Cyclacel Pharmaceuticals, Inc.
Form 10-Q
August 13, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2010

OR

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

Commission file number 0-50626

CYCLACEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1707622**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
200 Connell Drive, Suite 1500 Berkeley Heights, New Jersey	**07922**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: (**908) 517-7330**

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

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company þ
		(Do not check if a 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 o No þ

As of August 12, 2010 there were 36,950,549 shares of the registrant s common stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

CYCLACEL PHARMACEUTICALS, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(In $000s, except share amounts)

	December 31, 2009	June 30, 2010 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	11,493	19,543
Inventory	145	39
Prepaid expenses and other current assets	1,731	1,925
Total current assets	13,369	21,507
Property, plant and equipment (net)	901	606
Deposits and other assets	196	196
Total assets	14,466	22,309
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	1,709	1,550
Accrued liabilities and other current liabilities	6,709	5,255
Warrant liability	342	858
Other accrued restructuring charges	1,062	492
Total current liabilities	9,822	8,155
Total liabilities	9,822	8,155
Commitments and contingencies (Note 7)		
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2009 and June 30, 2010; 2,046,813 and 1,213,142 shares issued and outstanding at December 31, 2009 and June 30, 2010, respectively. Aggregate preference in liquidation of $21,696,218 and $13,162,591 at December 31, 2009 and June 30, 2010, respectively	2	1
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2009 and June 30, 2010; 25,743,363 and 36,920,343 shares issued and outstanding at December 31, 2009 and June 30, 2010	26	37
Additional paid-in capital	226,881	248,314
Accumulated other comprehensive income	20	42
Deficit accumulated during the development stage	(222,285)	(234,240)
Total stockholders equity	4,644	14,154
Total liabilities and stockholders equity	14,466	22,309

The accompanying notes are an integral part of these consolidated financial statements.

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CYCLACEL PHARMACEUTICALS, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In $000s, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2009	2010	2009	2010	2010
	(Restated)		(Restated)		(Restated)
Revenues:					
Collaboration and research and development revenue		100		100	3,100
Product revenue	249	19	465	273	2,021
Grant revenue	17		29	16	3,652
Total revenue	266	119	494	389	8,773
Operating expenses:					
Cost of goods sold	192	92	308	234	1,208
Research and development	2,683	1,322	5,780	3,497	173,676
Selling, general and administrative	2,285	3,091	4,515	5,491	77,337
Goodwill and intangibles impairment					7,934
Restructuring expenses	366		366		2,634
Total operating expenses	5,526	4,505	10,969	9,222	262,789
Operating loss	(5,260)	(4,386)	(10,475)	(8,833)	(254,016)
Other income (expense):					
Costs associated with aborted 2004 IPO					(3,550)
Payment under guarantee	(1,652)		(1,652)		(1,652)
Change in valuation of derivative					(308)
Change in valuation of warrants	(288)	273	(296)	(516)	5,848
Foreign exchange gains/(losses)	(111)	(49)	(248)	(38)	(4,225)
Interest income	46	8	92	17	13,660
Interest expense	(13)	(9)	(120)	(33)	(4,667)
Total other income (expense)	(2,018)	223	(2,224)	(570)	5,106

Loss before taxes	(7,278)	(4,163)	(12,699)	(9,403)	(248,910)
Income tax benefit	233	230	591	363	17,585
Net loss	(7,045)	(3,933)	(12,108)	(9,040)	(231,325)
Dividends on preferred ordinary shares					(38,123)
Deemed dividend on convertible exchangeable preferred shares		(2,496)		(2,915)	(2,915)
Dividend on convertible exchangeable preferred shares	(307)	(114)	(614)	(403)	(2,960)
Net loss applicable to common shareholders	(7,352)	(6,543)	(12,722)	(12,358)	(275,323)
Net loss per share Basic and diluted	$ (0.36)	$ (0.18)	$ (0.62)	$ (0.36)	
Weighted average common shares outstanding	**20,433,129**	**36,565,972**	**20,433,129**	**34,157,279**	

The accompanying notes are an integral part of these consolidated financial statements.

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CYCLACEL PHARMACEUTICALS, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In $000s)
(Unaudited)

	Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2009 (Restated)	2010	2010 (Restated)
Cash flows from operating activities:			
Net loss	(12,108)	(9,040)	(231,325)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accretion of interest on notes payable, net of amortization of debt premium	18	2	102
Amortization of investment premiums, net	20		(2,297)
Change in valuation of derivative			308
Change in valuation of warrants	296	516	(5,892)
Warrant re-pricing			44
Depreciation and amortization	604	240	12,097
Amortization of intangible assets			886
Fixed asset impairment			221
Goodwill and intangibles impairment			7,934
Unrealized foreign exchange loss			7,747
Deferred revenue			(98)
Compensation for warrants issued to non employees			1,215
Shares issued for IP rights			446
(Gain) loss on disposal of property, plant and equipment	(10)	(9)	103
Stock based compensation	168	786	17,181
Provision for restructuring	146		1,779
Amortization of issuance costs of Preferred Ordinary C shares			2,517
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(1,189)	(88)	(836)
Accounts payable and other current liabilities	1,617	(2,183)	(3,169)
Net cash used in operating activities	(10,438)	(9,776)	(191,037)
Investing activities:			
Purchase of ALIGN			(3,763)
Purchase of property, plant and equipment	(10)	(8)	(8,831)
Proceeds from sale of property, plant and equipment	13	35	152
Purchase of short-term investments			(156,657)
Redemptions of short-term investments, net of maturities	1,502		162,729
Net cash provided by (used in) investing activities	1,505	27	(6,370)

Financing activities:			
Payment of capital lease obligations			(3,719)
Proceeds from issuance of ordinary and preferred ordinary shares, net of issuance costs			90,858
Proceeds from issuance of common stock and warrants, net of issuance costs		15,155	94,983
Net proceeds from stock options and warrants exercised		2,700	2,870
Payment of preferred stock dividend	(307)		(3,372)

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CYCLACEL PHARMACEUTICALS, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In $000s)
(Unaudited)

	Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2009 (Restated)	2010	2010 (Restated)
Repayment of government loan			(455)
Government loan received			414
Loan received from Cyclacel Group Plc			9,103
Proceeds of committable loan notes issued from shareholders			8,883
Loans received from shareholders			1,645
Cash and cash equivalents assumed on stock purchase			17,915
Costs associated with stock purchase			(1,951)
Net cash (used in) provided by financing activities	(307)	17,855	217,174
Effect of exchange rate changes on cash and cash equivalents	884	(56)	(224)
Net (decrease) increase in cash and cash equivalents	(8,356)	8,050	19,543
Cash and cash equivalents at beginning of period	24,220	11,493	
Cash and cash equivalents at end of period	15,864	19,543	19,543
Supplemental disclosure of cash flows information:			
Cash received during the period for:			
Interest	57	11	11,715
Taxes	1,527	110	16,550
Cash paid during the period for:			
Interest	(75)	(187)	(1,946)
Schedule of non-cash transactions:			
Acquisitions of equipment purchased through capital leases			3,470
Issuance of Ordinary shares in connection with license agreements			592
Issuance of Ordinary shares on conversion of bridging loan			1,638
Issuance of Preferred Ordinary C shares on conversion of secured convertible loan notes and accrued interest			8,893
Issuance of Ordinary shares in lieu of cash bonus			164
Issuance of other long term payable on ALIGN acquisition			1,122
Dividends accrued but not paid on convertible exchangeable preferred shares (1)	307	403	1,631
Deemed dividend on conversion of exchangeable preferred shares		2,915	2,915

(1) Certain dividends that previously had been accrued but unpaid were forfeited by the preferred shareholders upon their voluntary conversion of the convertible exchangeable preferred shares into common shares of stock in March and April 2010. As a result, the accrual for previous unpaid dividends was reversed in 2010. However, the preferred shareholders received additional shares of common stock issued to them upon conversion as compared to what they would have been entitled to receive under the stated rate of exchange of one preferred share to 0.42553 common shares, which has been reflected as a deemed dividend in the condensed consolidated financial statements. See Note 8, Stockholders Equity-Preferred

Stock for further details.

The accompanying notes are an integral part of these consolidated financial statements.

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CYCLACEL PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Cyclacel Pharmaceuticals, Inc. (Cyclacel or the Company) is a development-stage biopharmaceutical company dedicated to the development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Cyclacel s strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Clinical Programs

Cyclacel s clinical development priorities are focused on sapacitabine in the following indications:

Acute myeloid leukemia, or AML in the elderly;
Myelodysplastic syndromes, or MDS; and
Non-small cell lung cancer or NSCLC.

In June 2010, at the American Society of Clinical Oncology, or ASCO, meeting the Company reported interim response data for the ongoing Phase 2 clinical trial of sapacitabine in older patients with MDS. The study has recently completed enrollment of patients aged 60 or older with MDS who were previously treated with azacitidine or decitabine or both.

In June 2010, the Company announced that the U.S. Food and Drug Administration, or FDA, granted orphan drug designation to the Company s sapacitabine product candidate for the treatment of both AML and MDS.

The Company has additional clinical programs in development which are currently pending availability of clinical data. Once data become available and are reviewed, the Company will determine the feasibility of pursuing further development and/or partnering these assets, including sapacitabine in combination with seliciclib, seliciclib in NSCLC and nasopharyngeal cancer or NPC and CYC116.

Commercial Products

The Company markets directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia.

Basis of Presentation

As a development-stage company, substantially all the Company s efforts to date have been devoted to performing research and development, conducting clinical trials, developing and acquiring intellectual property, raising capital and recruiting and training personnel. The Company was incorporated in the state of Delaware in 1996 and is headquartered in Berkeley Heights, New Jersey, with a research facility located in Dundee, Scotland.

The condensed consolidated balance sheet as of June 30, 2010, the condensed consolidated statements of operations for the three and six months ended June 30, 2010 and 2009 and the condensed consolidated statements of cash flows for the six months ended June 30, 2010 and 2009, and related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2009 is derived from the audited consolidated financial statements included in the 2009 Annual Report on Form 10-K/A filed with the Securities and Exchange Commission (the SEC). The condensed consolidated financial statements are presented on the basis of accounting principles that are generally accepted in the United States for interim financial information and in accordance with the rules and regulations of the SEC. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States for a complete set of financial statements. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the condensed consolidated balance sheet as of June 30, 2010, the results of operations for the three and six months ended June 30, 2010 and 2009 and the consolidated statements of cash flows for the six months ended June 30, 2010 and 2009 have been made. The interim results for the three and six months ended June 30, 2010 are not necessarily indicative of the results to be expected for the year ending December 31, 2010 or for any other year. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2009, included in the Company s Annual Report on Form 10-K/A filed with the SEC on May 17, 2010 and subsequently amended again on May 19, 2010.

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Recent Developments

During April 2010, Cyclacel issued upon settlement an aggregate of 1,416,203 shares of its common stock to several of its stockholders in exchange for such stockholders delivery to the Company of an aggregate of 710,271 shares of the Company s Preferred Stock. These transactions settled by April 23, 2010, after which time, a total of 1,213,142 shares of Preferred Stock remain outstanding. Each stockholder approached the Company with the proposed exchange transaction and the terms of the exchange were determined by arms-length negotiation between the parties. The preferred shareholders received approximately 1.1 million additional shares of common stock than what they would have been entitled to receive under the stated rate of exchange of one preferred share to 0.42553 of common share. The value of the additional shares issued has been considered a deemed dividend and reflected in the computation of earnings per share for the three and six months ended June 30, 2010.

On April 27, 2010, Cyclacel was served with a complaint filed by Celgene Corporation in the United States District Court for the District of Delaware seeking a declaratory judgment that four of its own patents, claiming the use of romidepsin injection in T-cell lymphomas, are invalid and not infringed by Celgene s products. The four patents cited in the complaint do not involve the Company s clinical development candidates or its commercial products. On June 17, 2010, Cyclacel filed its Answer and Counterclaims to the declaratory judgment complaint. Cyclacel has filed counterclaims charging Celgene with infringement of each of its four patents and seeking damages for Celgene s infringement as well as injunctive relief. The four patents directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product. Given that the Company s answer and counterclaims were only recently filed, the Company has not made an assessment at this time as to whether an adverse result would be probable, reasonably possible or remote. Any potential impact on the Company s financial position, results of operations or cash flows is not at this time expected to be material in view of the fact that the inventions of the patents are not utilized in the Company s products. Accordingly, an adverse result is expected to have only a minimal impact, if any, on the Company s financial position, results of operations or cash flows. Cyclacel intends to vigorously defend the validity of these patents and enforce its patent rights.

On May 17, 2010, Cyclacel filed an amendment to its Form 10-K for the year ended December 31, 2009 in order to restate its annual consolidated financial statement for the period ended December 31, 2009 (the Financial Statements) to correct an error in the computation of the net loss per share and in the presentation of preferred dividends in its consolidated statements of cash flows. Although Cyclacel had accrued for the unpaid dividends in its Financial Statements, it did not include the accrued amount when calculating basic and diluted loss per common share for the year ended December 31, 2009. As a result, the net loss per common share was revised from $0.88 per share, to $0.94 per share. For the three months ended June 30, 2009, the net loss per common share was revised from $0.34 per share to $0.36 per share. For the six months ended June 30, 2009, the net loss per common share was revised from $0.59 per share to $0.62 per share. The restatement had no effect on net cash flows, the reported net loss or the consolidated balance sheet. Cyclacel also determined that the Financial Statements should not be relied upon and filed a Current Report on Form 8-K under item 4.02-Non-reliance on previously issued financial statements-on May 13, 2010. On May 19, 2010, the Company filed Amendment No. 2 to its Annual Report on Form 10-K/A, pursuant to which it corrected the date of the report issued by its independent registered public accounting firm from May 14, 2010 to May 17, 2010, as such date appears in items 8 and 9T of such filing.

Subsequent Developments

On July 16, 2010, the Board of Directors of Cyclacel resolved, pursuant to the Certificate of Designations, not to declare the quarterly cash dividend on the Company s Preferred Stock, with respect to the second quarter of 2010 that would otherwise have been payable on August 1, 2010. As the Company has not paid an aggregate amount equal to six quarterly dividends on the Preferred Stock, the size of the Company s Board has been increased by two members and the holders of the Preferred Stock, voting separately as a class, are entitled to vote to fill the two vacancies created thereby until the Company pays all accrued but unpaid dividends, at which time such right is terminated. The Company has received a request from a holder of at least 10% of the issued and outstanding Preferred Stock that the Company call a special meeting of the holders of Preferred Stock for the election of directors to fill the two vacancies. To date, approximately $1.0 million of dividends remain accrued and unpaid.

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries for the indicated periods. All significant intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company reviews its estimates on an ongoing basis. The estimates were based on historical experience and on various other assumptions that the Company believes to be reasonable under the circumstances. Actual results may differ from these estimates.

Cash and Cash Equivalents

Cash equivalents are stated at cost when purchased, which is substantially the same as fair value. The Company considers all highly liquid investments with an original maturity of three months or less at the time of acquisition to be cash equivalents. The objectives of the Company s cash management policy are the safety and preservation of funds, liquidity sufficient to meet the Company s cash flow requirements and attainment of a market rate of return.

Trade Accounts Receivable and Allowance for Doubtful Accounts

The allowance for doubtful accounts is based on aging categories and historical collection experience, taking into consideration the type of payer, historical and projected collection experience, and current economic and business conditions that could affect the collectability of our receivables. The allowance for doubtful accounts is reviewed for adequacy, at a minimum, on a quarterly basis. Changes in the allowance for doubtful accounts are recorded as an adjustment to bad debt expense within general and administrative expenses. Material revisions to reserve estimates may result from adverse changes in collection experience. The Company writes off accounts against the allowance for doubtful accounts when reasonable collection efforts have been unsuccessful and it is probable the receivable will not be recovered.

Inventory

Cyclacel values inventories at lower of cost or market value. The Company determines cost using the first-in, first-out method. As December 31, 2009 and June 30, 2010, all inventories were classified as finished goods. The Company analyzes its inventory levels quarterly and writes-down inventory that has become obsolete or that has a cost basis in excess of its expected net realizable value. Expired inventory is disposed of and the related costs are written off. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required in future periods.

The Company analyzes its inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. The determination of whether or not inventory costs will be realizable requires estimates by the Company s management. A critical input in this determination is future expected inventory requirements, based on internal sales forecasts. The Company then compares these requirements to the expiry dates of inventory on hand. To the extent that inventory is expected to expire prior to being sold, the Company will write down the value of inventory. If actual results differ from those estimates, additional inventory write-offs may be required.

Revenue Recognition

Product sales

The Company recognizes revenue from product sales when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the selling price is fixed and determinable; and collectability is reasonably assured.

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The Company offers a general right of return on these product sales, and has considered the guidance in ASC 605-15, *Revenue Recognition Products* (ASC 605-15) and ASC 605 10 *Revenue Recognition Overall* (ASC 605- Under these guidelines, the Company accounts for all product sales using the sell-through method. Under the sell-through method, revenue is not recognized upon shipment of product to distributors. Instead, the Company records deferred revenue at gross invoice sales price and deferred cost of sales at the cost at which those goods were held in inventory. The Company recognizes revenue when such inventory is sold through to the end user. To estimate product sold through to end users, the Company relies on third-party information, including information obtained from the Company s distributor customers with respect to their inventory levels and sell-through to customers. For the three months ended June 30, 2010, the Company recorded $0.2 million of product returns due to a higher than anticipated amount of returns related to expiring product with a two-year shelf-life previously sold into the marketplace. From the first quarter of 2010 the Company s supplier has increased the product shelf-life to three-years to assist in the management of the product supply chain.

