ZIOPHARM ONCOLOGY INC
Form 10-Q
August 08, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2013

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.)**

One First Avenue, Parris Building 34, Navy Yard Plaza

Boston, Massachusetts 02129

(617) 259-1970

(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: x 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: x 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	x
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: x

The number of shares of the registrant s common stock, $.001 par value, outstanding as of July 31, 2013, was 83,522,763 shares.

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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 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, research and development costs and other expenses;
- 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 our synthetic biology product candidates and Palifosfamide; and
- 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.

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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, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,932	$ 73,306
Receivables	31	58
Prepaid expenses and other current assets	4,067	6,912
Total current assets	43,030	80,276
Property and equipment, net	1,713	1,994
Deposits	128	133
Other non-current assets	732	1,001
Total assets	$ 45,603	$ 83,404
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,165	$ 1,509
Accrued expenses	18,969	16,516
Deferred revenue - current portion	800	800
Deferred rent - current portion	63	39
Total current liabilities	20,997	18,864
Deferred revenue	2,333	2,733
Deferred rent	365	400
Warrant liabilities	2,576	12,962
Total liabilities	26,271	34,959
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; 83,540,682 and 83,236,840 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively	84	83
Additional paid-in capital - common stock	330,735	325,177
Additional paid-in capital - warrants issued	3,728	6,909
Deficit accumulated during the development stage	(315,215)	(283,724)

Total stockholders equity		19,332		48,445
Total liabilities and stockholders equity	$	45,603	$	83,404

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

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ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except share and per share data)

	For the Three Months Ended June 30, 2013	For the Three Months Ended June 30, 2012	For the Six Months Ended June 30, 2013	For the Six Months Ended June 30, 2012	Period from September 9, 2003 (date of inception) through June 30, 2013
Research contract revenue	$ 200	$ 200	$ 400	$ 400	$ 1,867
Operating expenses:					
Research and development, including costs of research contracts	14,775	18,264	33,887	32,249	246,232
General and administrative	3,721	4,902	8,392	9,750	96,710
Total operating expenses	18,496	23,166	42,279	41,999	342,942
Loss from operations	(18,296)	(22,966)	(41,879)	(41,599)	(341,075)
Other income (expense), net	7	3	3	(23)	4,704
Change in fair value of warrants	(403)	(650)	10,385	(6,461)	21,156
Net loss	$ (18,692)	$ (23,613)	$ (31,491)	$ (48,083)	$ (315,215)
Net loss per share - basic and diluted	$ (0.22)	$ (0.30)	$ (0.38)	$ (0.62)	
Weighted average common shares outstanding to compute net loss per share - basic and diluted	83,082,633	78,514,718	82,994,845	77,067,424	

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

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ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENT OF STOCKHOLDERS EQUITY

For the six Months Ended June 30, 2013

(unaudited)

(in thousands, except share and per share data)

	Preferred Stock		Common Stock		Stockholders Equity 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, 2012		$	83,236,840	$ 83	$ 325,177	$ 6,909	$ (283,724)	$ 48,445
Stock-based compensation					1,673			1,673
Exercise of employee stock options			455,168	1	853			854
Exercise of warrants to purchase common stock			49,315		172	(71)		101
Expired warrants					3,110	(3,110)		
Cancelled restricted stock			(140,600)					
Repurchase of shares of restricted common stock			(60,041)		(250)			(250)
Net loss							(31,491)	(31,491)
Balance at June 30, 2013		$	83,540,682	$ 84	$ 330,735	$ 3,728	$ (315,215)	$ 19,332

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

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ZIOPHARM Oncology, Inc. (a development stage company)

STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	For the Six Months Ended June 30, 2013	For the Six Months Ended June 30, 2012	Period from September 9, 2003 (date of inception) through June 30, 2013
Cash flows from operating activities:			
Net loss	$ (31,491)	$ (48,083)	$ (315,215)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	396	265	2,970
Stock-based compensation	1,673	2,290	21,854
Change in fair value of warrants	(10,385)	6,461	(21,156)
Loss on disposal of fixed assets			57
Common stock issued in exchange for in-process research and development			36,151
Change in operating assets and liabilities:			
(Increase) decrease in:			
Receivables	27	79	(31)
Prepaid expenses and other current assets	2,845	(7,738)	(4,067)
Other noncurrent assets	269	(53)	(732)
Deposits	4	(41)	(130)
Increase (decrease) in:			
Accounts payable	(344)	(258)	1,165
Accrued expenses	2,453	4,681	18,969
Deferred revenue	(400)	(400)	3,133
Deferred rent	(11)	172	428
Net cash used in operating activities	(34,964)	(42,625)	(256,604)
Cash flows from investing activities:			
Purchases of property and equipment	(115)	(1,107)	(4,741)
Proceeds from sale of property and equipment			1
Net cash used in investing activities	(115)	(1,107)	(4,740)
Cash flows from financing activities:			
Stockholders capital contribution			500
Proceeds from exercise of stock options	854	30	2,227
Payments to employees for repurchase of common stock	(250)		(3,117)
Proceeds from exercise of warrants	101	210	13,180
Proceeds from issuance of common stock and warrants, net		49,170	270,726
Proceeds from issuance of preferred stock, net			16,760
Net cash provided by financing activities	705	49,410	300,276
Net increase (decrease) in cash and cash equivalents	(34,374)	5,678	38,932
Cash and cash equivalents, beginning of period	73,306	104,713	

