

/s/ Jonathan Lewis
Jonathan Lewis, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)
Dated: August 2, 2012

/s/ Jason A. Amello
Jason A. Amello
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: August 2, 2012

EXHIBIT INDEX

10.1	Employment Agreement, dated May 8, 2012 by and between the Company and Jason Amello (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 10, 2012)
10.2	ZIOPHARM Oncology, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 26, 2012)
10.3	Form of Restricted Stock Agreement granted under the ZIOPHARM Oncology, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 26, 2012)
10.4	Form of Option Agreement Granted under the ZIOPHARM Oncology, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed June 26, 2012)
31.1*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications pursuant to 18 U.S.C. Section 1350
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** To be furnished in an amendment to this Form 10-Q to be filed no later than 30 days after the filing date of this Form 10-Q, as permitted by Rule 405 of Regulation S-T.

EXHIBIT 31.1

CERTIFICATION

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: August 2, 2012

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

EXHIBIT 31.2

CERTIFICATION

I, Jason A. Amello, 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: August 2, 2012

/s/ Jason A. Amello
Jason A. Amello
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION

In connection with the Quarterly Report on Form 10-Q of ZIOPHARM Oncology, Inc. (the "Company") for the period ended June 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we Jonathan Lewis, the Principal Executive Officer of the Company and Jason A. Amello, the Principal Financial and Accounting Officer of the Company, hereby certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to our knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and
(2) the information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 2, 2012

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

Dated: August 2, 2012

/s/ Jason A. Amello
Jason A. Amello
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)