Collaboration, research and development, and grant revenue

Certain of the Company s revenues are earned from collaborative agreements. Consistent with its general revenue recognition policies, the Company recognizes revenue when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed and determinable; and collectability is reasonably assured. Determination of whether these criteria have been met is based on management s judgments regarding the nature of the research performed, the substance of the milestones met relative to those the Company must still perform, and the collectability of any related fees. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

Research and development revenues, which are earned under agreements with third parties for contract research and development activities, are recorded as the related services are performed. Milestone payments are non-refundable and recognized as revenue when earned, as evidenced by achievement of the specified milestones and the absence of ongoing performance obligations. Any amounts received in advance of performance are recorded as deferred revenue. None of the revenues recognized to date are refundable if the relevant research effort is not successful.

Grant revenues from government agencies and private research foundations are recognized as the related qualified research and development costs are incurred, up to the limit of the prior approval funding amounts. Grant revenues are not refundable.

Clinical Trial Accounting

Data management and monitoring of all of the Company s clinical trials are performed by contract research organizations (CROs) or clinical research associates (CRAs). Typically, CROs and some CRAs bill monthly for services performed, and others bill based upon milestones achieved. For outstanding amounts, the Company accrues unbilled clinical trial expenses based on estimates of the level of services performed each period. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as research and development expenses. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial and any initial payment made to the clinical trial site is recognized upon execution of the clinical trial agreements and expensed as research and development expenses.

Research and Development Expenditures

Research and development expenses consist primarily of costs associated with the Company s product candidates, upfront fees, milestones, compensation and other expenses for research and development personnel, supplies and development materials, costs for consultants and related contract research, facility costs, amortization of purchased technology and depreciation. Expenditures relating to research and development are expensed as incurred.

Foreign currency transactions and currency translation

Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange (losses)/gains in the statement of operations.

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The assets and liabilities of the Company s international subsidiary are translated from its functional currency into United States dollars at exchange rates prevailing at the balance sheet date. Average rates of exchange during the period are used to translate the statement of operations, while historical rates of exchange are used to translate any equity transactions.

Translation adjustments arising on consolidation due to differences between average rates and balance sheet rates, as well as unrealized foreign exchange gains or losses arising on translation of intercompany loans which are of a long-term-investment nature, are recorded in other comprehensive income.

Warrants Liability

The Company issued warrants to purchase shares of common stock under the registered direct financing completed in February 2007. These warrants are being accounted for as a liability in accordance with ASC 815 *Derivatives and Hedging* (ASC 815). ASC 815 requires freestanding contracts that are settled in the Company s own stock, including common stock warrants, to be classified as an equity instrument, asset or liability. Under the provisions of ASC 815, an instrument classified as an asset or a liability must be carried at fair value until exercised or expired, with any changes in fair value recorded in the results of operations. A contract instrument designated as an equity instrument must be included within equity, and no subsequent fair value adjustments are required. The Company reviews the classification of its warrants at each balance sheet date. With respect to warrants issued in February 2007, the Company has classified those instruments as a liability pursuant to ASC 815, since the Company is unable to control all the events or actions necessary to settle the warrants in registered shares. The fair value of this liability is estimated using an option-pricing model, which includes variables such as the expected volatility of the Company s share price, interest rates, and expected dividend yields. These variables are projected based on historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrants liability.

At the date of the transaction, the fair value of the warrants of $6.8 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 4.68%, expected volatility 85%, expected dividend yield 0%, and a remaining contractual life of 7 years. The value of the warrant shares is being marked to market each reporting period as a derivative gain or loss on the consolidated statement of operations until exercised or expiration. At December 31, 2009, the fair value of the warrants was $0.3 million (utilizing the following assumptions: risk free interest rate 2.13%, expected volatility 96%, expected dividend yield 0%, and a remaining contractual life of 4.13 years). At June 30, 2010, the fair value of the warrants was approximately $0.9 million (utilizing the following assumptions: risk free interest rate 1.578%, expected volatility 113%, expected dividend yield 0%, and a remaining contractual life of 3.63 years). For the three months ended June 30, 2010, the Company recognized the change in the value of warrants of approximately $0.3 million, as a gain on the consolidated statement of operations as compared to a $0.3 million loss for the three months ended June 30, 2009. For the six months ended June 30, 2009 and 2010, the Company recognized the change in the value of warrants of approximately $0.3 million and $0.5 million, respectively, as a loss on the consolidated statement of operations.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company applies the guidance codified in ASC 740 *Income taxes* (ASC 740) on uncertain tax positions. The Company only recognizes tax benefits that it believes are more likely than not to be sustained upon review by the relevant taxing authority. The amount recognized is based on the amount that cumulatively is more likely than not be sustained.

Credit is taken in the accounting period for research and development tax credits, which will be claimed from H. M. Revenue & Customs, the United Kingdom s taxation and customs authority, in respect of qualifying research and development costs incurred in the same accounting period.

Stock-based Compensation

The Company grants stock options, restricted stock units and restricted stock to officers, employees and directors under the 2006 Amended and Restated 2006 Equity Incentive Plan (2006 Plan), which was approved on March 16, 2006 and subsequently amended. The Company also has outstanding options under various stock-based compensation plans for employees and directors. These plans are described more fully in Note 6 Stock-Based Compensation . The Company accounts for these plans under ASC 718 Compensation Stock Compensation (ASC 718).

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ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of the Company s common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using an option-pricing model, which includes variables such as the expected volatility of the Company s share price, the anticipated exercise behavior of the Company s employees, interest rates and dividend yields. These variables are projected based on historical data, experience and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments. The value of stock-based awards is recognized as expense over the service period, net of estimated forfeitures, using the straight-line attribution method. The estimation of stock-based awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. The Company considers many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. Actual results and future estimates may differ substantially from the Company s current estimates.

Segments

The Company has determined its reportable segments in accordance with ASC 280, *Segment Reporting* (ASC 280). After consideration of its business activities and geographic area, the Company has concluded that it has one operating segment being the discovery, development and commercialization of novel, mechanism-targeted drugs to treat cancer and other serious disorders, with development operations in two geographic areas, namely the United States and the United Kingdom.

Net Loss per Common Share

The Company calculates net loss per common share in accordance with ASC 260 *Earnings Per Share* (ASC 260). Basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. The Company s potentially dilutive shares, which include outstanding common stock options, restricted stock, restricted stock units, convertible preferred stock, and common stock warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

	June 30, 2009	**June 30, 2010**
Stock options	3,558,933	3,187,291
Restricted stock and restricted stock units	141,700	75,515
Convertible preferred stock	870,980	516,228
Common stock warrants	3,808,841	5,843,597
Total shares excluded from calculation	8,380,454	9,622,631

Comprehensive Income (Loss)

In accordance with ASC 220, *Comprehensive Income* (ASC 220) all components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments, are reported, net of any related tax effect, to arrive at comprehensive income (loss). No taxes were recorded on these items.

3. FAIR VALUE MEASUREMENTS

Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 *Fair Value Measurements and Disclosures* (ASC 820) establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

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Level 2: Inputs other than quoted prices within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs that are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value. The Company determined that it has not made any Level 1 or 3 measurements as of December 31, 2009 or June 30, 2010. The following financial assets and liabilities, which are reported at fair value on a recurring basis, have been valued using Level 2 inputs:

	December 31, 2009	June 30, 2010
	($000s)	
Warrants	342	858

The Company used the Black-Scholes option-pricing model with the following assumptions to value the above warrants:

	December 31, 2009	June 30, 2010
Exercise price	$ 8.44	$ 8.44
Expected term	4.13 Yrs	3.63 Yrs
Risk free interest rate	2.13%	1.578%
Expected volatility	96%	113%
Expected dividend yield over expected term		

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	December 31, 2009	June 30, 2010
	($000s)	
Research and development tax credit receivable	1,096	1,291
Prepayments	456	446
Other current assets	179	188
Total prepaid expenses and other current assets	1,731	1,925

5. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES

Accrued and other current liabilities consisted of the following:

	December 31, 2009	June 30, 2010
	($000s)	
Accrued research and development	2,654	2,847
Accrued IP / Patent costs	283	30
Accrued compensation	136	68
Amount payable under license agreement	651	
Amount payable under guarantee (1)	796	

Preferred dividend	1,228	1,032
Other current liabilities	961	1,278
	6,709	5,255

(1) For more information please see Note 7 Commitments and Contingencies Guarantee.

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6. STOCK BASED COMPENSATION

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the three and six months ended June 30, 2009 and 2010 as shown in the following table:

	For the three months ended June 30,		For the six months ended June 30,	
	2009	2010	2009	2010
	($000s)		($000s)	
Research and development	149	93	53	165
General and administrative	199	374	115	621
Stock-based compensation costs before income taxes	348	467	168	786

At the Company s annual shareholder meeting on May 14, 2008, the stockholders approved to increase the number of shares reserved under the 2006 Plan to 5,200,000 shares of the Company s common stock, up from 3,000,000 shares. The shares reserved under the 2006 Plan have a maximum maturity of 10 years and generally vest over a four-year period from the date of grant.

A summary of activity for the options under the Company s 2006 Plan for the six months ended June 30, 2010 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in $000s)
Options outstanding at December 31, 2009	3,349,876	$ 4.21	7.76	698
Granted	192,000	$ 2.39		
Exercised	(124,277)	$ 0.44		
Expired				
Cancelled / forfeited	(230,308)	$ 5.14		
Options outstanding at June 30, 2010	3,187,291	$ 4.18	7.40	1,280
Unvested at June 30, 2010	1,158,521	$ 2.58	8.23	701
Vested and exercisable at June 30, 2010	2,028,770	$ 5.10	6.92	579

ASC 718 requires compensation expense associated with share-based awards to be recognized over the requisite service period, which for the Company is the period between the grant date and the date the award vests or becomes exercisable. Most of the awards granted by the Company, vest ratably over four years, with 1/4 of the award vesting one year from the date of grant and 1/48 of the award vesting each month thereafter. However, certain awards made to executive officers vest over three to five years, depending on the terms of their employment with the Company.

ASC 718 also requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. This analysis is evaluated quarterly and the forfeiture rate adjusted as necessary. Ultimately, the actual expense recognized over the vesting period is based on only those shares that vest.

The Company used the Black-Scholes option-pricing model with the following assumptions for stock option grants to employees and directors for the six months ended June 30, 2009 and 2010:

	For the six months ended June 30,	
	2009	**2010**
Expected term	0.75 5 Yrs	5 6Yrs
Risk free interest rate	0.405 1.84%	2.37 2.96%
Expected volatility	65 169%	90 100%
Expected dividend yield over expected term		
Resulting weighted average grant fair value	$ 0.39	$ 1.80

The expected term assumption was estimated using past history of early exercise behavior and expectations about future behaviors. Due to the Company s limited existence of being a public company, the expected volatility assumption was based on the historical volatility of peer companies over the expected term of the option awards.

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Estimates of pre-vesting option forfeitures are based on the Company s experience. Currently the Company uses a forfeiture rate of 0 50% depending on when and to whom the options are granted. The Company adjusts its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and may impact the amount of compensation expense to be recognized in future periods.

In the second quarter of 2010, the Company adjusted forfeiture rates on certain awards granted in December 2006 from 8% to 0%, reflecting the increased likelihood that these remaining awards will vest in their entirety. This change in assumption resulted in approximately $0.1 million of additional compensation cost recognized in the quarter ended June 30, 2010. During the quarter ended June 30, 2009 the Company adjusted its prior estimates of forfeitures because actual forfeiture rates were higher than that previously estimated, primarily due to the lapsing of stock option grants on the termination of employees. The change in the estimated forfeiture assumptions resulted in a negative adjustment to stock-based compensation costs of approximately $0.2 million during the quarter ended June 30, 2009. In connection with the reduction in workforce during the second quarter of 2009, the Company agreed to extend the option exercise term for terminated employees from 30 days to 9 months. In accordance with ASC 718, the Company recorded a charge of $0.3 million during the second quarter of 2009 related to this modification.

The weighted average risk-free interest rate represents interest rate for treasury constant maturities published by the Federal Reserve Board. If the term of available treasury constant maturity instruments is not equal to the expected term of an employee option, Cyclacel uses the weighted average of the two Federal Reserve securities closest to the expected term of the employee option.

There were no exercises of stock options during the six months ended June 30, 2009. During the six months ended June 30, 2010, there were 124,277 stock options exercised for proceeds totaling approximately $0.1 million. As the Company presently has tax loss carry forwards from prior periods and expects to incur tax losses in 2010, the Company is not able to benefit from the deduction for exercised stock options in the current reporting period.

Cash used to settle equity instruments granted under share-based payment arrangements amounted to $0 during all periods presented.

Restricted Stock

In November 2008, the Company issued restricted common stock to an employee subject to certain forfeiture provisions. Specifically, one quarter of the award vests one year from the date of grant and 1/48 of the award effectively vests each month thereafter. This restricted stock grant is accounted for at fair value at the date of grant and an expense is recognized during the vesting term. Summarized information for restricted stock grants for the six months ended June 30, 2010 is as follows:

	Restricted Stock	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2009	36,458	$ 0.44
Vested	(6,252)	$ 0.44
Non-vested at June 30, 2010	30,206	$ 0.44

Restricted Stock Units

Restricted stock units were issued to senior executives of the Company in November 2008, which entitle the holders to receive a specified number of shares of the Company s common stock over the four year vesting term. A restricted stock unit grant is accounted for at fair value at the date of grant which is equivalent to the market price of a share of the Company s common stock, and an expense is recognized during the vesting term. Summarized information for restricted stock units grants for the six months ended June 30, 2010 is as follows:

	Weighted Average Grant Date Value Per Share

	Restricted Stock Units		
Non-vested at December 31, 2009	54,687	$	0.44
Vested	(9,378)	$	0.44
Non-vested at June 30, 2010	45,309	$	0.44

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7. COMMITMENTS AND CONTINGENCIES

Restructuring

In 2005, the Company recorded an accrued restructuring liability associated with abandoning the facility in Bothell, Washington. The lease term on this space expires December 2010. The Bothell restructuring liability was computed as the present value of the difference between the remaining lease payments due less the estimate of net sublease income and expenses. The accrual balance was adjusted in 2006 to reflect a change in estimate due to continued deterioration in the local real estate market. As of June 30, 2010, the Bothell accrued restructuring liability was $0.5 million. This represents the Company s best estimate of the fair value of the liability. Subsequent changes in the liability due to accretion, or changes in estimates of sublease assumptions, etc. will be recognized as adjustments to restructuring charges in future periods.

The Company records payments of rent related to the Bothell facility as a reduction in the amount of the accrued restructuring liability. Accretion expense is recognized due to the passage of time and is reflected in Selling, General and Administrative costs and Interest Expense on the condensed consolidated statement of operations. Based on our current projections of estimated sublease income and a discount rate of 7.8%, the Company expects to record additional accretion expense of approximately $10,000 over the remaining term of the lease.

The restructuring accrual at June 30, 2010 is as follows:

	$000s
Restructuring provision at December 31, 2009	1,062
Accretion expense for the current period	28
Payments made in the period	(598)
As of June 30, 2010	492
Less: amounts due within one year	(492)
Other accrued restructuring charges long term	

Guarantee

On July 28, 2005 and amended on March 27, 2006, Cyclacel Group plc (Group) signed a convertible Loan Note Instrument constituting convertible unsecured loan notes (the Loan) and entered into a Facility Agreement (Agreement) with Scottish Enterprise (SE), as lender, whereby SE subscribed for £5 million, or approximately $9 million at the time, of the convertible loan notes. The loan was subsequently converted into 1,231,527 preferred D shares of the Group in satisfaction of all amounts owed by Group under the convertible loan notes. The number of preferred D shares that SE received was calculated by dividing the principal amount outstanding under the loan note by £4.06. The preferred D shares were exchanged for shares in Xcyte Therapies, Inc. on March 27, 2006 as part of the transaction between Xcyte and Cyclacel Limited. However, Scottish Enterprise retained the ability it had under the Agreement to receive a cash payment should the research operations in Scotland be significantly reduced. Cyclacel Limited guaranteed approximately £5 million, the amount potentially due to SE, which will be calculated as a maximum of £5 million less the market value of the shares held (or would have held in the event they dispose of any shares) by SE at the time of any significant reduction in research facilities.

On June 22, 2009, the Company amended the March 2006 Agreement with SE, in order to allow the Company to implement a reduction of the Company s research operations located in Scotland in exchange for the parties agreement to modify the payment terms of the Agreement in the principal amount of £5 million (approximately $8.0 million at June 30, 2010), which SE had previously entered into with the Company. The original agreement dated March 27, 2006, provided for repayment of £5 million in the event the Company significantly reduced its Scottish research operations. Pursuant to the terms of the Amendment, in association with Cyclacel s material reduction in staff at its Scottish research facility, the parties agreed to a modified payment of £1 million (approximately $1.7 million at June 22, 2009) payable in two equal tranches. On July 1, 2009 the first installment of £0.5 (approximately $0.8 million) million was paid and the remaining amount of £0.5 million (approximately $0.8 million) was paid on January 6, 2010. In addition, should a further reduction below current minimum staff levels be effectuated before July 2014 without SE s prior consent, the Company will guarantee approximately £4 million, the amount potentially

due to SE, which will be calculated as a maximum of £4 million less the market value of the shares held (or would have held in the event they dispose of any shares) by SE at the time of any further reduction in research facilities. This resulted in a charge to the income statement in the second quarter of 2009 of £1 million ($1.7 million), with the outstanding liability being recorded under accrued liabilities on the condensed consolidated balance sheet as at December 31, 2009.