Cash and cash equivalents, end of period	$	38,932	$	110,391	$	38,932
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	$	72	$	166	$	9,396
Exercise of liability-classified warrants to common shares	$		$	412	$	352

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

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS

(unaudited)

1. 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, a diverse portfolio of cancer drugs that can address unmet medical needs through the development of a proprietary synthetic biology platform and small molecule drug candidates.

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, 2013. 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, 2013, the Company s accumulated deficit was approximately $315.2 million. Following the restructuring described in Note 3, the Company currently believes that it has sufficient capital to fund development and commercialization activities into the first quarter of 2014. 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, 2012, 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, 2013 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.

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

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. During this period, the Company did not have any material recognizable or disclosable subsequent events.

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, 2012 and are substantially unchanged.

3. Restructuring

On April 3, 2013, the Company completed a workforce reduction plan to reduce costs as part of the Company s decision to terminate development of palifosfamide in first-line metastatic soft tissue sarcoma and place exclusive strategic focus on its synthetic biology programs, which are being developed in partnership with Intrexon Corporation (Notes 6, 7 and 9). Pursuant to the workforce reduction plan, the Company eliminated a total of 65 positions, comprised of 40 filled positions and 25 unfilled positions across various functions and locations. Employees whose positions were eliminated as part of the plan were notified beginning on April 2, 2013. Affected employees were offered separation benefits, including severance payments, and temporary healthcare coverage assistance. In connection with the elimination of filled positions as part of the workforce reduction plan, the Company incurred charges of $1.6 million during the second quarter of 2013, primarily for one-time contractual severance benefits. Additionally, the Company is evaluating its facilities and the associated contractual obligations to determine the appropriate course of action and any associated charges for exit and disposal activities. The Company currently cannot estimate these amounts, but expects to file an amended Current Report on Form 8-K within four business days of making such determination.

On July 16, 2012, the Company announced that it restructured its management team and closed its Germantown, MD office. As a result of this action, the Company recorded a restructuring charge, consisting primarily of severance, stock based compensation associated with stock option modifications (see Note 9) and health benefit continuation costs of approximately $1.3 million. These costs are included in general and administrative expense for the period from inception (September 9, 2003) through June 30, 2013.

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

4. Fair Value Measurements

The Company accounts for its financial assets and liabilities using fair value measurements. 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, 2013 and December 31, 2012 are as follows:

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	Balance as of June 30, 2013	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 36,709	$ 36,709	$	$
Warrant liability	$ 2,576	$	$ 2,576	$

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

4. Fair Value Measurements (continued)

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	Balance as of December 31, 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	$ 72,002	$ 72,002	$	$
Warrant liability	$ 12,962	$	$ 12,962	$

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 1 asset. The Company s Level 2 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 anti-dilutive. Such potential shares of common stock at June 30, 2013 and 2012 consist of the following:

	June 30,	
	2013	2012
Stock options	6,538,419	5,397,154
Unvested restricted common stock	454,325	1,029,848
Warrants	10,441,431	11,268,678
	17,434,175	17,695,680

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). Our director, Randall J. Kirk, is the CEO, a director, and the largest stockholder of Intrexon. 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 balance sheet as of June 30, 2012. During the six months ended June 30, 2013, the Company was billed $3.7 million for services performed by Intrexon, which was applied against the prepaid balance. As of June 30, 2013, the prepaid balance in other current assets on the accompanying balance sheet was $1.1 million.

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

On November 7, 2012, the Company issued 3,636,926 shares of common stock to Intrexon (see Note 9).

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

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.

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 since 2006.

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

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 since 2010.

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, 2011 and 2012. 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 thousand. 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 since the agreement s inception.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

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 manufacture indibulin. During the year ended December 31, 2012, a milestone of $250 thousand was reached and expensed. No milestones under the license agreement were reached or expensed during the six months ended June 30, 2013.

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 DC-RTS-IL-12 and Ad-RTS-IL-12 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.

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

7. Commitments and Contingencies (continued)

Intrexon may 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. 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.

Also see Notes 6 and 9.

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. Subject to renewal or extension by the parties, the term of the agreement was for a one year period that expired April 8, 2009. Following such expiration, the parties continued to operate under the terms of the agreement and, in 2010, the agreement was formally extended through April 8, 2011 and again through April 8, 2012. The agreement was extended through November 8, 2012 upon which date it expired. The Company expensed $240 thousand during the years ended December 31, 2010 and 2011 and expensed $200 thousand during the year ended December 31, 2012 for consulting services per the aforementioned agreement. No milestones under the collaboration agreement were reached or expensed since the agreement s inception.

On June 27, 2013, the Company signed a new collaboration agreement with 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 $15 thousand per month for the consulting services. Subject to renewal or extension by the parties, the term of the agreement is for a one year period.

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.

ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

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.

We are party to a Master Clinical Research Organization Services Agreement with PPD Development, L.P., or PPD, 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, or CRO, services in support of our clinical trials. PPD is entitled to cumulative payments of up to $19.9 million under these arrangements, which is payable by us in varying amounts upon PPD achieving specified milestones. During the year ended December 31, 2010, we 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 we recorded an aggregate $4.0 million expense. During the year ended December 31, 2012, additional enrollment-based and contract modification milestones were met and expensed totaling $3.8 million. During the six months ended June 30, 2013, patient progression and data based milestones were met and expensed totaling $9.1 million.

CRO Services Agreement with Pharmaceutical Research Associates, Inc.

On December 13, 2011, we entered into a Master Clinical Research Organization Services Agreement with Pharmaceutical Research Associates, Inc., or PRA, under which PRA provides CRO services in support of our clinical trials. PRA is entitled to cumulative payments of up to $9.5 million under these arrangements, which is payable by us in varying amounts upon PRA achieving specified milestones. During the year ended December 31, 2012, we expensed $7.3 million upon the achievement of various letter of intent and enrollment-based milestones. During the six months ended June 30, 2013, contract modification and patient enrollment based milestones were met and expensed totaling $2.2 million.

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

7. Commitments and Contingencies (continued)

CRO Services Agreement with Novella Clinical, Inc.

On December 4, 2008, we entered into a Master Clinical Research Organization Services Agreement with Novella Clinical, Inc., or Novella, under which PRA provides CRO services in support of our clinical trials. The work order for the current trial being conducted by Novella was signed on November 2, 2012. Novella is entitled to cumulative payments of up to $790 thousand under these arrangements, which is payable by us in varying amounts upon Novella achieving specified milestones. During the year ended December 31, 2012, we expensed $256 thousand upon the achievement of various milestones. During the six months ended June 30, 2013, two database related milestones were met and expensed totaling $126 thousand.

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, 2013 and December 31, 2012 were as follows:

	June 30, 2013	December 31, 2012
Liability-classified warrants	8,050,709	8,050,709
Equity-classified warrants	2,390,722	3,146,745
Total warrants	10,441,431	11,197,454

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

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), 11,083 of which were subsequently exercised. The remaining 408,703 warrants 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. Of the total warrant tranche, 419,207 were exercised and the remaining 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.

The Company uses the Binomial/Monte Carlo pricing model to estimate the value of the liability-classified warrants. The following assumptions were used in the Binomial/Monte Carlo valuation model at June 30, 2013 and 2012:

	June 30, 2013	June 30, 2012
Risk-free interest rate	0.26%	0.37%
Expected life in years	1.44	2.44
Expected volatility	70%	70%
Expected dividend yield	0	0
Steps per year	12	12

The change in the fair value of the warrant liability resulted in a loss of $0.4 million and a gain of $10.4 million for the three and six months ended June 30, 2013, respectively. 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 was charged to other income (expense) in the Statements of Operations.

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

8. Warrants (continued)

During the six months ended June 30, 2013, 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	49,315		49,315	$	$ 101
Cashless exercises					
	49,315		49,315	$	$ 101

During the six months ended June 30, 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 six months ended June 30, 2013, 706,708 warrants issued on May 3, 2006, exercisable at $5.09, expired unexercised on May 3, 2013.

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, pursuant to an underwriting agreement between the Company and J. P. Morgan Securities LLC, as representative of the several underwriters named therein, the Company completed the sale of an aggregate 10,114,401 shares of the Company s common stock at a price of $5.20 per share in a public offering. The total gross proceeds resulting from the 2012 public offering were approximately $52.6 million, before deducting selling commissions and expenses.

On November 7, 2012, the Company issued 3,636,926 shares of our common stock, which we refer to as the Milestone Shares, to Intrexon under the terms of its Stock Purchase Agreement with Intrexon dated January 6, 2011. Under the terms of the Stock Purchase Agreement with Intrexon, the Company agreed to issue the Milestone Shares under certain conditions upon dosing of the first patient in a ZIOPHARM-conducted Phase 2 clinical trial in the Unites States, or similar study as the parties may agree in a country other than the United States, of a product candidate that is created, produced, developed or identified directly or indirectly by us during the term of the Channel Agreement and that, subject to certain exceptions, involves DNA administered to humans for expression of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer. On October 24, 2012, the Company initiated dosing in a Phase 2 study of Ad-RTS-IL-12 for unresectable

Stage III or IV melanoma, triggering the issuance of the Milestone Shares.