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Supply arrangements

In connection with the asset acquisition of ALIGN on October 5, 2007, the Company acquired license agreements for the exclusive rights to sell and distribute three products in the United States. The Company, as part of securing long term supply arrangements had commitments to make future payments totaling approximately $1.3 million of which $0.6 million was paid in May 2009 and the remainder of $0.7 million was paid in May 2010.

Purchase Obligations

The Company has a minimum purchase obligation in relation to the purchase of manufactured products within the ALIGN business equivalent to the value of product purchased in the previous year. For the year ended December 31, 2010 this equates to $0.1 million.

Licensing Agreements

Cyclacel has entered into a number of licensing agreements that require the Company to make payments to the other party to the agreement upon the Company attaining certain milestones as defined in the agreements. The Company may be required to make future milestone payments, totaling approximately $11.3 million, depending upon the success and timing of future clinical trials and the attainment of other milestones as defined in the respective agreement. The Company is also obligated to make future royalty payments to collaborators. The Company cannot reasonably determine the amount and timing of such royalty payments, if any.

8. STOCKHOLDERS EQUITY

Preferred stock

As of June 30, 2010 there were 1,213,142 shares of Preferred Stock issued and outstanding at an issue price of $10.00 per share. Dividends on the Preferred Stock are cumulative from the date of original issuance at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of February, May, August and November, commencing February 1, 2005. Since inception until April 6, 2009, the Company declared and paid these dividends when due. However, as part of the Company s program to reduce expenditure, with respect to six quarters, the Company s Board of Directors resolved not to declare payment of, but continue to accumulate, the cash dividend. Any dividends must be declared by the Company s Board of Directors and must come from funds that are legally available for dividend payments. The Preferred Stock has a liquidation preference of $10 per share, plus accrued and unpaid dividends.

To the extent that any dividends payable on the Preferred Stock are not declared and paid, such unpaid dividends are accumulated. As the Company has not paid an aggregate amount equal to six quarterly dividends on the Preferred Stock, the size of the Company s Board has been increased by two members and the holders of the Preferred Stock, voting separately as a class, are entitled to vote to fill the two vacancies created thereby until the Company pays all accrued but unpaid dividends, at which time such right is terminated. The Company has received a request from a holder of at least 10% of the issued and outstanding Preferred Stock that the Company call a special meeting of the holders of Preferred Stock for the election of directors to fill the two vacancies.

The Preferred Stock is convertible at the option of the holder at any time into the Company s common stock at a conversion rate of approximately 0.42553 shares of common stock for each share of Preferred Stock based on a price of $23.50. During the six months ended June 30, 2010, 833,671 shares of Preferred Stock were converted into 1,655,599 shares of the Company s common stock. Since inception through June 30, 2010, holders have voluntarily converted 1,776,858 shares of Preferred Stock into common stock. The Company has reserved 516,228 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at June 30, 2010. The shares of Preferred Stock have been retired and canceled and shall upon cancellation be restored to the status of authorized but unissued shares of preferred stock, subject to reissuance by the Board of Directors as shares of preferred stock of one or more series.

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Conversion of Convertible Preferred Stock

During the three and six months ended June 30, 2010, Cyclacel entered into an agreement to exchange the Company s Preferred Stock into shares of common stock. There were no exchanges of the Company s Preferred Stock into shares of common stock in 2009. The table below provides details of the aggregate activities in 2010:

	For the three months ended June 30, 2010	For the six months ended June 30, 2010
Preferred shares exchanged	710,271	833,671
Common shares issued:		
At stated convertible option	302,242	354,752
Incremental shares issued under the exchange transaction	1,113,961	1,300,847
Total common shares issued:	1,416,203	1,655,599

As the preferred shareholders received additional shares of common stock issued to them upon conversion as compared to what they would have been entitled to receive under the stated rate of exchange, the Company recorded the excess of (1) the fair value of all securities and other consideration transferred to the holders of the Preferred Stock and (2) the fair value of securities issuable pursuant to the original conversion terms as an increase in the net loss attributable to common shareholders. Specifically, the Company recorded deemed dividends related to the additional shares issued under the exchange transactions of approximately $2.5 million and $2.9 million for the three and six months ended June 30, 2010, respectively.

The Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

Common Stock

January 2010 Registered Direct Financings

On January 25, 2010, the Company completed the sale of 2,350,000 units in a registered direct offering at a purchase price of $2.50 per unit to certain institutional investors of the Company for gross proceeds of approximately $5.9 million. Each unit consisted of one share of the Company s common stock and one warrant to purchase 0.30 of one share of its common stock. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance and will be exercisable at an exercise price of $2.85 per share of common stock. As of June 30, 2010, warrants issued to the investors have been classified as equity. The transaction date fair value of the warrants of $1.0 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate - 2.39%, expected volatility 90%, expected dividend yield 0%, and a remaining contractual life of 5.00 years. As of June 30, 2010, all the warrants are outstanding.

On January 13, 2010, the Company completed the sale of 2,850,000 units in a registered direct offering to certain institutional investors. Each unit was sold at a purchase price of $2.51 per unit and consists of one share of the Company s common stock and one warrant to purchase 0.25 of one share of its common stock for gross proceeds of approximately $7.2 million. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance and will be exercisable at an exercise price of $3.26 per share of common stock. As of June 30, 2010, warrants issued to the investors have been classified as equity. The transaction date fair value of the warrants of $1.3 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate - 2.55%, expected volatility 90%, expected dividend yield 0%, and a remaining contractual life of 5.00 years. As of June 30, 2010, all the warrants are outstanding.

July 2009 Registered Direct Financing

On July 29, 2009, the Company sold its securities to select institutional investors consisting of 4,000,000 units in a registered direct offering (the Offering) at a purchase price of $0.85 per unit (each, a Unit). Each Unit consisted o (i) one share of the Company s common stock, (the Common Stock), (ii) one warrant to purchase 0.625 of one share of

Common Stock (a Series I Warrant) and (iii) one warrant to purchase 0.1838805 of one share of Common Stock (a Series II Warrant). The Series I Warrants had a seven-month term from the date of issuance, were exercisable beginning six months from the date of issuance and were exercisable at an exercise price of $1.00 per share of Common Stock. During the first quarter of 2010, all of The Series I Warrants were exercised for $2.5 million. The Series II Warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance and are exercisable at an exercise price of $1.00 per share of Common Stock. During the first quarter of 2010, 43,266 warrants were exercised for $43,266.

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The sale of the Units was made pursuant to Subscription Agreements, dated July 23, 2009, with each of the investors. The net proceeds to the Company from the sale of the Units, after deducting for the Placement Agent s fees and offering expenses, were approximately $2.9 million. As of June 30, 2010, the remaining Series II Warrants outstanding of 692,256 issued to the investors have been classified as equity. The transaction date fair value of the Series II Warrants of $0.6 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 2.69%, expected volatility 90%, expected dividend yield 0%, and a remaining contractual life of 5.00 years.

December 2007 Committed Equity Financing Facility

On December 10, 2007 and as amended on November 24, 2009, Cyclacel entered into a CEFF with Kingsbridge, in which Kingsbridge committed to purchase the lesser of 4,084,590 shares of common stock or $60 million of common stock from Cyclacel over a three-year period. Under the terms of the agreement, Cyclacel will determine the exact timing and amount of any CEFF financings, subject to certain conditions. All amounts drawn down under the CEFF will be settled via the issuance of Cyclacel s common stock. Cyclacel may access capital under the CEFF in tranches of either (a) 2% of Cyclacel s market capitalization at the time of the draw down or (b) the lesser of (i) 3% of Cyclacel s market capitalization at the time of the draw down and (ii) an alternative draw down amount based on the product of (A) the average trading volume of the 30-day trading period preceding the draw down excluding the five highest and five lowest trading days during such period, (B) the volume-weighted average trading price (VWAP) on the trading day prior to the notice of draw down, (C) the number of days during the draw down period and (D) 85%, subject to certain conditions. Each tranche will be issued and priced over an eight-day pricing period. Kingsbridge will purchase shares of common stock pursuant to the CEFF at discounts ranging from 10% to 20% depending on the average market price of the common stock during the eight-day pricing period, provided that the minimum acceptable purchase price for any shares to be issued to Kingsbridge during the eight-day period is determined by the higher of $0.40 or 90% of Cyclacel s common stock closing price the day before the commencement of each draw down.

During 2010, the Company sold 1,563,208 shares of its common stock to Kingsbridge under the CEFF, in consideration of aggregate proceeds of $3.1 million. Since inception to June 30, 2010, the Company sold an aggregate of 2,818,232 shares of its common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of $4.1 million.

In connection with an amendment to the CEFF dated November 24, 2009, the Company issued an amended and restated warrant to Kingsbridge to purchase 175,000 shares of its common stock at an exercise price of $1.40 per share, (from an original exercise price of $7.17) which represents 175% of the closing bid price of the Company s common stock on the date prior to the date on which the Amendment was signed. The warrant amends and restates the original warrant issued by the Company to Kingsbridge in connection with the CEFF. No other changes were made to the original warrant. As a result of the change in exercise price, the Company recorded an expense of approximately $44,000 during the fourth quarter of 2009. The warrant is exercisable, subject to certain exceptions, until December 12, 2012. During the first quarter of 2010, Kingsbridge exercised its warrant to purchase 75,000 shares of common stock for approximately $0.1 million.

As of June 30, 2010, the balance of the outstanding warrants issued to Kingsbridge has been classified as equity. The transaction date fair value of the warrant of $0.6 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 3.605%, expected volatility 70%, expected dividend yield 0%, and a remaining contractual life of 5.5 years.

Common Stock Warrants

In connection with the Company s February 16, 2007 Registered Direct Offering the Company issued to investors warrants to purchase 1,062,412 shares of common stock. The warrants issued to the investors are being accounted for as a liability. At the date of the transaction, the fair value of the warrants of $6.8 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 4.58%, expected volatility - 85%, expected dividend yield 0%, and a remaining contractual life of 6.88 years. The value of the warrant shares is being marked to market each reporting period as a derivative gain or loss on the consolidated statement of operations until exercised or expiration. At December 31, 2009 and June 30, 2010, the fair value of the warrants determined utilizing the Black-Scholes option pricing model was approximately $0.3 million and $0.9 million,

respectively. The fair value at June 30, 2010 reflects the increase in the Company s common stock price of $1.72 per share at June 30, 2010 as compared to the common stock price of $1.04 per share at December 31, 2009. For the three months ended June 30, 2010, the Company recognized the change in the value of warrants of approximately $0.3 million, as a gain on the consolidated statement of operations as compared to a $0.3 million loss for the three months ended June 30, 2009. For the six months ended June 30, 2009 and 2010, the Company recognized the change in the value of warrants of approximately $0.3 million and $0.5 million, respectively, as a loss on the consolidated statement of operations.

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The following table summarizes information about warrants outstanding at June 30, 2010:

Issued in Connection With	Expiration Date	Common Shares Issuable	Weighted Average Exercise Price
March 2006 stock issuance	2013	2,571,429	7.00
February 2007 stock issuance	2014	1,062,412	8.44
December 2007 CEFF	2013	100,000	1.40
July 2009 Series II stock issuance	2014	692,256	1.00
January 2010 stock Issuance	2015	712,500	3.26
January 2010 stock Issuance	2015	705,000	2.85
Total		5,843,597	$ 5.50

Exercise of Stock Options

There were no stock option exercises during the six months ended June 30, 2009. During the six months ended June 30, 2010, there were 124,277 stock option exercises totaling approximately $0.1 million.

9. RECENT ACCOUNTING PRONOUNCEMENTS

In April 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-17, *Revenue Recognition-Milestone Method (Topic 605): Milestone Method of Revenue Recognition, a consensus of the FASB Emerging Issues Task Force* (ASU 2010-17). The amendments in ASU No. 2010-17 deal with research and development contracts that are tied to completing a phase of a study or achieving a specific result in a research project. The objective of ASU No. 2010-17 is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Prior to issuance of ASU No. 2010-17, authoritative guidance on the use of the milestone method did not exist. An entity s decision to use the milestone method of revenue recognition over other proportional revenue recognition methods is a policy decision made by the entity. Use of the milestone method will require certain disclosures. The guidance provided by ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted, with certain restrictions. The Company does not expect the adoption of this new ASU to have a material impact on its consolidated financial statements.

In January 2010, the FASB issued an amendment to the accounting standards related to the disclosures about an entity s use of fair value measurements. Among these amendments, entities will be required to provide enhanced disclosures about transfers into and out of the Level 1 (fair value determined based on quoted prices in active markets for identical assets and liabilities) and Level 2 (fair value determined based on significant other observable inputs) classifications, provide separate disclosures about purchases, sales, issuances and settlements relating to the tabular reconciliation of beginning and ending balances of the Level 3 (fair value determined based on significant unobservable inputs) classification and provide greater disaggregation for each class of assets and liabilities that use fair value measurements. Except for the detailed Level 3 roll-forward disclosures, the new standard is effective for the Company for interim and annual reporting periods beginning after December 31, 2009. The adoption of this accounting standards amendment did not have a material impact on the Company s consolidated financial statements. The requirement to provide detailed disclosures about the purchases, sales, issuances and settlements in the roll-forward activity for Level 3 fair value measurements is effective for the Company for interim and annual reporting periods beginning after December 31, 2010. The Company does not expect that the adoption of these new disclosure requirements will have a material impact on its consolidated financial statements.

In February 2010, the FASB issued an amendment to the accounting standards related to the accounting for, and disclosure of, subsequent events in an entity s consolidated financial statements. This standard amends the authoritative guidance for subsequent events that was previously issued and among other things exempts Securities

and Exchange Commission registrants from the requirement to disclose the date through which it has evaluated subsequent events for either original or restated financial statements. This standard does not apply to subsequent events or transactions that are within the scope of other applicable GAAP that provides different guidance on the accounting treatment for subsequent events or transactions. The adoption of this standard did not have a material impact on the Company s consolidated financial statements.

10. SUBSEQUENT EVENTS

On July 16, 2010, the Board of Directors of Cyclacel resolved, pursuant to the Certificate of Designations, not to declare the quarterly cash dividend on the Company s Preferred Stock, with respect to the second quarter of 2010 that would otherwise have been payable on August 1, 2010. . As the Company has not paid an aggregate amount equal to six quarterly dividends on the Preferred Stock, the size of the Company s Board has been increased by two members and the holders of the Preferred Stock, voting separately as a class, are entitled to vote to fill the two vacancies created thereby until the Company pays all accrued but unpaid dividends, at which time such right is terminated. The Company has received a request from a holder of at least 10% of the issued and outstanding Preferred Stock that the Company call a special meeting of the holders of Preferred Stock for the election of directors to fill the two vacancies.

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including, without limitation, Management s Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). We intend that the forward-looking statements be covered by the safe harbor for forward-looking statements in the Exchange Act. The forward-looking information is based on various factors and was derived using numerous assumptions. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. These forward-looking statements are usually accompanied by words such as believe, anticipate, plan, seek, expect, intend and similar expressions.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward looking statements due to a number of factors, including those set forth in Part I, Item 1A, entitled Risk Factors, of our Annual Report on Form 10-K for the year ended December 31, 2009, as amended, and updated and supplemented by Part II, Item 1A, entitled Risk Factors, appears elsewhere in this Quarterly Report. These factors as well as other cautionary statements made in this Quarterly Report on Form 10-Q, should be read and understood as being applicable to all related forward-looking statements wherever they appear herein. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our judgment as of the date hereof. We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements. In this report, Cyclacel, the Company, we, us, and our refer to Cyclacel Pharmaceuticals, Inc.

Overview

We are a development-stage biopharmaceutical company dedicated to the development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Our strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Clinical programs

Our clinical development priorities are focused on sapacitabine in the following indications:

- Acute myeloid leukemia, or AML in the elderly;
- Myelodysplastic syndromes, or MDS; and
- Non-small cell lung cancer or NSCLC.

The planning, execution and results of our clinical programs are significant factors that can affect our operating and financial results. In our sapacitabine clinical program we:

- continue to work with U.S. Food and Drug Administration, or FDA, in their review of the Special Protocol Assessment, or SPA, for a randomized Phase 3 study of sapacitabine in elderly patients with AML;

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reported in June 2010, at the American Society of Clinical Oncology, or ASCO, meeting interim response data for the ongoing Phase 2 clinical trial of sapacitabine in older patients with MDS. The study has recently completed enrollment of 61 patients aged 60 or older with MDS who were previously treated with azacitidine or decitabine or both. In this three-arm study Arms B & C enrolled 20 patients each while Arm A enrolled 21 patients across the same three dosing schedules of sapacitabine (Arms A, B and C) tested in the AML stratum of the study. All patients have received at least one hypomethylating agent and 15 patients (25%) have received two hypomethylating agents, i.e., azacitidine and decitabine. Approximately 51% of the 61 patients had baseline bone marrow blast counts above 10%. Based on interim data, the overall response rate is 24% on Arm A, the 7-day low dose schedule, 35% on Arm B, the 7-day high dose schedule, and 10% on Arm C, the 3-day high dose schedule. Two patients achieved complete remission and both were treated on Arm A. Thirty-day mortality from all-causes is 4.8% on Arm A, 0% on Arm B and 15% on Arm C. Approximately 34% of the patients received 4 or more cycles of sapacitabine; and

announced in June 2010 that FDA, granted orphan drug designation to our sapacitabine product candidate for the treatment of both AML and MDS.

We have additional clinical programs in development which are currently pending availability of clinical data. Once data become available and are reviewed, we will determine the feasibility of pursuing further development and/or partnering these assets, including sapacitabine in combination with seliciclib, seliciclib in NSCLC and nasopharyngeal cancer or NPC and CYC116.