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

10. Stock-Based Compensation

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

(in thousands)	For the three months ended June 30, 2013	For the three months ended June 30, 2012	For the six months ended June 30, 2013	For the six months ended June 30, 2012
Research and development	$ (145)	$ 426	$ 392	$ 942
General and administrative	277	652	1,281	1,348
Stock-based employee compensation expense	$ 132	$ 1,078	$ 1,673	$ 2,290

The Company granted 1,315,500 and 1,426,400 stock options during the three and six months ended June 30, 2013 that had a weighted-average grant date fair value of $1.77 and $1.89 per share, respectively. 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.

At June 30, 2013, total unrecognized compensation costs related to unvested stock options outstanding amounted to $6.3 million. The cost is expected to be recognized over a weighted-average period of 1.74 years.

On July 16, 2012, the Company extended the contractual life of 829,488 fully vested stock options held by 3 employees from 12 to 18 months, and extended the vesting period for 200,000 unvested stock options and 147,427 unvested shares of restricted stock held by 2 employees from 6 to 12 months (also see Note 3 Restructuring).

On May 31, 2013, the Company extended the contractual life of 66,667 fully vested stock options held by one employee from 3 to 12 months.

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ZIOPHARM Oncology, Inc. (a development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

10. Stock-Based Compensation (continued)

For the six months ended June 30, 2013 and 2012, 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,	
	2013	**2012**
Risk-free interest rate	1.65%	0.93 - 1.10%
Expected life in years	6	6
Expected volatility	95.45%	83.36 - 83.52%
Expected dividend yield	0	0

Stock option activity under the Company s stock option plan for the six months ended June 30, 2013 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, 2012	7,147,303	$ 4.11		
Granted	1,426,400	2.49		
Exercised	(455,168)	1.87		
Cancelled	(1,580,116)	4.73		
Outstanding, June 30, 2013	6,538,419	$ 3.76	7.11	$ 956
Vested and unvested expected to vest at June 30, 2013	6,481,884	$ 3.85	5.03	$ 948
Options exercisable, June 30, 2013	3,406,985	$ 3.85	5.03	$ 956
Options exercisable, December 31, 2012	3,683,786	$ 3.56	5.28	$ 3,972
Options available for future grant	1,430,403			

A summary of the status of unvested restricted stock for the six months ended June 30, 2013 is as follows:

	Number of Shares	**Weighted-Average Grant Date Fair**

			Value
Non-vested, December 31, 2012	733,739	$	4.37
Granted			
Vested	(138,814)		4.26
Cancelled	(140,600)		4.42
Non-vested, June 30, 2013	454,325	$	4.38

At June 30, 2013, total unrecognized compensation costs related to unvested restricted stock outstanding amounted to $1.4 million. The cost is expected to be recognized over a weighted-average period of 1.44 years.

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

Forward Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In particular, statements contained in this Form 10-Q, including but not limited to, statements regarding the costs and timing our clinical trials and of the development and commercialization of our pipeline products and services; the sufficiency of our cash, investments and cash flows from operations and our expected uses of cash; our ability to finance our operations and business initiatives and obtain funding for such activities; 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, g 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 acquire, develop and commercialize, on its own or with other commercial partners, a diverse portfolio of cancer therapies that can address unmet medical needs through the licensing and development of a synthetic biology platform and proprietary small molecule drug candidates. On March 26, 2013, we announced that our Phase 3 trial of palifosfamide in first-line metastatic soft tissue sarcoma, entitled PICASSO 3, did not meet its primary endpoint of progression-free survival. With this outcome, we made the decision to immediately terminate development of palifosfamide in first-line metastatic soft tissue sarcoma and place exclusive strategic focus on our synthetic biology programs in the field of cancer, pursuit to a partnership agreement with Intrexon Corporation, or Intrexon. Under the agreement, we obtained rights to Intrexon s effector platform for use in the field of oncology, which includes two existing clinical stage product candidates, DC-RTS-IL-12 + Activator Ligand and Ad-RTS-IL-12 + Activator Ligand. 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, utilizing our capabilities to translate science to the patient setting. More detailed descriptions of DC-RTS-IL-12, Ad-RTS-IL-12, and our small molecule programs, 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, 2012, and in other reports that we file from time to time with the Securities and Exchange Commission.

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Product Candidates

Synthetic Biology Programs: DC-RTS-IL-12 + Activator Ligand and *Ad-RTS-IL-12 + Activator Ligand*

General. On January 6, 2011, we entered into an Exclusive Channel Partner Agreement with Intrexon to develop and commercialize novel DNA-based therapeutics in the field of cancer treatment. In partnership with Intrexon Corporation, ZIOPHARM s DNA synthetic biology platform employs an inducible gene-delivery system that enables controlled delivery of genes that produce therapeutic proteins to treat cancer. The first example of this regulated controlled delivery is achieved by producing IL-12 under the control of Intrexon s proprietary biological switch (the RheoSwitch Therapeutic System® or RTS® platform) to turn on/off the therapeutic protein expression at the tumor site. DC-RTS-IL-12 and Ad-RTS-IL-12 are the two clinical-stage products and Ad-RTS-IL-12 is currently being tested in two Phase 2 studies, the first for the treatment of advanced melanoma, and the second in combination with palifosfamide for the treatment of non-resectable recurrent or metastatic breast cancer. Ad-RTS-IL-12 uses synthetic biology to enable controlled delivery of therapeutic interleukin-12 (IL-12), a protein important for enhancing the development of an immune response to cancer.

Clinical Development Plan for the Synthetic Biology Program. We completed enrollment in a Phase 1b dose escalation study of DC-RTS-IL-12 in the second quarter of 2012 in the United States. DC-RTS-IL-12 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. DC-RTS-IL-12, through the 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 incompetent adenoviral vector carrying the IL-12 gene under the control of the RTS®. In addition, another Phase 1 study employs direct injection of Ad-RTS-IL-12 for the regulated expression of human IL-12 for the treatment of patients with stage III or IV melanoma. The binding of the small molecule activator to the fusion proteins of RTS® regulates the timing and level of IL-12 expression. In the absence of the activator ligand, the level of IL-12 is below detectable levels. Currently, there are no actively enrolling studies using DC-RTS-IL-12, as we have prioritized our clinical development efforts on Ad-RTS-IL-12.

A clinical study of Ad-RTS-IL-12 is currently ongoing in a Phase 1/2 study for metastatic melanoma. The Phase 1 portion of the study evaluated safety in addition to immunological and biological effects and efficacy of the therapeutic candidate in patients with advanced melanoma. Enrollment in the Phase 1 portion of the study is complete and the Phase 2 portion is actively enrolling patients.

In the Phase 1 portion of the study, clinical activity was observed at the two highest dose levels. The data also showed a correlation between T-cell immune responses and biological response. We reported that clinical activity was observed in injected and non-injected lesions, and that the therapy was generally well-tolerated with a safety profile consistent with other immunotherapies at the 2013 annual meeting of the American Society of Clinical Oncology, or ASCO.

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Based on early activity, and a determination of a biologically effective dose, we advanced to Phase 2 and enrollment is on-going in this study. The Phase 2 study is a multi-center, single-arm, open-label study that is enrolling patients with unresectable Stage III or IV melanoma and further evaluating the safety and efficacy of intratumoral injections of Ad-RTS-IL-12 in combination with an oral activator ligand. Data from this Phase 2 study are expected in the second half of 2013.

We also initiated a Phase 2 trial of Ad-RTS-IL-12 and palifosfamide for breast cancer in the first quarter of 2013. Part one of this two-part study will consist of a safety assessment for Ad-RTS-IL-12 and palifosfamide, alone or in combination. Part two will consist of an efficacy evaluation of the Ad-RTS-IL-12 only arm and the combination arm. The primary endpoint of the study is rate of progression-free survival at 16 weeks. Secondary endpoints include objective response rate, duration of response and evaluation of pharmacodynamic tumor markers.

This two-part multi-center U.S. study will enroll patients with non-resectable, recurrent or metastatic breast cancer who have visible lesions or lesions accessible by injection. The study is designed to assess the safety and efficacy of the drug combination of Ad-RTS IL-12 and a chemotherapy agent. Although this study was initiated with palifosfamide as the chemotherapy and second investigational therapy, we may substitute palifosfamide with an FDA-approved chemotherapeutic or other agent.

Preclinical mouse glioma studies evaluating either DC-RTS-IL-12 or Ad-RTS-IL-12 therapy demonstrated a survival benefit in all animals treated at higher doses with no adverse clinical signs and symptoms. Additional preclinical studies are currently ongoing with Ad-RTS-IL-12 to enable initiation of a Phase 1 clinical study in the first half of 2014. This Phase 1 clinical study will evaluate the safety and tolerability of the Ad-RTS-IL-12 therapy in patients with recurring glioblastoma.

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

Palifosfamide, ZIO-201

General. Palifosfamide, or isophosphoramide mustard, referred to as IPM, is a proprietary active metabolite of the pro-drug ifosfamide. Because palifosfamide is the stabilized active metabolite of ifosfamide and a distinct pharmaceutical composition without the acrolein or chloroacetaldehyde metabolites we believe that the administration of palifosfamide may be a more effective and well tolerated agent to treat cancer.

In addition to anticipated lower toxicity, palifosfamide may have other advantages over ifosfamide and cyclophosphamide. Palifosfamide cross-links DNA differently than the active metabolite of cyclophosphamide, resulting in a different activity profile.

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Small-Cell Lung Cancer. SCLC is almost exclusively associated with smoking. 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 a separation of enhanced efficacy from increased toxicity.

Clinical Development Plan for Palifosfamide. Previously we have studied palifosfamide in combination with doxorubicin in patients with soft tissue sarcoma. In March 2013, we announced that the Phase 3 study, PICASSO 3, did not meet its primary endpoint of progression-free survival (PFS) and that we would terminate our development program in metastatic soft tissue sarcoma. PICASSO 3 study data has been submitted for presentation at an upcoming major scientific meeting.