Our pipeline and expertise in cell cycle biology

Our core area of expertise is in cell cycle biology and we focus primarily on the development of orally available anticancer agents that target the cell cycle with the aim of slowing the progression or shrinking the size of tumors, and enhancing the quality of life and improving survival rates of cancer patients. We are generating several families of anticancer drugs that act on the cell cycle including nucleoside analogues, cyclin dependent kinase or CDK inhibitors and Aurora kinase/Vascular Endothelial Growth Factor Receptor 2 or AK/VEGFR2 inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitor and AK inhibitor drugs, we believe that our drug candidates are differentiated in that they are orally available and interact with unique target profiles and mechanisms. For example we believe that our sapacitabine is the only orally available nucleoside analogue presently being tested in Phase 2 trials in AML and MDS and seliciclib is the most advanced orally available CDK inhibitor in Phase 2 trials. Although our resources are primarily directed towards advancing our anticancer drug candidate sapacitabine through in-house development activities we are also progressing, but with lower levels of investment than in previous years, our other novel drug series, which are at earlier stages. As a consequence of our focus on sapacitabine clinical development and related cost reduction program, research and development expenditures for the three months ended June 30, 2010 were reduced by $1.4 million, or 52%, to $1.3 million compared to $2.7 million for the three months ended June 30, 2009.

We have retained rights to commercialize our clinical development candidates and our business strategy is to enter into selective partnership arrangements with these programs.

Commercial products

We market directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. All three products are approved in the United States under FDA 510 (k) or medical device registrations. As described below under Results of Operations, during the three months ended June 30, 2009 and 2010, we recognized product revenue totaling $0.2 million and approximately $19,000, respectively. For the six months ended June 30, 2009 and 2010, we recognized revenue totaling $0.5 million and $0.3 million, respectively.

General

Our corporate headquarters is located in Berkeley Heights, New Jersey, with a research facility located in the United Kingdom.

From our inception in 1996 through June 30, 2010, we have devoted substantially all our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of June 30, 2010, our accumulated deficit during the development stage was approximately $275.3 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates. Our operating expenses comprise research and development expenses and selling and general and administrative expenses.

To date, we have not generated significant product revenue but have financed our operations and internal growth through private placements, licensing revenue, interest on investments, government grants and research and development tax credits. Prior to October 2007, our revenue consisted of collaboration and grant revenue. Beginning in 2008, we recognized revenue from sales of commercial products, for the first time, following the ALIGN acquisition in October 2007. We have recognized revenues from inception through June 30, 2010 totaling approximately $8.8 million of which approximately $2.0 million is derived from product sales, approximately $3.1 million from fees under collaborative agreements and approximately $3.7 million of grant revenue from various government grant awards.

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Recent Developments

During April 2010, we issued upon settlement an aggregate of 1,416,203 shares of our common stock to several of our stockholders in exchange for such stockholders delivery to us of an aggregate of 710,271 shares of our Preferred Stock. These transactions settled by April 23, 2010, after which time, a total of 1,213,142 shares of Preferred Stock remain outstanding. Each stockholder approached the Company with the proposed exchange transaction and the terms of the exchange were determined by arms-length negotiation between the parties. The preferred shareholders received approximately 1.1 million additional shares of common stock than what they would have been entitled to receive under the stated rate of exchange of one preferred share to 0.42553 of common share. The value of the additional shares issued has been considered a deemed dividend and reflected in the computation of earnings per share for the three and six-month periods ended June 30, 2010.

On April 27, 2010, we were served with a complaint filed by Celgene Corporation in the United States District Court for the District of Delaware seeking a Declaratory Judgment that four of our own patents, claiming the use of romidepsin injection in T-cell lymphomas, are invalid and not infringed by Celgene s products. The four patents cited in the complaint do not involve our clinical development candidates or our commercial products. On June 17, 2010, we filed our Answer and Counterclaims to the declaratory judgment complaint. We have filed counterclaims charging Celgene with infringement of each of our four patents and seeking damages for Celgene s infringement as well as injunctive relief. The four patents directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product. Given that our answer and counterclaims were only recently filed, the Company has not made an assessment at this time as to whether an adverse result would be probable, reasonably possible or remote. Any potential impact on the Company s financial position, results of operations or cash flows is not at this time expected to be material in view of the fact that the inventions of the patents are not utilized in the Company s products. Accordingly, an adverse result is expected to have only a minimal impact, if any, on the Company s financial position, results of operations or cash flows. Cyclacel intends to vigorously defend the validity of these patents and enforce its patent rights.

On May 17, 2010, we filed an amendment to our Form 10-K for the year ended December 31, 2009 in order to restate our annual consolidated financial statement for the period ended as of and for December 31, 2009 (the Financial Statements) to correct an error in the computation of the net loss per share and in the presentation of preferred dividends in our consolidated statements of cash flows. Although we had accrued for the unpaid dividends in its Financial Statements, we did not include the accrued amount when calculating basic and diluted loss per common share for the year ended December 31, 2009. As a result, the net loss per common share was revised from $0.88 per share, to $0.94 per share. For the three months ended June 30, 2009, the net loss per common share was revised from $0.34 per share to $0.36 per share. For the six months ended June 30, 2009, the net loss per common share was revised from $0.59 per share to $0.62 per share. The restatement had no effect on net cash flows, the reported net loss or the consolidated balance sheet. We also determined that the Financial Statements should not be relied upon and filed a Current Report on Form 8-K under item 4.02-Non-reliance on previously issued financial statements on May 13, 2010. On May 19, 2010, we filed Amendment No. 2 to our Annual Report on Form 10-K/A, pursuant to which we corrected the date of the report issued by our independent registered public accounting firm from May 14, 2010 to May 17, 2010, as such date appears in items 8 and 9T of such filing.

Subsequent Events

On July 16, 2010, the Board of Directors of Cyclacel resolved, pursuant to the Certificate of Designations, not to declare the quarterly cash dividend on our Preferred Stock, with respect to the second quarter of 2010 that would otherwise have been payable on August 1, 2010. As we have not paid an aggregate amount equal to six quarterly dividends on the Preferred Stock, the size of the our Board has been increased by two members and the holders of the Preferred Stock, voting separately as a class, are entitled to vote to fill the two vacancies created thereby until we pay all accrued but unpaid dividends, at which time such right is terminated. We have received a request from a holder of at least 10% of the issued and outstanding Preferred Stock that we call a special meeting of the holders of Preferred Stock for the election of directors to fill the two vacancies. To date, approximately $1.0 million of dividends remain accrued and unpaid.

Results of Operations

The results of operations for the three and six months ended June 30, 2009 and 2010 and balance sheet data as at December 31, 2009 and June 30, 2010 reflect the operations of us and our subsidiaries.

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Three Months Ended June 30, 2009 and 2010

Revenues

The following table summarizes the components of our revenues for the three months ended June 30, 2009 and 2010:

	Three months ended June 30,			
	2009	**2010**	**Difference**	**Difference**
		($000s)		**%**
Collaboration and research and development revenue		100	100	100
Product revenue	249	19	(230)	(92)
Grant revenue	17		(17)	(100)
Total revenue	266	119	(147)	(55)

Collaboration and research and development revenue in 2010 is derived from an agreement with a pharmaceutical company under which we provide one of our compounds for evaluation in the field of eye care.

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. During the three months ended June 30, 2009 and 2010, product sales were approximately $0.2 million and approximately $19,000, respectively. The decrease in product revenue in the second quarter of 2010 was due to a higher than anticipated amount of product returns, approximating $0.2 million, related to expiring product with a two-year shelf-life previously sold into the marketplace.

Grant revenue is recognized as we incur and pay for qualifying costs and services under the applicable grant. Grant revenue is primarily derived from various United Kingdom government grant awards. There was no grant revenue during the three months ending June 30, 2010 due to our programs not qualifying for these grant awards.

The future

We expect the ALIGN sales trend to approximate the first quarter 2010 levels during the remainder of the year. From the first quarter of 2010 our supplier has increased the product shelf-life to three-years to assist in the management of the product supply chain. We do not expect that grant revenue will increase as we focus our expenditure on the advancement of sapacitabine, which is currently waiting to advance into a Phase 3 clinical trial, and away from grant qualifying research expenditure.

Cost of goods sold

	Three months ended June 30,			
	2009	**2010**	**Difference**	**Difference**
		($000s)		**%**
Cost of goods sold	192	92	100	(52)

Total cost of sales represented 77% of product revenue for the three months ended June 30, 2009. For the three months ended June 30, 2010, costs of sales exceeded product revenue due to product returns.

Research and development expenses

To date, we have focused on drug discovery and development programs, with particular emphasis on orally available anticancer agents. Our research and development expenses have represented costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for sapacitabine, seliciclib, sapacitabine in combination with seliciclib, and CYC116. We have also incurred costs in the advancement of product candidates toward clinical and preclinical trials and the development of in-house research to advance our biomarker program and technology platforms. However, during 2008 and 2009, in response to changing market conditions, we extensively reduced or stopped expenditure on development and preclinical activities outside of our core focus on sapacitabine. The benefit of these cost reductions was realized in 2009 and will be also be realized in 2010. We expense all research and development costs as they are incurred. Research and development expenses primarily include:

clinical trial and regulatory-related costs;
payroll and personnel-related expenses, including consultants and contract research;

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preclinical studies and laboratory supplies and materials;
technology license costs; and
rent and facility expenses for our laboratories.

The following table provides information with respect to our research and development expenditure for the three months ended June 30, 2009 and 2010:

	Three months ended June 30,			
	2009	2010	Difference	Difference
		($000s)		%
Sapacitabine	1,585	1,186	(399)	(25)
Seliciclib	(164)	72	236	(144)
CYC116	9		(9)	(100)
Other research and development costs	1,253	64	(1,189)	(95)
Total research and development expenses	2,683	1,322	(1,361)	(51)

Total research and development expenses represented 49% and 29% of our operating expenses for the three months ended June 30, 2009 and 2010, respectively.

Research and development expenditure decreased by $1.4 million from $2.7 million for the three months ended June 30, 2009 to $1.3 million for the three months ended June 30, 2010. The reduction in costs of $1.4 million is primarily associated with the cost containment measures implemented in 2008 and 2009 which reduced headcount and focused resources on sapacitabine. Sapacitabine costs decreased by $0.4 million from $1.6 million for the three months ended June, 30, 2009 to $1.2 million for the three months ended June 30, 2010 as Phase 2 trials completed recruitment. For the three months ended June 30, 2010, $72,000 of costs incurred within the seliciclib program, relating primarily to study close out fees. During the three months to June 30, 2009, there was a net credit for the seliciclib program due to the reversal of accruals related to clinical trial costs of the APPRAISE trial. There were no costs incurred against the CYC116 program for the three months ended June 30, 2010 as this program has been placed on hold until more data is available. Other research and development costs were reduced by approximately $1.2 million from $1.3 million for the three months ended June 30, 2009 to $64,000 for three months ended June 30, 2010 due to the cost containment measures implemented in 2009.

The future

Following our reduction of expenditure in 2008 and 2009 in our non-core research and development programs, we have concentrated our resources on the development of sapacitabine in three indications. We anticipate that overall research and development expenditures in 2010 will be lower or similar to 2009 levels. We are in negotiation with the FDA for an SPA for a randomized Phase 3 registration study for sapacitabine in elderly patients with AML. We expect to begin a pivotal Phase 3 trial in that indication in 2010. Phase 3 clinical trials are time-consuming and expensive, and because we have limited resources, we may be required to collaborate with a third party or raise additional funds. However, there is no assurance that we will be able to do so.

Selling, general and administrative expenses

Selling, general and administrative expenses include costs for sales and marketing and administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the selling, general and administrative expenses for the three months ended June 30, 2009 and 2010:

	Three months ended June 30,			
	2009	2010	Difference	Difference
		($000s)		%
Total selling, general and administrative expenses	2,285	3,091	806	35

Total selling, general and administration expenses represented 41% and 69% of our operating expenses for the three months ended June 30, 2009 and 2010, respectively.

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Our selling, general and administrative expenditure increased by $0.8 million to $3.1 million for the three months ended June 30, 2010 from $2.3 million for the three months ended June 30, 2009. The increase of $0.8 million in expenses was primarily attributable to an increase in professional and consultancy fees of $0.5 million and legal cost of $0.2 million.

The future

We expect our selling, general and administrative expenditures in 2010 to remain at approximately the same levels for the balance of 2010.

Other income (expense)

The following table summarizes other income (expense) for the three months ended June 30, 2009 and 2010:

	Three months ended June 30,			
	2009	**2010**	**Difference**	**Difference**
		($000s)		**%**
Payment under guarantee	(1,652)		1,652	100
Change in valuation of warrants	(288)	273	561	195
Foreign exchange losses	(111)	(49)	62	56
Interest income	46	8	(38)	(83)
Interest expense	(13)	(9)	4	31
Total other income (expense)	(2,018)	223	2,241	(111)

Total other income and expense, net, increased by approximately $2.2 million to net income of $0.2 million for the three months ended June 30, 2010 from a net expense of $2.0 million for the three months ended June 30, 2009. The most significant impact was from the payment under guarantee to Scottish Enterprise, or SE, during the 3 months to June 30, 2009 and the change in the valuation of the warrant liability due to the significant increase in the company s share price as noted below.

The payment under guarantee which relates to SE during the second quarter of 2009 was a settlement of a liability which we incurred as a result of the headcount reductions in the Dundee facility which took place in that period. No liability arose during the three months ended June 30, 2010.

The change in valuation of warrants relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007. The warrants issued to the investors meet the requirements of and are being accounted for as a liability. The value of the warrants is being marked to market each reporting period as a derivative gain or loss until exercised or expiration. For the three months ended June 30, 2009 the change in the value of warrants was a loss of $0.3 million versus a gain of $0.3 million for the three months ended June 30, 2010.

For the three months ended June 30, 2009 there were foreign exchange charges of approximately $0.1 million recorded as compared a loss of approximately $49,000 for the three months ended June 30, 2010 on the consolidated statement of operations within the separate line item foreign exchange gains/(losses), within other income (expense).

Interest income decreased by approximately $38,000 from $46,000 for the three months to June 30, 2009 to $8,000 for the three months to June 30, 2010. This is a direct result from lower annualized returns from money market investments, following the reduction in interest rates.

Interest expense decreased by $4,000 from approximately $13,000 for the three months ended June 30, 2009 to $9,000 for the three months ended June 30, 2010. This reduction was due to the settlement during 2009 of license payments which were accruing interest expense and accretion costs on restructuring charges in respect of the lease of the Bothell facility.

The future

The valuation of the warrant liability will continue to be re-measured at the end of each reporting period. The valuation of the warrants is dependent upon many factors, including our stock price, interest rates and the remaining term of the instrument and may fluctuate significantly, which may have a significant impact on our statement of operations.

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Income tax benefit

Credit is taken for research and development tax credits, which are claimed from the United Kingdom s revenue and customs authority, or HMRC, in respect of qualifying research and development costs incurred.

The following table summarizes research and development tax credits for the three months ended June 30, 2009 and 2010:

	Three months ended June 30,			
	2009	**2010**	**Difference**	**Difference**
		($000s)		**%**
Total income tax benefit	233	230	(3)	(1)

Research and development tax credits recoverable remained at $0.2 million for each of the three months ended June 30, 2009 and 2010. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year, but restricted to payroll taxes paid by us in the United Kingdom in that same year.

The future

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so. However, as a result of the reduction in employee numbers the amount of payroll taxes payable in future periods will be lower than in previous periods, restricting available research and development tax credits to that lower amount.

Six Months Ended June 30, 2009 and 2010

Revenues

The following table summarizes the components of our revenues for the six months ended June 30, 2009 and 2010:

	Six months ended June 30,			
	2009	**2010**	**Difference**	**Difference**
		($000s)		**%**
Collaboration and research and development revenue		100	100	100
Product revenue	465	273	(192)	(41)
Grant revenue	29	16	(13)	(45)
Total revenue	494	389	(105)	(21)

Collaboration and research and development revenue in 2010 is derived from an agreement with a pharmaceutical company under which we provide one of our compounds for evaluation in the field of eye care.

Grant revenue is recognized as we incur and pay for qualifying costs and services under the applicable grant. Grant revenue is primarily derived from various United Kingdom government grant awards.

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. During the six months ended June 30, 2009 and 2010, we recorded sales of $0.5 million and $0.3 million, respectively. The decrease in product revenue in the second quarter of 2010 was due to a higher than anticipated amount of product returns approximating $0.2 million, related to expiring product with a two-year shelf-life previously sold into the marketplace. From the first quarter of 2010 our supplier has increased the product shelf-life to three-years to assist in the management of the product supply chain.

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Cost of goods sold

	Six months ended June 30,			
	2009	**2010**	**Difference**	**Difference**
		($000s)		**%**
Cost of goods sold	308	234	(74)	(24)

Total cost of sales represented 66% and 86% of product revenue for the six months ended June 30, 2009 and 2010, respectively. The increase in the cost of sales as a percentage of revenue in 2010 was due the lower product revenues as discussed above under Revenues for the three-months ended June 30, 2010.

Research and development expenses

The following table provides information with respect to our research and development expenditure for the six months ended June 30, 2009 and 2010:

	Six months ended June 30,			
	2009	**2010**	**Difference**	**Difference**
		($000s)		**%**
Sapacitabine	3,451	2,803	(648)	(19)
Seliciclib	103	133	30	29
CYC116	130	17	(113)	(87)
Other research and development costs	2,096	544	(1,552)	(74)
Total research and development expenses	5,780	3,497	(2,283)	(39)

Total research and development expenses represented 53% and 38% of our operating expenses for the six months ended June 30, 2009 and 2010, respectively.

Research and development expenditures decreased by $2.3 million from $5.8 million for the six months ended June 30, 2009 to $3.5 million for the six months ended June 30, 2010. Of the $2.3 million reduction in costs, $1.5 million is associated with the cost containment measures implemented 2009 which reduced headcount and focused resources on sapacitabine. Sapacitabine costs reduced by $0.7 million from $3.5 million for the three months ended June 30, 2009 to $2.8 million for the six months ending June 30, 2010. This was primarily due to cost of manufacturing in 2009 not required in 2010. The CYC116 program expenditures were lower by $0.1 million during the six months ended June 30, 2010 as compared to the same period in 2009 as this program is not currently being progressed.

Selling, general and administrative expenses

Selling, general and administrative expenses include costs for sales and marketing and administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the selling, general and administrative expenses for the six months ended June 30, 2009 and 2010:

	Six months ended June 30,			
	2009	**2010**	**Difference**	**Difference**
		($000s)		**%**
Total selling, general and administrative expenses	4,515	5,491	976	22

Total selling, general and administration expenses represented 41% and 60% of our operating expenses for each of the six months ended June 30, 2009 and 2010, respectively.

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Our selling, general and administrative expenditure increased by $1.0 million to $5.5 million for the six months ended June 30, 2010 from $4.5 million for the six months ended June 30, 2009. The increase of $1.0 million in expenses was primarily attributable to an increase in professional and consultancy costs.

Restructuring charge

As of June 30, 2010, the restructuring liability associated with exiting the Bothell facility was $0.5 million accounting for the estimated fair value of the remaining lease payments, net of estimated sub-lease income. The restructuring liability is subject to a variety of assumptions and estimates. We review these assumptions and estimates on a quarterly basis and will adjust the accrual if necessary. There was no change in the estimate for the six months ended June 30, 2010.

For the six months ended June 30, 2010, we recorded accretion expense associated with the Bothell restructuring lease of $0.1 million on the consolidated statement of operations as interest expense. A further $10,000 of accretion expense will be recognized over the remaining life of the lease to December 2010.

As a result of the continual review of our operating plan, in June 2009 additional actions were further implemented to the restructuring plan announced in September 2008. These actions reduced the workforce across all locations by an additional 26 people making a total reduction of 51 (or 63% of the workforce) since September 2008. An additional restructuring accrual of $0.4 million was recorded in connection with the severance payments liability during the second quarter of 2009.

Other income (expense)

Other income (expense) is comprised of the change in valuation of the derivative, change in value of liability classified warrants, interest income and interest expense. The following table summarizes the other income (expense) for the six months ended June 30, 2009 and 2010:

	Six months ended June 30,			
	2009	**2010**	**Difference**	**Difference**
		($000s)		**%**
Payment under guarantee	(1,652)		1,652	100
Change in valuation of warrants	(296)	(516)	220	74
Foreign exchange gains/(losses)	(248)	(38)	(210)	(85)
Interest income	92	17	(75)	(82)
Interest expense	(120)	(33)	(87)	(73)
Total other income (expense)	(2,224)	(570)	1,654	74

The payment under guarantee is payable to SE as a result of a reduction in the Company s research operations.

The change in valuation of warrants relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007. The warrants issued to the investors meet the requirements of and are being accounted for as a liability in accordance with ASC 815. The value of the warrants is being marked to market each reporting period as a derivative gain or loss until exercised or expiration. For the six months ended June 30, 2009 and 2010, we recognized the change in the value of warrants of approximately $0.3 million and $0.5 million, respectively as an expense within other income (expense) on the condensed consolidated statement of operations.

Interest income decreased by approximately $75,000 from $92,000 for the six months ended June 30, 2009 to approximately $17,000 million for the six months ended June 30, 2010. The decrease is primarily attributable to lower average balances of cash and cash equivalents and short-term investments in 2010 as compared to 2009.

Interest expense decreased by approximately $87,000 from $0.1 million for the six months ended June 30, 2009 to approximately $33,000 for the six months ended June 30, 2009. In May 2009, we paid our note payable to Sinclair earlier than the contractual terms resulting in only five months of interest. In May 2010, we paid the remaining note payable to Sinclair.

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Income tax benefit

Credit is taken for research and development tax credits, which are claimed from HMRC, in respect of qualifying research and development costs incurred.

The following table summarizes research and development tax credits for the six months ended June 30, 2009 and 2010:

	Six months ended June 30,			
	2009	2010	Difference	Difference
		($000s)		%
Total income tax benefit	591	363	(228)	(39)

Research and development tax credits recoverable decreased by $0.2 million from $0.6 million for the six months ended June 30, 2009 to $0.4 million for the six months ended June 30, 2010. The decrease was a reflection of decreased income taxes available for recovery as a consequence of the lower eligible research and development payroll expenses in 2010.

Liquidity and Capital Resources

The following is a summary of our key liquidity measures at December 31, 2009 and June 30, 2010:

	December 31, 2009	June 30, 2010	$ Difference	% Difference
		($000s)		
Cash and cash equivalents	$ 11,493	19,543	8,050	70
Current assets	13,369	21,507	8,138	61
Current liabilities	9,822	8,155	(1,667)	(17)
Working capital	3,547	13,352	9,805	276

At June 30, 2010, we had cash and cash equivalents of $19.5 million as compared to $11.5 million at December 31, 2009. The increased balance at June 30, 2010 was primarily due to the completion of two registered direct offerings in January 2010 for net proceeds of approximately $11.9 million, the issuing of 1.6 million common shares for approximately $3.1 million as part of the Kingsbridge CEFF drawdown and the exercise of warrants totaling $2.6 million during the two quarters of 2010. Since our inception, we have not generated any significant revenue and have relied primarily on the proceeds from sales of equity and preferred securities to finance our operations and internal growth. Additional funding has come through interest on investments, licensing revenue, government grants and research and development tax credits. We have incurred significant losses since our inception. As of June 30, 2010, we had an accumulated deficit of $234.2 million. We believe that existing funds together with cash generated from operations and recent financing activities are sufficient to satisfy our planned working capital, capital expenditures, debt service and other financial commitments for at least the next twelve months. Current business and capital market risks could have a detrimental affect on the availability of sources of funding and our ability to access them in the future which may delay or impede our progress of advancing our drugs currently in the clinic to approval by the FDA for commercialization.

Cash provided by (used in) operating, investing and financing activities

Cash provided by (used in) operating, investing and financing activities for the six months ended June 30, 2009 and 2010, is summarized as follows:

	Six months ended June 30,	
	2009	2010
	($000s)	

Net cash used in operating activities	(10,438)	(9,776)
Net cash provided by investing activities	1,505	27
Net cash (used in) provided by financing activities	(307)	17,855

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Operating activities

Net cash used in operating activities was $10.4 million and $9.8 million for the six months ended June 30, 2009 and 2010, respectively. Net cash used in operating activities during the six months ended June 30, 2010 of $9.8 million resulted from our net loss of $9.0 million, adjusted for material non-cash activities comprising amortization of investment premiums (discounts), change in valuation of liability-classified warrants, depreciation and amortization and non-cash stock based compensation expense, amounting to $1.5 million and a net increase in working capital of $2.3 million due to a decrease in prepaid expenses combined with a decrease in accounts payable and other current liabilities.

Investing activities

Net cash provided by investing activities for the six months ended June 30, 2009 and 2010 was $1.5 million and $27,000, respectively.

Financing activities

For the six months ended June 30, 2010, net cash provided by financing activities was $17.9 million. We completed two registered direct offerings in January 2010 for net proceeds of approximately $11.9 million, drew down from the Kingsbridge CEFF totaling approximately $3.1 million and had investors exercising warrants totaling $2.7 million.

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur substantial operating losses in the future. While we have generated modest product revenues from ALIGN product sales from October 2007 through June 30, 2010, we cannot guarantee that we will generate any significant product revenues until a product candidate has been approved by the FDA or similar regulatory agencies in other countries and successfully commercialized.

We currently anticipate that our cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. We can not be certain that any of our programs will be successful or that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in development, should they succeed. Additionally, we plan to continue to evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

Our future funding requirements will depend on many factors, including but not limited to:

- the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;
- the costs associated with establishing manufacturing and commercialization capabilities;
- the costs of acquiring or investing in businesses, product candidates and technologies;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the effect of competing technological and market developments; and
- the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. Although we are not reliant on institutional credit finance and therefore not subject to debt covenant compliance requirements or potential withdrawal of credit by banks, the current economic climate has also impacted the availability of funds and activity in equity markets. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or make changes to our operating plan similar to the revision made in September 2008 and June 2009. In addition, we may have to partner one or more of our product candidate programs at an earlier stage of development, which would lower the economic value of those programs to us.

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Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. We believe the judgments and estimates required by the following accounting policies to be critical in the preparation of our consolidated financial statements.

Revenue Recognition

Product sales

We have adopted the following revenue recognition policy related to the sales of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. We recognize revenue from these product sales when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed and determinable; and collectability is reasonably assured.

As we offer a general right of return on these product sales, we must consider the guidance in ASC 605, and ASC 605 10. Under these pronouncements, we account for all product sales using the sell-through method. Under the sell-through method, revenue is not recognized upon shipment of product to distributors. Instead, we record deferred revenue at gross invoice sales price and deferred cost of sales at the cost at which those goods were held in inventory. We recognize revenue when such inventory is sold through to the end user. To estimate product sold through to end users, we rely on third-party information, including information obtained from significant distributors with respect to their inventory levels and sell-through to customers.

Collaboration, research and development, and grant revenue

Certain of our revenues are earned from collaborative agreements. We recognize revenue when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed and determinable; and collectability is reasonably assured. Determination of whether these criteria have been met is based on management s judgments regarding the nature of the research performed, the substance of the milestones met relative to those we must still perform, and the collectability of any related fees. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

Research and development revenues, which are earned under agreements with third parties for contract research and development activities, are recorded as the related services are performed. Milestone payments are non-refundable and recognized as revenue when earned, as evidenced by achievement of the specified milestones and the absence of ongoing performance obligations. Any amounts received in advance of performance are recorded as deferred revenue. None of the revenues recognized to date are refundable if the relevant research effort is not successful.

Grant revenues from government agencies and private research foundations are recognized as the related qualified research and development costs are incurred, up to the limit of the prior approved funding amounts. Grant revenues are not refundable.

Stock-based Compensation

The Company grants stock options, restricted stock units and restricted stock to officers, employees, directors and consultants under the Company s 2006 Amended and Restated 2006 Equity Incentive Plan, which was amended and restated as of April 14, 2008. We also have outstanding options under various stock-based compensation plans for employees and directors.

ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of our common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, the anticipated exercise behavior of our employees, interest rates, and dividend yields. These variables are projected based

on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments.

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Such value is recognized as an expense over the requisite service period, net of estimated forfeitures, using the straight-line attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. In the second quarter of 2010, we adjusted forfeiture rates on certain awards granted in December 2006 from 8% to 0%, reflecting the increased likelihood that these remaining awards will vest in their entirety. During the quarter ended March 31, 2009, we revised the forfeiture rates because actual forfeiture rates were higher than that previously estimated primarily due to the lapsing of stock option grants on the termination of employees. The revision to past forfeiture estimates for the three months ended March 31, 2009 resulted in a reversal of stock-based compensation cost recognized in prior years with a consequent net gain of approximately $0.2 million on the consolidated statement of operations. During the second and third quarters of 2009, we reduced the scale of our operations, including a workforce reduction across all locations. As a result, we recorded an expense of approximately $0.4 million.

Warrants Liability

February 2007 Financing

ASC 815 requires freestanding contracts that are settled in our own stock, including common stock warrants to be designated as an equity instrument, asset or liability. Under the provisions of ASC 815, a contract designated as an asset or a liability must be carried at fair value until exercised or expired, with any changes in fair value recorded in the results of operations. A contract designated as an equity instrument must be included within equity, and no subsequent fair value adjustments are required. We review the classification of the contracts at each balance sheet date. Pursuant to ASC 815, since we are unable to control all the events or actions necessary to settle the warrants in registered shares the warrants have been recorded as a current liability at fair value. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the consolidated statements of operations. For the three months ended June 30, 2010, we recognized the change in the value of warrants of approximately $0.3 million, as a gain on the consolidated statement of operations as compared to a $0.3 million loss for the three months ended June 30, 2009. For the six months ended June 30, 2009 and 2010, we recognized the change in the value of warrants of approximately $0.3 million and $0.5 million, respectively, as a loss on the consolidated statement of operations. Fair value is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrants liability.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to fluctuations in foreign currency exchange rates, interest rates and investment credit ratings.

Investment and Interest Rate Risk

Financial instruments which potentially subject us to interest rate risk consist principally of cash and cash equivalents and short-term investments. At June 30, 2010, our cash and cash equivalents of $19.5 million are primarily invested in highly liquid money market accounts, and commercial paper, which had original maturities at the time of acquisition of 90 days or less. .

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. Pursuant to our investment guidelines, all investments in commercial paper and corporate bonds of financial institutions and corporations are rated A or better by both Moody s and Standard and Poor s, no one individual security shall have a maturity of greater than 18 months and investments in any one corporation is restricted to 5% of the total portfolio. To minimize our exposure to adverse shifts in interest rates, we invest in short-term instruments and at June 30, 2010 we held no investments with a maturity in excess of one year. Due to the short-term nature of our investments, portfolio diversification, and our investment policy we believe that our exposure to market interest rate fluctuations is minimal, liquidity is maintained and we do not have a material financial market risk exposure.

A hypothetical 10% change in short-term interest rates from those in effect at June 30, 2010 would not have a significant impact on our financial position or our expected results of operations, however we may continue to have risk exposure to our holdings in cash, money market accounts and cash equivalents, which may adversely impact the fair value of our holdings. As of June 30, 2010, there were no indicators of credit risk impact to the valuation of our cash, cash equivalents or short term investments. We do not currently hold any derivative financial instruments with interest rate risk.

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Foreign Currency Risk

We are exposed to foreign currency rate fluctuations related to the operation of our subsidiary in the United Kingdom. At the end of each reporting period, income and expenses of the subsidiary are translated into United States dollars using the average currency rate in effect for the period and assets and liabilities are translated into United States dollars using the exchange rate in effect at the end of the period (or the historical rate for equity transactions).

In conjunction with the operational review conducted by us in September 2008, the nature of intercompany funding was considered. It was concluded that as repayment of intercompany loans between our United States and United Kingdom operations is not expected in the foreseeable future, the nature of the funding advanced was of a long-term investment nature and that the terms of the loans should be amended to reflect this. Effective October 1, 2008, intercompany loans ceased to be repayable on demand and have no fixed repayment date. As a result of the change in repayment terms, from October 1, 2008 all unrealized foreign exchange gains or losses arising on intercompany loans are recognized in other comprehensive income. This accounting will potentially result in significant volatility in our consolidated shareholders equity.

We currently do not engage in foreign currency hedging. We enter into certain transactions denominated in foreign currencies in respect of underlying operations and, therefore, we are subject to currency exchange risks. During the six months ended June 30, 2009 and 2010, we realized losses of $0.2 million and gains of approximately $38,000 on such transactions, respectively. Other differences on foreign currency translation arising on consolidation of $4.0 million are also recorded as a movement in other comprehensive income.

Common Stock Price Risk

In February 2007, we issued common stock and warrants. Pursuant to ASC 840, we recorded the fair value of the warrants as a current liability. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the condensed consolidated statements of operations. For the three months ended June 30, 2010, we recognized the change in the value of warrants of approximately $0.3 million, as a gain on the consolidated statement of operations as compared to a $0.3 million loss for the three months ended June 30, 2009. For the six months ended June 30, 2009 and 2010, we recognized the change in the value of warrants of approximately $0.3 million and $0.5 million, respectively, as a loss on the consolidated statement of operations. Fair value of the derivative instruments will be affected by estimates of various factors that may affect the respective instrument, including our stock price, the risk free rate of return and expected volatility in the fair value of our stock price. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

In December 2007 and amended in November 2009, we entered into a CEFF with Kingsbridge, in which Kingsbridge committed to provide us up to $60 million of capital during the next three years. We may access capital under the CEFF in tranches, with each tranche being issued and priced over an eight-day pricing period. Kingsbridge will purchase shares of common stock pursuant to the CEFF at discounts ranging from 10% to 20% depending on the average market price of the common stock during the eight-day pricing period, provided that the minimum acceptable purchase price for any shares to be issued to Kingsbridge during the eight-day period is determined by the higher of $0.40 or 85% of our common stock closing price the day before the commencement of each draw down. The lower the price per share of our common stock will result in a higher discount given to Kingsbridge each draw down resulting in less proceeds to us. Since inception through June 30, 2010, we sold an aggregate of 2,818,232 shares of our common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of $4.1 million in funds received by us.

Item 4T. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness, as of June 30, 2010, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. The purpose of this evaluation was to determine whether as of the evaluation date our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded,

processed, summarized and reported within the time periods specified in the SEC s rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, management has concluded that as of June 30, 2010, our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weaknesses in our internal controls described in Amendments No. 1 and 2 to our Annual Report on Form 10-K filed on March 29, 2010, filed on May 17, 2010 and May 19, 2010, respectively, in the section captioned Item 9T Controls and Procedures Management s Annual Report on Internal Control Over Financial Reporting that remain present.

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Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than those described below.