Data from a Phase 1 trial palifosfamide in combination with etoposide and carboplatin informed appropriate dosing for initiating an adaptive Phase 3 trial in first-line, metastatic SCLC. In June 2012, the Company initiated an international, multi-center, open-label, adaptive, randomized study of palifosfamide in combination with carboplatin and etoposide, or PaCE, chemotherapy versus carboplatin and etoposide, or CE, alone in chemotherapy naïve patients with metastatic small cell lung cancer, which we refer to as MATISSE. The trial s primary endpoint is overall survival.

Based on the outcome of PICASSO 3 in soft tissue sarcoma and the resulting revision in the company s development plans for palifosfamide, enrollment in this study was suspended with 188 patients enrolled. The interim analysis of Overall Survival events in MATISSE is forecasted to be reached in the first half of 2014.

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. *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.

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, we believe importantly, 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 a focus on IV-administered darinaparsin in PTCL. Further, clinical studies are currently ongoing with Solasia.

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Indibulin, ZIO-301

General. Indibulin is a novel, small molecule inhibitor of tubulin polymerization. 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. In spite of their effectiveness, the use of these drugs is associated with significant toxicities, notably peripheral neurotoxicity.

Indibulin is potentially safer than other tubulin inhibitors as no neurotoxicity has been observed in preclinical studies and in Phase 1 clinical trials. 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.

Clinical Development Plan for Indibulin. Preclinical work established a dosing schedule, five days on drug and nine days off, to enhance activity while managing toxicity. A Phase 1 study using this dosing regimen was conducted in late stage metastatic breast cancer and was proven to be safe and tolerable. We are currently evaluating possible third-party collaboration with respect to the further clinical development of indibulin.

Development Plans

We are currently pursuing several clinical development opportunities, principally in our synthetic biology programs in addition to continuing to pursue opportunities in our small molecule programs. We are also evaluating additional potential preclinical candidates and continuing discovery efforts aimed at identifying other potential product candidates under our Channel Agreement with Intrexon. In addition, we may seek to enhance our pipeline in synthetic biology through highly focused strategic transactions, which may include acquisitions, partnerships and in-licensing activities. We may also seek to out-license some or all of our small molecule programs to further support our synthetic biology efforts.

Our current plans involve using our principal internal financial resources to develop the synthetic biology program, with the intention of ultimately partnering or otherwise raising additional capital to support further development activities for our strategic product candidates. As of June 30, 2013, we had approximately $38.9 million of cash and cash equivalents. Based upon our current plans, we anticipate that our cash resources will be sufficient to fund our operations into the first quarter of 2014. This forecast of cash resources 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.

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Financial Overview

Overview of Results of Operations

Three and six months ended June 30, 2013 compared to three and six months ended June 30, 2012

Revenue. Revenue during the three and six months ended June 30, 2013 and 2012 was as follows:

($ in thousands)	Three months ended June 30, 2013	Three months ended June 30, 2012	Change		Six months ended June 30, 2013	Six months ended June 30, 2012	Change	
Collaboration revenue	$ 200	$ 200	$	0%	$ 400	$ 400	$	0%

Revenue for the three and six months ended June 30, 2013 was the same as the three and six months ended June 30, 2012. This is due to the continued recognition of income related to our entry into the collaboration agreement with Solasia Pharma K.K. on March 7, 2011. Under this agreement we received $5.0 million in research and development funding which we are recognizing over the estimated period of performance under the agreement, currently 75 months.

Research and development expenses. Research and development expenses during the three and six months ended June 30, 2013 and 2012 were as follows:

($ in thousands)	Three months ended June 30, 2013	Three months ended June 30, 2012	Change		Six months ended June 30, 2013	Six months ended June 30, 2012	Change	
Research and development	$ 14,775	$ 18,264	$ (3,489)	(19%)	$ 33,887	$ 32,249	$ 1,638	5%

Research and development expenses for the three months ended June 30, 2013 decreased by $3.5 million when compared to the three months ended June 30, 2012. On March 26, 2013, we announced the decision to immediately terminate development of palifosfamide in first-line metastatic soft tissue sarcoma and during the quarter ended June 30, 2013, completed a workforce reduction plan to reduce costs (see Note 3). This resulted in lower costs of $1.8 million related to the Phase 3 palifosfamide study in SCLC as the decision was made to suspend enrollment pending further data, lower preclinical trial costs of $1.7 million, lower employee-related costs of $0.9 million and lower manufacturing costs of $0.3 million. The decrease was offset by an increase of $1.0 million in discovery activities related to our synthetic biology program and other costs of $0.2 million.