In the Company s Annual Report on Form 10-K for the year ended December 31, 2009, filed on March 29, 2010, management concluded that our internal control over financial reporting was effective as of December 31, 2009. Subsequently, our management identified a deficiency in respect of our internal control over financial reporting, specifically in our controls over the computation of net loss per share and the financial statement presentation of our preferred stock dividends in the statement of cash flows that constitutes a material weakness as described in SEC s guidance regarding Management s Report on Internal Control Over Financial Reporting as of December 31, 2009. As a result of this deficiency, the financial statements included in Form 10-K for the year ended December 31, 2009, included errors related to the presentation and disclosure of our preferred stock dividends in the net loss per share disclosure and in the statement of cash flows. As a result of this material weakness, management concluded that we did not maintain effective internal control over financial reporting as of December 31, 2009, based on the criteria established in *Internal Control Integrated Framework,* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

To remediate the material weakness in our internal control over financial reporting as described above, management is enhancing its controls over financial statement presentation and disclosures in this area, specifically by adding additional review procedures over the Company s computation of net loss per share and in the presentation and disclosure of preferred stock dividends in the statement of cash flows. We anticipate that the actions described above will remediate the December 31, 2009 material weakness. The material weakness will only be considered remediated when the revised internal controls are operational for a period of time and are tested and management has concluded that the controls are operating effectively.

Inherent Limitation on the Effectiveness of Internal Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

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PART II. Other Information

Item 1. Legal proceedings

On April 27, 2010, we were served with a complaint filed by Celgene Corporation in the United States District Court for the District of Delaware seeking a declaratory judgment that four of our own patents, claiming the use of romidepsin injection in T-cell lymphomas, are invalid and not infringed by Celgene s products, but directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product. On June 17, 2010, we filed our answer and counterclaims to the declaratory judgment complaint. We have filed counterclaims charging Celgene with infringement of each of our four patents and seeking damages for Celgene s infringement as well as injunctive relief. The four patents directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product.

Item 1A. Risk Factors

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2009, as amended. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed above in Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this Quarterly Report on Form 10-Q. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

We believe regulatory agencies will not accept registration pathways based on Phase 2 data and, therefore, we will need to conduct randomized Phase 3 studies, which are time-consuming and expensive.

Regulatory agencies, including, but not limited to, the FDA, have in certain instances accepted Phase 2 data from uncontrolled studies as sufficient for approval in indications where an unmet medical need exists or in exceptional circumstances. Recently, however, the Oncologic Drugs Advisory Committee (ODAC), which is the cancer drug advisory panel of the FDA, voted in favor of completion of a randomized trial prior to regulatory approval with respect to drugs submitted for approval as treatments for patients with AML and likely in respect of drugs submitted for approval as treatments for patients with other forms of cancer. Therefore, we believe that to gain regulatory approval from the FDA, we will need to conduct a randomized Phase 3 trial. Randomized Phase 3 studies are time-consuming and expensive, and because we have limited resources any such requirements may adversely impact our operating results and financial condition and delay or block our ability to commercialize our lead drug candidates.

Even if we believe that the data collected from clinical trials of our drug candidates are promising with respect to safety and efficacy, such data may not be deemed sufficient by regulatory authorities to warrant product approval. Clinical data can be interpreted in different ways. Regulatory officials could interpret such data in different ways than we do which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our lead drug candidates, or in receiving regulatory approval for the commercialization of our lead drug candidates, may adversely affect our business.

The current economic conditions and financial market turmoil could adversely affect our business and results of operations.

Economic conditions remain difficult with the continuing uncertainty in the global credit markets, the financial services industry and the United States capital markets and with the United States economy as a whole experiencing a period of substantial turmoil and uncertainty characterized by unprecedented intervention by the United States federal government and the failure, bankruptcy, or sale of various financial and other institutions. We believe the current economic conditions and financial market turmoil could adversely affect our operations, business and prospects, as well as our ability to obtain funds and manage our liquidity. If these circumstances persist or continue to worsen, our future operating results could be adversely affected, particularly relative to our current expectations.

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We are at an early stage of development as a company and we do not have, and may never have, any products that generate significant revenues.

We are at an early stage of development as a company and have a limited operating history on which to evaluate our business and prospects. While we have earned modest product revenues from the ALIGN business acquired in October 2007, since beginning operations in 1996, we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products and we do not anticipate material revenues from the ALIGN products in the foreseeable future. We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA, and other regulatory authorities in the United States, the European Union and elsewhere. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. Sapacitabine and seliciclib, our most advanced drug candidates for the treatment of cancer, are currently our only drug candidates in Phase 2 clinical trials. A combination trial of sapacitabine and seliciclib and CYC116 are currently in a Phase 1 clinical trial. We have been in ongoing dialogue with the FDA regarding our special protocol assessment, or SPA, request for randomized, registration directed, Phase 3 study of sapacitabine in elderly patients with acute myeloid leukemia, or AML. While the FDA has accepted our proposed primary endpoint of overall survival and key design components as being eligible for SPA, there is no assurance that our process with the FDA will reach a successful conclusion. If it does not, we will have to revise several of our corporate plans. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

We have a history of operating losses and we may never become profitable. Our stock is a highly speculative investment.

We have incurred operating losses in each year since beginning operations in 1996 due to costs incurred in connection with our research and development activities and selling, general and administrative costs associated with our operations, and we may never achieve profitability. As of June 30, 2010, our accumulated deficit was $234.2 million. Our net loss for each of the three months ended June 30, 2009 and 2010 was $7.0 million and $3.9 million. Our net loss for each of the six months ended June 30, 2009 and 2010 was $12.1 million and $9.0 million. Our net loss applicable to common shareholders from inception through June 30, 2010 was $275.3 million. Our drug candidates are in the mid-stages of clinical testing and we must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of our drugs. We expect to incur continued losses for several years, as we continue our research and development of our drug candidates, seek regulatory approvals, commercialize any approved drugs and market and promote the ALIGN products: Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. If our drug candidates are unsuccessful in clinical trials or we are unable to obtain regulatory approvals, or if our drugs are unsuccessful in the market, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, particularly in light of the current economic conditions, you could lose all or part of your investment.

Capital markets are currently experiencing a period of disruption and instability, which has had and could continue to have a negative impact on the availability and cost of capital.

The general disruption in the United States capital markets has impacted the broader worldwide financial and credit markets and reduced the availability of debt and equity capital for the market as a whole. These global conditions could persist for a prolonged period of time or worsen in the future. Our ability to access the capital markets may be restricted at a time when we would like, or need, to access those markets, which could have an impact on our flexibility to react to changing economic and business conditions. The resulting lack of available credit, lack of confidence in the financial sector, increased volatility in the financial markets could materially and adversely affect

the cost of debt financing and the proceeds of equity financing may be materially adversely impacted by these market conditions.

If we fail to comply with the continued listing requirements of the NASDAQ Global Market our common stock price may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed for trading on the NASDAQ Global Market. We must satisfy NASDAQ s continued listing requirements, including among other things, a minimum stockholders equity of $10.0 million and a minimum bid price for our common stock of $1.00 per share, or risk delisting, which would have a material adverse affect on our business. A delisting of our common stock from the NASDAQ Global Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. During 2009, Cyclacel received notification from the NASDAQ Stock Market that the Company was not in compliance with the minimum $10 million stockholders equity requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(b)(1)(A). On January 27, 2010, NASDAQ notified the Company that it regained compliance with the minimum $50 million market value of listed securities requirement and that it currently complies with all other applicable standards for continued listing on The NASDAQ Global Market. Accordingly, the Company s shares of common and preferred stock will continue to trade on The NASDAQ Global Market.

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Raising additional capital in the future may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing stockholders would experience further dilution. If we fail to obtain additional funding, we may be unable to complete the development and commercialization of our lead drug candidate, sapacitabine, or continue to fund our research and development programs.

We have funded all of our operations and capital expenditures with proceeds from the issuance of public equity securities, private placements of our securities, interest on investments, licensing revenue, government grants, research and development tax credits and product revenue. In order to conduct the lengthy and expensive research, preclinical testing and clinical trials necessary to complete the development and marketing of our drug candidates, we will require substantial additional funds. Based on our current operating plans of focusing on the advancement of sapacitabine, we expect our existing resources to be sufficient to fund our planned operations for at least the next twelve months. To meet our long-term financing requirements, we may raise funds through public or private equity offerings, debt financings or strategic alliances. Raising additional funds by issuing equity or convertible debt securities may cause our stockholders to experience substantial dilution in their ownership interests and new investors may have rights superior to the rights of our other stockholders. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities and options. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights to our drug discovery and other technologies, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. Additional funding may not be available to us on favorable terms, or at all, particularly in light of the current economic conditions. If we are unable to obtain additional funds, we may be forced to delay or terminate our current clinical trials and the development and marketing of our drug candidates including sapacitabine.

Our committed equity financing facility with Kingsbridge may not be available to us if we elect to make a draw down or may require us to make additional blackout or other payments to Kingsbridge, which may result in dilution to our stockholders.

On December 10, 2007 and as amended on November 24, 2009, we entered into the committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge. The CEFF entitles us to sell and obligates Kingsbridge to purchase from us the lesser of 4,084,590 shares of our common stock or $60 million of our common stock, during the three years term of the CEFF, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include, among other things, a minimum price for our common stock of $0.40 per share, effectiveness of the registration statement covering the shares subject to the CEFF and the continued listing of our stock on The NASDAQ Global Market.

Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 days from the date Kingsbridge provides us notice of such material and adverse event. In such a case, we would be unable to access any capital through the CEFF.

We are entitled, in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement which became effective in December 2007, and prohibit Kingsbridge from selling shares. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement is not effective in circumstances not permitted by the CEFF, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of the number of shares held by Kingsbridge exclusive of shares that Kingsbridge may hold pursuant to exercise of the Kingsbridge warrant and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout or other payment to be made by us could be significant.

Should we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effective on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to 20% from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share

price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price. During December 2009 and January 2010, we sold an aggregate of 1,583,626 shares of our common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of $1.3 million in funds drawn down from the CEFF by us. During March 2010, we sold another 1,234,606 shares of our common stock to Kingsbridge in consideration of an aggregate of $2.8 million in funds drawn down from the CEFF by us. Any additional sales of shares of our common stock to Kingsbridge under the CEFF will result in further dilution to our stockholders.

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To the extent we elect to fund the development of a drug candidate or the commercialization of a drug at our expense, we will need substantial additional funding.

We plan to market drugs on our own, with or without a partner, that can be effectively commercialized and sold in concentrated markets that do not require a large sales force to be competitive. To achieve this goal, we will need to establish our own specialized sales force, marketing organization and supporting distribution capabilities. The development and commercialization of our drug candidates is very expensive, including our anticipated Phase 3 clinical trials for sapacitabine. To the extent we elect to fund the full development of a drug candidate or the commercialization of a drug at our expense, we will need to raise substantial additional funding to:

- fund research and development and clinical trials connected with our research;
- fund clinical trials and seek regulatory approvals;
- build or access manufacturing and commercialization capabilities;
- implement additional internal control systems and infrastructure;
- commercialize and secure coverage, payment and reimbursement of our drug candidates, if any such candidates receive regulatory approval;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional management, sales and scientific personnel.

Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs associated with establishing sales and marketing capabilities;
- the effect of competing technological and market developments; and
- the payment, other terms and timing of any strategic alliance, licensing or other arrangements that we may establish.

If we are not able to secure additional funding when needed, especially in light of the current economic conditions and financial market turmoil, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or future commercialization efforts.

If we do not realize the expected benefits from the restructuring plans we announced in September 2008 and June 2009, our operating results and financial conditions could be negatively impacted.

In September 2008 and June 2009, we announced a strategic restructuring designed to focus our resources on our lead drug, sapacitabine, while maintaining the Company s core competency in drug discovery and cell cycle biology. We cannot guarantee that we will not have to undertake additional restructuring activities, that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our restructuring. If we are unable to realize the expected operational efficiencies from our restructuring activities, our operating results and financial condition could be adversely affected.

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Any future workforce and expense reductions may have an adverse impact on our internal programs, strategic plans, and our ability to hire and retain key personnel, and may also be distracting to our management.

Further workforce and expense reductions in addition to those carried out in September 2008 and June 2009 could result in significant delays in implementing our strategic plans. In addition, employees, whether or not directly affected by such reduction, may seek future employment with our business partners or competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidential nature of certain proprietary information may not be maintained in the course of any such future employment. In addition, any additional workforce reductions or restructurings would be expected to involve significant expense as a result of contractual terms in certain of our existing agreements, including potential severance obligations as well as any payments that may, under certain circumstances, be required under our agreement with the Scottish Enterprise. Further, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled personnel. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce and expense reductions. Finally, the implementation of expense reduction programs may result in the diversion of the time and attention of our executive management team and other key employees, which could adversely affect our business.

Budget constraints resulting from our restructuring plan may negatively impact our research and development, forcing us to delay our efforts to develop certain product candidates in favor of developing others, which may prevent us from commercializing our product candidates as quickly as possible.

Research and development is an expensive process. As part of our restructuring plan, we have decided to focus our clinical development priorities on sapacitabine, while still possibly continuing to progress additional programs pending the availability of clinical data and the availability of funds, at which time we will determine the feasibility of pursuing, if at all, further advanced development of seliciclib, CYC116 or additional programs. Because we have had to prioritize our development candidates as a result of budget constraints, we may not be able to fully realize the value of our product candidates in a timely manner, if at all.

If we fail to enter into and maintain successful strategic alliances for our drug candidates, we may have to reduce or delay our drug candidate development or increase our expenditures.

An important element of our strategy for developing, manufacturing and commercializing our drug candidates is entering into strategic alliances with pharmaceutical companies or other industry participants to advance our programs and enable us to maintain our financial and operational capacity.

We face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. In addition, these alliances may be unsuccessful. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our drug development or research programs. If we elect to fund drug development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

We are exposed to risks related to foreign currency exchange rates.

Some of our costs and expenses are denominated in foreign currencies. Most of our foreign expenses are associated with our research and development operations of our United Kingdom-based wholly-owned subsidiary. When the United States dollar weakens against the British pound, the United States dollar value of the foreign currency denominated expense increases, and when the United States dollar strengthens against the British pound, the United States dollar value of the foreign currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations.

We are exposed to risk related to the marketable securities we may purchase.

We may invest cash not required to meet short term obligations in short term marketable securities. We may purchase securities in United States government, government-sponsored agencies and highly rated corporate and asset-backed securities subject to an approved investment policy. Historically, investment in these securities has been highly liquid and has experienced only very limited defaults. However, recent volatility in the financial markets has created additional uncertainty regarding the liquidity and safety of these investments. Although we believe our marketable securities investments are safe and highly liquid, we cannot guarantee that our investment portfolio will not be

negatively impacted by recent or future market volatility or credit restrictions.

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Clinical trials are expensive, time consuming, subject to delay and may be required to continue beyond our available funding.

Clinical trials are expensive, complex can take many years to conduct and may have uncertain outcomes. We estimate that clinical trials of our most advanced drug candidates may be required to continue beyond our available funding and may take several years more to complete. The designs used in some of our trials have not been used widely by other pharmaceutical companies. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future drug candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for our clinical trials;
- delays in obtaining institutional review board, or IRB, and other regulatory approvals to commence a clinical trial;
- slower than anticipated rates of patient recruitment and enrollment, or reaching the targeted number of patients because of competition for patients from other trials or other reasons;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues may or may not be related to suboptimal pharmacokinetic and pharmacodynamic behaviors;
- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unavailability of clinical trial supplies.

If we suffer any significant delays, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue development of our drug candidates or generate revenue and our development costs could increase significantly.

Adverse events have been observed in our clinical trials and may force us to stop development of our product candidates or prevent regulatory approval of our product candidates.

Adverse or inconclusive results from our clinical trials may substantially delay, or halt entirely, any further development of our drug candidates. Many companies have failed to demonstrate the safety or effectiveness of drug candidates in later stage clinical trials notwithstanding favorable results in early stage clinical trials. Previously unforeseen and unacceptable side effects could interrupt, delay or halt clinical trials of our drug candidates and could result in the FDA or other regulatory authorities denying approval of our drug candidates. We will need to demonstrate safety and efficacy for specific indications of use, and monitor safety and compliance with clinical trial protocols throughout the development process. To date, long-term safety and efficacy has not been demonstrated in clinical trials for any of our drug candidates. Toxicity and serious adverse events as defined in trial protocols have been noted in preclinical and clinical trials involving certain of our drug candidates. For example, neutropenia and gastro-intestinal toxicity were observed in patients receiving sapacitabine and elevations of liver enzymes and decrease in potassium levels have been observed in patients receiving seliciclib.

In addition, we may pursue clinical trials for sapacitabine and seliciclib in more than one indication. There is a risk that severe toxicity observed in a trial for one indication could result in the delay or suspension of all trials involving the same drug candidate. Even if we believe the data collected from clinical trials of our drug candidates are promising with respect to safety and efficacy, such data may not be deemed sufficient by regulatory authorities to warrant product approval. Clinical data can be interpreted in different ways. Regulatory officials could interpret such data in different ways than we do which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our drug candidates, or in receiving regulatory approval for the commercialization of our drug

candidates, may severely harm our business and reputation.

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If our understanding of the role played by CDKs or AKs in regulating the cell cycle is incorrect, this may hinder pursuit of our clinical and regulatory strategy.

Our development of small molecule inhibitors of CDK and AK is based on our understanding of the mechanisms of action of CDK and AK inhibitors and their interaction with other cellular mechanisms. One of our drug candidates, seliciclib, is a CDK inhibitor, and CYC116 is an AK and VEGFR2 inhibitor. Although a number of pharmaceutical and biotechnology companies are attempting to develop CDK or AK inhibitor drugs for the treatment of cancer, no CDK or AK inhibitor has yet reached the market. If our understanding of the role played by CDK or AK inhibitors in regulating the cell cycle is incorrect, seliciclib and/or CYC116 may fail to produce therapeutically relevant results hindering our ability to pursue our clinical and regulatory strategy.