Research and development expenses for the six months ended June 30, 2013 increased by $1.6 million when compared to the six months ended June 30, 2012. The increase was primarily due to $1.8 million increased discovery activities related to our synthetic biology programs, $0.8 million of costs related to the Phase 3 palifosfamide study in SCLC, higher manufacturing activities of $2.1 million and other clinical costs of $0.9 million. This was offset by a decrease in preclinical trial costs of $2.7 million, a decrease of $0.4 million related to our new safety database, lower employee-related costs of $0.5 million and decreased other clinical costs of $0.2 million, as we announced the decision to immediately terminate development of palifosfamide in first-line metastatic soft tissue sarcoma and completed a workforce reduction plan to reduce costs (see Note 3).

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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.

For the six months ended June 30, 2013, our clinical projects consisted primarily of two Phase 3 projects for palifosfamide. The expenses for our Phase 3 palifosfamide study in STS incurred by us to third parties were $9.8 million for the six months ended June 30, 2013 and $44.5 million from the project inception in July 2010 through June 30, 2013. The expenses for our Phase 3 palifosfamide study in SCLC incurred by us to third parties were $4.8 million for the six months ended June 30, 2013, and $15.6 million from the project inception in December 2011 through June 30, 2013.

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.

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General and administrative expenses. General and administrative expenses during the three and six months ended June 30, 2013 and 2012 were as follows:

($ in thousands)	Three months ended June 30, 2013	Three months ended June 30, 2012	Change		Six months ended June 30, 2013	Six months ended June 30, 2012	Change	
General and administrative	$ 3,721	$ 4,902	$ (1,181)	(24%)	$ 8,392	$ 9,750	$ (1,358)	(14%)

General and administrative expenses for the three months ended June 30, 2013 decreased by $1.2 million when compared to the three months ended June 30, 2012. The decrease was primarily due to lower employee-related costs of $0.6 million as a result of our workforce reduction plan (see Note 3) as well as $0.5 million in non-employee contracted costs and other costs of $0.1 million.

General and administrative expenses for the six months ended June 30, 2013 decreased by $1.4 million when compared to the six months ended June 30, 2012. The decrease was primarily due to lower employee-related costs of $0.8M as a result of our workforce reduction plan (Note 3) as well as $0.5 million in non-employee contracted costs and other costs of $0.1 million.

Other income (expense). Other income (expense) for the three and six months ended June 30, 2013 and 2012 was as follows:

($ in thousands)	Three months ended June 30, 2013	Three months ended June 30, 2012	Change		Six months ended June 30, 2013	Six months ended June 30, 2012	Change	
Other income, net	$ 7	$ 3	$ 4	133%	$ 3	$ (23)	$ 26	(113)%
Change in fair value of warrants	(403)	(650)	247	(38)%	10,385	(6,461)	16,846	(261)%
Total	$ (396)	$ (647)	$ 251		$ 10,388	$ (6,484)	$ 16,872	

The increase in total other income (expense) of $0.3 million from the three months ended June 30, 2013 compared to the three months ended June 30, 2012 was primarily due to the change in the fair value of liability-classified warrants which was driven by an increase in our stock price.

The increase in total other income (expense) of $16.9 million from the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was primarily due to the change in the fair value of liability-classified warrants which was driven by a decrease in our stock price.

Liquidity and Capital Resources

As of June 30, 2013, we had approximately $38.9 million in cash and cash equivalents, compared to $73.3 million in cash and cash equivalents as of December 31, 2012. We anticipate that our cash resources will be sufficient to fund our operations into the first quarter of 2014. 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 discontinuation of the 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 interim overall survival data in the MATISSE trial. Also included in the estimate are the advancement of our synthetic biology 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 synthetic biology products are greater than the corresponding costs associated with clinical trials for small molecule candidates.

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.

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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, 2013 and 2012:

	Six months ended June,	
($ in thousands)	**2013**	**2012**
Net cash provided by (used in):		
Operating activities	$ (34,964)	$ (42,625)
Investing activities	(115)	(1,107)
Financing activities	705	49,410
Net increase (decrease) in cash and cash equivalents	$ (34,374)	$ 5,678

Net cash used in operating activities was $35.0 million for the six months ended June 30, 2013 compared to $42.6 million for the six months ended June 30, 2012. The $7.6 million decrease was primarily due to a decrease in cash used for prepaid expenses, offset by an increase in accrued expenses.

Net cash used in investing activities was $0.1 million for the six months ended June 30, 2013 compared to $1.1 million for the six months ended June 30, 2012. The decrease was due to decreased spending on property, plant, and equipment in the New York and Boston offices.

Net cash provided by financing activities was $0.7 million for the six months ended June 30, 2013 compared to $49.4 million for the six months ended June 30, 2012. The change is primarily attributable to a $49.2 million financing that occurred during the first six months of 2012.

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Operating capital and capital expenditure requirements

We anticipate that losses will continue for the foreseeable future. At June 30, 2013, our accumulated deficit was approximately $315.2 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 the synthetic biology programs, palifosfamide, indibulin and our ability to secure further financing for darinaparsin development from a partner;
- Our ability to secure partnering arrangements;
- 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, 2013 was $22.0 million, consisting of $43.0 million in current assets and $21.0 million in current liabilities. Working capital as of December 31, 2012 was $61.4 million, consisting of $80.3 million in current assets and $18.9 million in current liabilities.