We are making use of biomarkers, which are not scientifically validated, and our reliance on biomarker data may thus lead us to direct our resources inefficiently.

We are making use of biomarkers in an effort to facilitate our drug development and to optimize our clinical trials. Biomarkers are proteins or other substances whose presence in the blood can serve as an indicator of specific cell processes. We believe that these biological markers serve a useful purpose in helping us to evaluate whether our drug candidates are having their intended effects through their assumed mechanisms, and thus enable us to identify more promising drug candidates at an early stage and to direct our resources efficiently. We also believe that biomarkers may eventually allow us to improve patient selection in connection with clinical trials and monitor patient compliance with trial protocols.

For most purposes, however, biomarkers have not been scientifically validated. If our understanding and use of biomarkers is inaccurate or flawed, or if our reliance on them is otherwise misplaced, then we will not only fail to realize any benefits from using biomarkers, but may also be led to invest time and financial resources inefficiently in attempting to develop inappropriate drug candidates. Moreover, although the FDA has issued for comment a draft guidance document on the potential use of biomarker data in clinical development, such data are not currently accepted by the FDA or other regulatory agencies in the United States, the European Union or elsewhere in applications for regulatory approval of drug candidates and there is no guarantee that such data will ever be accepted by the relevant authorities in this connection. Our biomarker data should not be interpreted as evidence of efficacy.

Due to our reliance on contract research organizations or other third parties to conduct clinical trials, we may be unable to directly control the timing, conduct and expense of our clinical trials.

We do not have the ability to independently conduct clinical trials required to obtain regulatory approvals for our drug candidates. We must rely on third parties, such as contract research organizations, data management companies, contract clinical research associates, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to assist with our preclinical development of drug candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates.

To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

Although we are not currently party to any collaboration arrangement or strategic alliance that is material to our business, in the future we expect to be dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our drug candidates particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our drug candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

We may be unable to locate and enter into favorable agreements with third parties, which could delay or impair our ability to develop and commercialize our drug candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;
our collaborators may experience financial difficulties;

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we may be required to relinquish important rights such as marketing and distribution rights; business combinations or significant changes in a collaborator s business strategy may also adversely affect a collaborator s willingness or ability to complete our obligations under any arrangement;

a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and

collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

We have no manufacturing capacity and will rely on third party manufacturers for the late stage development and commercialization of any drugs or devices we may develop or sell.

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates under development or our currently marketed ALIGN products. We currently lack the resources or the capacity to manufacture any of our products on a clinical or commercial scale. We depend upon a third party, Sinclair, to manufacture the commercial products sold by our ALIGN subsidiary and we can not rely upon Sinclair to continue to supply the products. We anticipate future reliance on a limited number of third party manufacturers until we are able, or decide to, expand our operations to include manufacturing capacities. Any performance failure on the part of manufacturers could delay late stage clinical development or regulatory approval of our drug, the commercialization of our drugs or our ability to sell our commercial products, producing additional losses and depriving us of potential product revenues.

If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities and will be required to secure alternative third-party suppliers to our current suppliers. To date, our drug candidates have been manufactured in small quantities for preclinical testing and clinical trials and we may not be able to successfully increase the manufacturing capacity, whether in collaboration with our current or future third-party manufacturers or on our own, for any of our drug candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA and other regulatory bodies must review and approve. If we are unable to successfully increase the manufacturing capacity for a drug candidate whether for late stage clinical trials or for commercial sale or are unable to secure alternative third-party suppliers to our current suppliers, the drug development, regulatory approval or commercial launch of any related drugs may be delayed or blocked or there may be a shortage in supply. Even if any third party manufacturer makes improvements in the manufacturing process for our drug candidates, we may not own, or may have to share, the intellectual property rights to such innovation.

As we evolve from a company primarily involved in discovery and development to one also involved in the commercialization of drugs and devices, we may encounter difficulties in managing our growth and expanding our operations successfully.

In order to execute our business strategy, we will need to expand our development, control and regulatory capabilities and develop financial, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Our ability to manage our operations and any growth will require us to make appropriate changes and upgrades, as necessary, to our operational, financial and management controls, reporting systems and procedures wherever we may operate. Any inability to manage growth could delay the execution of our business plan or disrupt our operations.

The failure to attract and retain skilled personnel and key relationships could impair our drug development and commercialization efforts.

We are highly dependent on our senior management and key scientific, technical and sales and marketing personnel. Competition for these types of personnel is intense. The loss of the services of any member of our senior management, scientific, technical or sales or marketing staff may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on our business, operating results and financial condition. We also rely on consultants and advisors to assist us in formulating our strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us. The success of the commercialization of the ALIGN products depends, in large part, on our

continued ability to develop and maintain important relationships with distributors and research and medical institutions. Failure to do that could have a material adverse effect on our ability to commercialize the ALIGN products.

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We intend to expand and develop new drug candidates. We will need to hire additional employees in order to continue our clinical trials and market our drug candidates and medical devices. This strategy will require us to recruit additional executive management and scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. The inability to attract and retain sufficient scientific, technical and managerial personnel could limit or delay our product development efforts, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

Our drug candidates are subject to extensive regulation, which can be costly and time-consuming, and we may not obtain approvals for the commercialization of any of our drug candidates.

The clinical development, manufacturing, selling and marketing of our drug candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States, the European Union and elsewhere. These regulations also vary in important, meaningful ways from country to country. We are not permitted to market a potential drug in the United States until we receive approval of an NDA from the FDA. We have not received an NDA approval from the FDA for any of our drug candidates.

Obtaining an NDA approval is expensive and is a complex, lengthy and uncertain process. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an Investigational New Drug, or IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are the pivotal or suitable for registration late Phase 2 or Phase 3 clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, an NDA may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In addition, failure to comply with the FDA and other applicable foreign and U.S. regulatory requirements may subject us to administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve either pending NDAs, or supplements to approved NDAs.

Despite the substantial time and expense invested in preparation and submission of an NDA or equivalents in other jurisdictions, regulatory approval is never guaranteed. The FDA and other regulatory authorities in the United States, the European Union and elsewhere exercise substantial discretion in the drug approval process. The number, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the drug candidate, the disease or condition for which the drug candidate is intended to be used and the regulations and guidance documents applicable to any particular drug candidate. The FDA or other regulators can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to:

- those discussed in the risk factor which immediately follows;
- the fact that the FDA or other regulatory officials may not approve our or our third party manufacturer s processes or facilities; or
- the fact that new regulations may be enacted by the FDA or other regulators may change their approval policies or adoption of new regulations requiring new or different evidence of safety and efficacy for the intended use of a drug candidate.

With regard to the ALIGN products, and following regulatory approval of any of our drug candidates, we are subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential products.

With regard to our ALIGN products and our drug candidates, if any, approved by the FDA or by another regulatory authority, we are held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or

to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the product or drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug or device, and could include withdrawal of the drug or device from the market.

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In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

Our applications for regulatory approval could be delayed or denied due to problems with studies conducted before we in-licensed the rights to some of our product candidates.

We currently license some of the compounds and drug candidates used in our research programs from third parties. These include sapacitabine which was licensed from Daiichi-Sankyo. Our present research involving these compounds relies upon previous research conducted by third parties over whom we had no control and before we in-licensed the drug candidates. In order to receive regulatory approval of a drug candidate, we must present all relevant data and information obtained during our research and development, including research conducted prior to our licensure of the drug candidate. Although we are not currently aware of any such problems, any problems that emerge with preclinical research and testing conducted prior to our in-licensing may affect future results or our ability to document prior research and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our drug candidates.

We face intense competition and our competitors may develop drugs that are less expensive, safer, or more effective than our drug candidates.

A large number of drug candidates are in development for the treatment of leukemia, lung cancer, lymphomas and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs or other products on the market or in clinical trials which may be competitive to sapacitabine in both hematological and oncology indications. These include Celgene, Cephalon, Eisai, Johnson & Johnson, Eli Lilly, Genzyme, GlaxoSmithKline, Hospira, Pfizer, Seattle Genetics, Sunesis and Vion. We believe that we are currently the only company that has an orally available CDK-specific agent in Phase 2 clinical trials but that there are a number of companies, including AstraZeneca, Eisai, Pfizer, Piramal Life Sciences, Roche, Merck and Bayer-Schering that are developing CDK inhibitors in early stage clinical trials in cancer patients. Although Aventis, a predecessor of Sanofi-Aventis, had previously announced that it has ceased Phase 2 development of alvocidib or flavopiridol, a CDK inhibitor, we believe that the National Cancer Institute s Cancer Therapy Evaluation Program, or CTEP, is continuing to enroll patients in a CTEP sponsored trial in patients with chronic leukemia. A number of companies are pursuing discovery and research activities in each of the other areas that are the subject of our research and drug development programs. We believe that AstraZeneca, Entremed, Merck, jointly with Vertex, Nerviano Medical Sciences, Pfizer, Rigel, Sunesis and Takeda-Millennium have commenced Phase 1 or Phase 2 clinical trials of Aurora kinase inhibitors in patients with advanced cancers. Several companies have reported selection of Aurora kinase inhibitor candidates for development and may have started or are expected to start clinical trials within the next twelve months. We believe that Boehringer Ingelheim, GlaxoSmithKline, Onconova and Nerviano Medical Sciences have commenced Phase 1 or Phase 2 clinical trials with Plk inhibitor candidates for oncology indications. For our ALIGN products, we believe that Beiersdorf, Daiichi-Sankyo, Eisai, Johnson & Johnson, MPM Medical and other companies market products for radiation dermatitis and xerostomia.

Our competitors, either alone or together with collaborators, may have substantially greater financial resources and research and development staff. Our competitors may also have more experience:

- developing drug candidates;
- conducting preclinical and clinical trials;
- obtaining regulatory approvals; and
- commercializing product candidates.

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Our competitors may succeed in obtaining patent protection and regulatory approval and may market drugs before we do. If our competitors market drugs that are less expensive, safer, more effective or more convenient to administer than our potential drugs, or that reach the market sooner than our potential drugs, we may not achieve commercial success. Scientific, clinical or technical developments by our competitors may render our drug candidates obsolete or noncompetitive. We anticipate that we will face increased competition in the future as new companies enter the markets and as scientific developments progress. If our drug candidates obtain regulatory approvals, but do not compete effectively in the marketplace, our business will suffer.

The commercial success of the ALIGN products and our drug candidates depends upon their market acceptance among physicians, patients, healthcare providers and payors and the medical community.

It is necessary that our and our distribution partners products, including Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges achieve and maintain market acceptance. If our drug candidates are approved by the FDA or by another regulatory authority, the resulting drugs, if any, may not gain market acceptance among physicians, healthcare providers and payors, patients and the medical community. The degree of market acceptance of any of our approved drugs or devices will depend on a variety of factors, including:

- timing of market introduction, number and clinical profile of competitive drugs;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- cost-effectiveness;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors;
- prevalence and severity of adverse side effects; and
- other potential advantages over alternative treatment methods.

If our drugs fail to achieve market acceptance, we may not be able to generate significant revenue and our business would suffer.

If we are unable to compete successfully in our market place, it will harm our business.

There are existing products in the marketplace that compete with our products. Companies may develop new products that compete with our products. Certain of these competitors and potential competitors have longer operating histories, substantially greater product development capabilities and financial, scientific, marketing and sales resources. Competitors and potential competitors may also develop products that are safer, more effective or have other potential advantages compared to our products. In addition, research, development and commercialization efforts by others could render our products obsolete or non-competitive. Certain of our competitors and potential competitors have broader product offerings and extensive customer bases allowing them to adopt aggressive pricing policies that would enable them to gain market share. Competitive pressures could result in price reductions, reduced margins and loss of market share. We could encounter potential customers that, due to existing relationships with our competitors, are committed to products offered by those competitors. As a result, those potential customers may not consider purchasing our products.

There is uncertainty related to coverage, reimbursement and payment by healthcare providers and payors for the ALIGN products and newly approved drugs, if any. The inability or failure to obtain or maintain coverage could affect our ability to market the ALIGN products and our future drugs and decrease our ability to generate revenue.

The availability and levels of coverage and reimbursement of newly approved drugs by healthcare providers and payors is subject to significant uncertainty. The commercial success of the ALIGN products and our drug candidates in both the United States and international markets is substantially dependent on whether third party coverage and reimbursement is available. The United States Centers for Medicare and Medicaid Services, health maintenance organizations and other third party payors in the United States, the European Union and other jurisdictions are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs and, as a result, they may not cover or provide adequate payment for our potential drugs. The ALIGN products and our drug candidates may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow the ALIGN products or our drug candidates to be marketed on a competitive basis.

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In some countries, pricing of prescription drugs is subject to government control. In such countries, pricing negotiations with governmental authorities can take three to 12 months or longer following application to the competent authorities. To obtain reimbursement or pricing approval in such countries may require conducting an additional clinical trial comparing the cost-effectiveness of the drug to other alternatives. In the United States, the Medicare Part D drug benefit implemented in 2006 will limit drug coverage through formularies and other cost and utilization management programs, while Medicare Part B limits drug payments to a certain percentage of average price or through restrictive payment policies of least costly alternatives and inherent reasonableness Our business could be materially harmed if coverage, reimbursement or pricing is unavailable or set at unsatisfactory levels.

We may be exposed to product liability claims that may damage our reputation and we may not be able to obtain adequate insurance.

Because we conduct clinical trials in humans, we face the risk that the use of our drug candidates will result in adverse effects. We believe that we have obtained reasonably adequate product liability insurance coverage for our trials. We cannot predict, however, the possible harm or side effects that may result from our clinical trials. Such claims may damage our reputation and we may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limit of, our insurance coverage.

As we market commercialized products through our ALIGN subsidiary we are exposed to additional risks of product liability claims. These risks exist even with respect to drugs and devices that are approved for commercial sale by the FDA or other regulatory authorities in the United States, the European Union or elsewhere and manufactured in facilities licensed and regulated by the FDA or other such regulatory authorities. We have secured limited product liability insurance coverage, but may not be able to maintain such insurance on acceptable terms with adequate coverage, or at a reasonable cost. There is also a risk that third parties that we have agreed to indemnify could incur liability. Even if we were ultimately successful in product liability litigation, the litigation would consume substantial amounts of our financial and managerial resources and may exceed insurance coverage creating adverse publicity, all of which would impair our ability to generate sales of the litigated product as well as our other potential drugs.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential drugs, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Defending against claims relating to improper handling, storage or disposal of hazardous chemical, radioactive or biological materials could be time consuming and expensive.

Our research and development involves the controlled use of hazardous materials, including chemicals, radioactive and biological materials such as chemical solvents, phosphorus and bacteria. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

We may be required to defend lawsuits or pay damages in connection with the alleged or actual violation of healthcare statutes such as fraud and abuse laws, and our corporate compliance programs can never guarantee that we are in compliance with all relevant laws and regulations.

Our commercialization efforts in the United States are subject to various federal and state laws pertaining to promotion and healthcare fraud and abuse, including federal and state anti-kickback, fraud and false claims laws. Anti-kickback laws make it illegal for a manufacturer to offer or pay any remuneration in exchange for, or to induce,

the referral of business, including the purchase of a product. The federal government has published many regulations relating to the anti-kickback statutes, including numerous safe harbors or exemptions for certain arrangements. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers including Medicare and Medicaid, claims for reimbursed products or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

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Our activities relating to the sale and marketing of our products will be subject to scrutiny under these laws and regulations. It may be difficult to determine whether or not our activities, comply with these complex legal requirements. Violations are punishable by significant criminal and/or civil fines and other penalties, as well as the possibility of exclusion of the product from coverage under governmental healthcare programs, including Medicare and Medicaid. If the government were to investigate or make allegations against us or any of our employees, or sanction or convict us or any of our employees, for violations of any of these legal requirements, this could have a material adverse effect on our business, including our stock price. Our activities could be subject to challenge for many reasons, including the broad scope and complexity of these laws and regulations, the difficulties in interpreting and applying these legal requirements, and the high degree of prosecutorial resources and attention being devoted to the biopharmaceutical industry and health care fraud by law enforcement authorities. During the last few years, numerous biopharmaceutical companies have paid multi-million dollar fines and entered into burdensome settlement agreements for alleged violation of these requirements, and other companies are under active investigation. Although we have developed and implemented corporate and field compliance programs as part of our commercialization efforts, we cannot assure you that we or our employees, directors or agents were, are or will be in compliance with all laws and regulations or that we will not come under investigation, allegation or sanction.

In addition, we may be required to prepare and report product pricing-related information to federal and state governmental authorities, such as the Department of Veterans Affairs and under the Medicaid program. The calculations used to generate the pricing-related information are complex and require the exercise of judgment. If we fail to accurately and timely report product pricing-related information or to comply with any of these or any other laws or regulations, various negative consequences could result, including criminal and/or civil prosecution, substantial criminal and/or civil penalties, exclusion of the approved product from coverage under governmental healthcare programs including Medicare and Medicaid, costly litigation and restatement of our financial statements. In addition, our efforts to comply with this wide range of laws and regulations are, and will continue to be, time-consuming and expensive.

If we fail to enforce adequately or defend our intellectual property rights our business may be harmed.