Contractual obligations

The following table summarizes our outstanding obligations as of June 30, 2013 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	$ 4,939	$ 1,175	$ 2,467	$ 1,127	$ 170
Royalty and license fees	1,400	275	550	550	25
Contract milestone payments	408	104	304		
Total	$ 6,747	$ 1,554	$ 3,321	$ 1,677	$ 195

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 the remaining lease term for our 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 Novella Clinical, Inc. Our contract milestone payments have been reduced from prior periods and are being replaced with service based payments. 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, 2013. On July 16, 2012, we decided to close our Germanton, Maryland office. In June 2013, we paid off the remainder of the Germantown, Maryland lease obligation.

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Off-balance sheet arrangements

During the six months ended June 30, 2013 and 2012, we did not engage in any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2012, 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, 2013.

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.

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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, 2013, 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, 2012. 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, 2012, 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, 2013, we had a net loss of $31.5 million, and, as of June 30, 2013, we have incurred approximately $315.2 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 as required.

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 synthetic biology and our adaptive Phase 3 trial for first-line SCLC for IV palifosfamide, MATISSE, further progress with the development of our other candidates may be significantly delayed and may depend on the licensing of those compounds to third parties.

We anticipate that our cash resources will be sufficient to fund our operations into the first quarter of 2014 and we have no current committed sources of additional capital. As a result, our independent registered public accounting firm has expressed a substantial doubt about our ability to continue as a going concern in their report on our financial statements. 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/or 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.

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**** 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, 2013, we had incurred approximately $315.2 million of cumulative net losses and had approximately $38.9 million of cash and cash equivalents. We anticipate that our cash resources will be sufficient to fund our operations into the first quarter of 2014. Following negative results in our PICASSO 3 pivotal trial in first-line STS in March 2013, we implemented a workforce reduction plan and other cost-cutting measures in an attempt to extend our cash resources as long as possible, though there are no assurances that such efforts will be effective. In addition, changes may occur that would consume our existing capital prior to the first quarter of 2014, including expansion of the scope of, and/or slower than expected progress of, our research and development efforts and changes in governmental regulation. As a result, our independent registered public accounting firm has expressed a substantial doubt about our ability to continue as a going concern in their report on our financial statements. 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 discontinuation of the 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 the interim analysis of data in the MATISSE trial. Also included in the estimate are the advancement of our synthetic biology 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.

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.

The unpredictability of the capital markets 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.

Our need for additional capital and limited capital resources may force us to accept financing terms that could be significantly dilutive to existing stockholders. 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.

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**** 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.

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 designations for darinaparsin for the treatment of peripheral T-cell lymphoma in both the United States and Europe, and we may be able to receive additional Orphan Drug designation from the FDA and EMA for other product candidates. In the United States, orphan designation is available to drugs intended to treat, diagnose or prevent a rare disease or condition that affects fewer than 200,000 people in the U.S. at the time of application for orphan designation. Orphan designation qualifies the sponsor of the product for the tax credit and marketing incentives. The first sponsor to receive FDA marketing approval for a drug with an orphan designation is entitled to a seven-year exclusive marketing period in the U.S. for that product for that indication and, typically, a waiver of the prescription drug user fee for its marketing application. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the U.S. during the seven-year exclusive marketing period. Orphan drug exclusive marketing rights may also be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. There is no guarantee that any of our other product candidates will receive Orphan Drug designation 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.

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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 synthetic biology effector platform in which we have acquired rights represents early-stage technology in the field of human oncologic biotherapeutics, with DC-RTS-IL-12 having completed a Phase 1 study in melanoma and Ad-RTS-IL-12 currently in two Phase 2 studies, in melanoma and breast cancer. 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 synthetic biology platform, in which we have acquired rights for cancer from Intrexon, includes two existing product candidates, 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, prior to the adoption of our March 2013 workforce reduction plan we added headcount in part to support our Channel Agreement endeavors, and we may need to do so again in the future which would 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.

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

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

- Continuing to undertake preclinical development and clinical trials;
- Participating in regulatory approval 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.

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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, Caesar J. Belbel, our Executive Vice President and Chief Legal Officer and our principal scientific, regulatory, and medical advisors. Dr. Lewis , and Mr. Belbel s employment are governed by written employment agreements. The employment agreement with Dr. Lewis provides for a term that expires in January 2014. Dr. Lewis and Mr. Belbel may terminate their employment with us at any time, subject, however, to certain non-compete and non-solicitation covenants. The loss of the technical knowledge and management and industry expertise of Dr. Lewis and Mr. Belbel, or any of our other key personnel, could result in delays in product development, loss of customers and sales, and diversion of management resources, which could adversely affect our operating results. We do not carry key person life insurance policies on any of our officers or key employees.

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

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

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

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

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

We currently carry clinical trial insurance and product liability insurance. However, 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 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