Our commercial success depends in large part on obtaining and maintaining patent and trade secret protection for our drug candidates, the methods used to manufacture those drug candidates and the methods for treating patients using those drug candidates. Specifically, sapacitabine is covered in granted, composition of matter patents that expire in 2014 in the US and 2012 outside the US. Sapacitabine is further protected by additional granted, composition of matter patents claiming certain, stable crystalline forms of sapacitabine and their pharmaceutical compositions and therapeutic uses that expire in 2022. In early development, amorphous sapacitabine was used. We have used one of the stable, crystalline forms of sapacitabine in nearly all our Phase 1 and in all of our Phase 2 clinical studies. We have also chosen this form for commercialization. Additional patents claim certain medical uses and formulations of sapacitabine which have emerged in our clinical trials. Seliciclib is protected by granted, composition of matter patents that expire in 2016. Additional patents claim certain medical uses which have emerged from our research programs.

Failure to obtain, maintain or extend the patents could adversely affect our business. We will only be able to protect our drug candidates and our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

Our ability to obtain patents is uncertain because legal means afford only limited protections and may not adequately protect our rights or permit it to gain or keep any competitive advantage. Some legal principles remain unresolved and the breadth or interpretation of claims allowed in patents in the United States, the European Union or elsewhere can still be difficult to ascertain or predict. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States, the European Union or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. In addition, we generally do not control the patent prosecution of subject matter that we license from others and have not controlled the earlier stages

of the patent prosecution. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we would over our own.

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Even if patents are issued regarding our drug candidates or methods of using them, those patents can be challenged by our competitors who may argue such patents are invalid and/or unenforceable. On April 27, 2010, we were served with a complaint filed by Celgene Corporation in the United States District Court for the District of Delaware seeking a declaratory judgment that four of our owned patents, claiming the use of romidepsin injection in T-cell lymphomas, are not infringed by Celgene s products and are invalid. The four patents cited in the complaint do not involve our clinical development candidates or commercial products. On June 17, 2010, Cyclacel filed its answer and counterclaims to the declaratory judgment complaint. Cyclacel has filed counterclaims charging Celgene with infringement of each of its four patents and seeking damages for Celgene s infringement as well as injunctive relief. The four patents directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product.

Patents also will not protect our drug candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The U.S. Federal Food, Drug and Cosmetic, or FD&C, Act and FDA regulations and policies and equivalents in other jurisdictions provide incentives to manufacturers to challenge patent validity or create modified, noninfringing versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage manufacturers to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor.

Proprietary trade secrets and unpatented know-how are also very important to our business. We rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Intellectual property rights of third parties may increase our costs or delay or prevent us from being able to commercialize our drug candidates and/or the ALIGN products.

There is a risk that we are infringing or will infringe the proprietary rights of third parties because patents and pending applications belonging to third parties exist in the United States, the European Union and elsewhere in the world in the areas of our research and/or the ALIGN products. Others might have been the first to make the inventions covered by each of our or our licensors pending patent applications and issued patents and might have been the first to file patent applications for these inventions. We are aware of several published patent applications, and understand that others may exist, that could support claims that, if granted, could cover various aspects of our developmental programs, including in some cases particular uses of our lead drug candidate sapacitabine, seliciclib or other therapeutic candidates, or gene sequences and techniques that we use in the course of our research and development. In addition, we understand that other applications and patents exist relating to potential uses of sapacitabine and seliciclib that are not part of our current clinical programs for these compounds. Numerous third-party United States and foreign issued patents and pending applications exist in the area of kinases, including CDK, AK and Plk for which we have research programs. For example, some pending patent applications contain broad claims that could represent freedom to operate limitations for some of our kinase programs should they be issued unchanged. Although we intend to continue to monitor these applications, we cannot predict what claims will ultimately be allowed and if allowed what their scope would be. In addition, because the patent application process can take several years to complete, there may be currently pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our drug candidates. If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that the owner asserts that we infringe its patents. In one case we have opposed a European patent relating to human aurora kinase and the patent has been finally revoked (no appeal was filed). We are also aware of a corresponding U.S. patent containing method of treatment claims for specific cancers using aurora kinase modulators which, if held valid, could potentially restrict the

use of our aurora kinase inhibitors once clinical trials are completed.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Defending against third party claims, including litigation in particular, would be costly and time consuming and would divert management s attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business. As a result of intellectual property infringement claims, or to avoid potential claims, we might:

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder;

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decide to move some of our screening work outside Europe;

be required to pay substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a competitor s patent or other proprietary rights; or

be required to redesign the formulation of a drug candidate so it does not infringe, which may not be possible or could require substantial funds and time.

The development programs for our two lead drug candidates are based in part on intellectual property rights we license from others, and any termination of those licenses could seriously harm our business.

We have in-licensed certain patent rights in connection with the development programs for each of our two lead drug candidates. Both of these license agreements impose payment and other material obligations on us. Under the Daiichi-Sankyo license, we are obligated to pay license fees, milestone payments and royalties. We are also obligated to use commercially reasonable efforts to commercialize products based on the licensed rights and to use reasonable efforts to obtain regulatory approval to sell the products in at least one country by September 2011, unless we have in-licensed certain patent rights in connection with the development programs for each of our two lead drug candidates. Under both of the license agreements relating to these drug candidates we are obligated to pay license fees, milestone payments and royalties. We are also obligated to use reasonable efforts to develop and commercialize products based on the licensed patents.

Pursuant to the Daiichi-Sankyo license under which we license sapacitabine, we are obligated to pay license fees, milestone payments and royalties, provide regular progress reports and use commercially reasonable efforts to commercialize products based on the licensed rights and obtain regulatory approval to sell the products in at least one country by September 2011, unless we are prevented from doing so by virtue of certain causes outside of our reasonable control, including but not limited to difficulties in patient recruitment into trials or significant, unexpected change in regulatory requirements affecting the development of our drug. Pursuant to the CNRS and Institut Curie license under which we license seliciclib, we are obligated to pay license fees, milestone payments and royalties and provide regular progress reports.

Although we are currently in compliance with all of our material obligations under these licenses, if we were to breach any such obligations our counterparties may be entitled to terminate the licenses. This would restrict or delay or eliminate our ability to develop and commercialize these drug candidates, which could adversely affect our business. With respect to seliciclib we hold a license from CNRS and Institut Curie under which we are obligated to pay license fees, milestone payments and royalties. We are obligated to use reasonable efforts to develop and commercialize products based on the licensed patents. Although we are currently in compliance with all of our material obligations under these licenses, if we were to breach any such obligations our counterparties could attempt to terminate the licenses and there can be no assurance as to what would constitute exceptional cause. This would restrict or delay or eliminate our ability to develop and commercialize these drug candidates, which could adversely affect our business.

Failure to achieve and maintain internal controls in accordance with Sections 302 and 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

We restated our financial statements and filed an amendment to our Annual Report of Form 10-K as and for the year ended December 31, 2009, in which we reported a material weakness in our internal control over financial reporting for the year then ended, specifically related to the operational failure of the controls in place to ensure the correct computation of net loss per share and presentation of preferred stock dividends in the consolidated statement of cash flows. If we fail to maintain our internal controls or fail to implement required new or improved controls, as such control standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting. Effective internal controls are necessary for us to produce reliable financial reports and are important in the prevention of financial fraud. If we cannot produce reliable financial reports or prevent fraud, our business and operating results could be harmed, investors may lose confidence in our reported financial information, and there could be a material adverse effect on our stock price.

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We incur increased costs and management resources as a result of being a public company, and we still may fail to comply with public company obligations.

As a public company, we face and will continue to face increased legal, accounting, administrative and other costs and expenses as a public company that we would not incur as a private company. Compliance with the Sarbanes Oxley Act of 2002, as well as other rules of the SEC, the Public Company Accounting Oversight Board and the NASDAQ Global Market resulted in a significant initial cost to us as well as an ongoing compliance costs. As a public company, we are subject to Section 404 of the Sarbanes Oxley Act relating to internal control over financial reporting. We completed, and later revisited, our formal process to evaluate our internal controls for purposes of Section 404. In performing this assessment, our management identified a deficiency in our internal control over financial reporting that constitutes a material weakness under standards established by the Public Company Accounting Oversight Board, or PCAOB, as of December 31, 2009. Specifically related to the operational failure of the controls in place to ensure the correct computation of net loss per share and presentation of preferred stock dividends in the statement of cash flows. Due to this deficiency, we concluded that the material weakness in internal control over financial reporting existed as of December 31, 2009 and continued as of March 31, 2010. Solely as a result of this material weakness, management concluded that we did not maintain effective internal control over financial reporting as of March 31, 2010, based on the criteria established in *Internal Control Integrated Framework*, issued by the COSO. As our business grows and changes, there can be no assurances that we can maintain the effectiveness of our internal controls over financial reporting.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed. We have completed a formal process to evaluate our internal control over financial reporting. However, guidance from regulatory authorities in the area of internal controls continues to evolve and substantial uncertainty exists regarding our on-going ability to comply by applicable deadlines. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our common stock may have a volatile public trading price.

An active public market for our common stock has not developed. Our stock can trade in small volumes which may make the price of our stock highly volatile. The last reported price of our stock may not represent the price at which you would be able to buy or sell the stock. The market prices for securities of companies comparable to us have been highly volatile. Often, these stocks have experienced significant price and volume fluctuations for reasons that are both related and unrelated to the operating performance of the individual companies. In addition, the stock market as a whole and biotechnology and other life science stocks in particular have experienced significant recent volatility. Like our common stock, these stocks have experienced significant price and volume fluctuations for reasons unrelated to the operating performance of the individual companies. In addition, due to our existing stock price, we may not continue to qualify for continued listing on the NASDAQ Global Market. To maintain listing, we are required to maintain a minimum closing bid price of $1.00 per share and, among other requirements, to maintain a minimum stockholders equity value of $10 million. Factors giving rise to this volatility may include:

- disclosure of actual or potential clinical results with respect to product candidates we are developing;
- regulatory developments in both the United States and abroad;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;
- public announcements by our competitors or others; and
- general market conditions and comments by securities analysts and investors.

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Fluctuations in our operating losses could adversely affect the price of our common stock.

Our operating losses may fluctuate significantly on a quarterly basis. Some of the factors that may cause our operating losses to fluctuate on a period-to-period basis include the status of our preclinical and clinical development programs, level of expenses incurred in connection with our preclinical and clinical development programs, implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, non-recurring revenue or expenses under any such agreement, and compliance with regulatory requirements. Period-to-period comparisons of our historical and future financial results may not be meaningful, and investors should not rely on them as an indication of future performance. Our fluctuating losses may fail to meet the expectations of securities analysts or investors. Our failure to meet these expectations may cause the price of our common stock to decline.

If securities or industry analysts do not publish research or reports about us, if they change their recommendations regarding our stock adversely or if our operating results do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock or if our operating results do not meet their expectations, our stock price could decline.

Anti-takeover provisions in our charter documents and provisions of Delaware law may make an acquisition more difficult and could result in the entrenchment of management.

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws may make a change in control or efforts to remove management more difficult. Also, under Delaware law, our Board of Directors may adopt additional anti-takeover measures.

We have the authority to issue up to 5 million shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If the Board of Directors exercises this power to issue preferred stock, it could be more difficult for a third party to acquire a majority of our outstanding voting stock and vote the stock they acquire to remove management or directors.

Our amended and restated certificate of incorporation and amended and restated bylaws also provides staggered terms for the members of our Board of Directors. Under Section 141 of the Delaware General Corporation Law, our directors may be removed by stockholders only for cause and only by vote of the holders of a majority of voting shares then outstanding. These provisions may prevent stockholders from replacing the entire board in a single proxy contest, making it more difficult for a third party to acquire control of us without the consent of our Board of Directors. These provisions could also delay the removal of management by the Board of Directors with or without cause. In addition, our directors may only be removed for cause and amended and restated bylaws limit the ability our stockholders to call special meetings of stockholders.

Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the Board of Directors approves the transaction. Our Board of Directors could use this provision to prevent changes in management. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

Certain severance-related agreements in our executive employment agreements may make an acquisition more difficult and could result in the entrenchment of management.

In March 2008 (as amended in December 2008 with respect to our President and Chief Executive Officer), we entered into employment agreements with our President and Chief Executive Officer and our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, which contain severance arrangements in the event that such executive s employment is terminated without cause or as a result of a change of control (as each such term is defined in each agreement). The financial obligations triggered by these provisions may prevent a business combination or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our stock.

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In the event of an acquisition of our common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time.

We may not effect a consolidation or merger with another entity without the vote or consent of the holders of at least a majority of the shares of our preferred stock (in addition to the approval of our common stockholders), unless the preferred stock that remains outstanding and its rights, privileges and preferences are unaffected or are converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our convertible preferred stock.

In addition, in the event a third party seeks to acquire our company or acquire control of our company by way of a merger, but the terms of such offer do not provide for our preferred stock to remain outstanding or be converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our preferred stock, the terms of the Certificate of Designation of our preferred stock provide for an adjustment to the conversion ratio of our preferred stock such that, depending on the terms of any such transaction, preferred stockholders may be entitled, by their terms, to receive up to $10.00 per share in common stock, causing our common stockholders not to receive as favorable a price as the price at which such shares may be trading at the time of any such transaction. As of August 13, 2010, there were 1,213,142 shares of our preferred stock issued and outstanding. If the transaction were one in which proceeds were received by the Company for distribution to shareholders, and the terms of the Certificate of Designation governing the preferred stock were strictly complied with, approximately $13 million would be paid to the preferred holders before any distribution to the common stockholders, although the form of transaction could affect how the holders of preferred stock are treated. In such an event, although such a transaction would be subject to the approval of our holders of common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time. Thus, the terms of our preferred stock might hamper a third party s acquisition of our company.

Our certificate of incorporation and bylaws and certain provisions of Delaware law may delay or prevent a change in our management and make it more difficult for a third party to acquire us.

Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change in our Board of Directors and management teams. Some of these provisions:

- authorize the issuance of preferred stock that can be created and issued by the Board of Directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of our common stock;
- provide for the Board of Directors to be divided into three classes; and
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of large stockholders to complete a business combination with, or acquisition of, us. These provisions may prevent a business combination or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our stock.

These provisions also make it more difficult for our stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team. Additionally, these provisions may prevent an acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our common stock.

We may have limited ability to pay cash dividends on the convertible preferred stock.

Delaware law may limit our ability to pay cash dividends on the convertible preferred stock. Under Delaware law, cash dividends on our convertible preferred stock may only be paid from surplus or, if there is no surplus, from the corporation s net profits for the current or preceding fiscal year. Delaware law defines surplus as the amount by which the total assets of a corporation, after subtracting its total liabilities, exceed the corporation s capital, as determined by its Board of Directors. Since we are not profitable, our ability to pay cash dividends will require the availability of

adequate surplus. Even if adequate surplus is available to pay cash dividends on the convertible preferred stock, we may not have sufficient cash to pay dividends on the convertible preferred stock or we may choose not to declare the dividends. If that was to happen, holders of preferred stock would be granted certain additional rights until such dividends were paid.

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We have not declared quarterly dividends on our 6% Convertible Exchangeable Preferred Stock for a total of six quarterly dividend periods. As a result, the holders of our Preferred Stock are entitled to additional rights with respect to the management of the Company.

Dividends have not been paid on the preferred stock for six quarters. As a result, the holders of the preferred stock are now entitled to vote to fill two new board positions. A holder of preferred stock who holds at least 10% of the issued and outstanding shares of preferred stock has requested that the Company call a special meeting of the preferred stockholders to elect two directors to fill such vacancies. Once elected, the directors elected by the preferred stockholders will have the ability to participate in the management of the Company until all such dividends have been paid in full.

Our common and convertible preferred stock may experience extreme price and volume fluctuations, which could lead to costly litigation for the Company and make an investment in the Company less appealing.

The market price of our common and convertible preferred stock may fluctuate substantially due to a variety of factors, including:

- additions to or departures of our key personnel;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements concerning our competitors or the biotechnology industry in general;
- new regulatory pronouncements and changes in regulatory guidelines;
- general and industry-specific economic conditions;
- changes in financial estimates or recommendations by securities analysts;
- variations in our quarterly results;
- announcements about our collaborators or licensors; and
- changes in accounting principles.

The market prices of the securities of biotechnology companies, particularly companies like us without product revenues and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the performance of particular companies. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Moreover, market prices for stocks of biotechnology-related and technology companies frequently reach levels that bear no relationship to the performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management s attention and resources and harm our financial condition and results of operations. In addition, due to our stock price from time to time, we may not continue to qualify for continued listing on the NASDAQ Global Market. Please see the risk factor entitled, *Our common stock may have a volatile public trading price.*

The future sale of our common and preferred stock and future issuances of our common stock upon conversion of our preferred stock, could negatively affect our stock price.

If our common or preferred stockholders sell substantial amounts of our stock in the public market, or the market perceives that such sales may occur, the market price of our common and preferred stock could fall. Thus if holders of preferred stock elect to convert their shares to shares of common stock at renegotiated prices, and the holders of our preferred stock have elected to so convert into common stock, such conversion as well as the sale of substantial amounts of our common or preferred stock, could cause dilution to existing holders of our common stock, thereby also negatively affecting the price of our common stock.

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If we exchange the convertible preferred stock for debentures, the exchange will be taxable but we will not provide any cash to pay any tax liability that any convertible preferred stockholder may incur.

An exchange of convertible preferred stock for debentures, as well as any dividend make-whole or interest make-whole payments paid in our common stock, will be taxable events for United States federal income tax purposes, which may result in tax liability for the holder of convertible preferred stock without any corresponding receipt of cash by the holder. In addition, the debentures may be treated as having original issue discount, a portion of which would generally be required to be included in the holder s gross income even though the cash to which such income is attributable would not be received until maturity or redemption of the debenture. We will not distribute any cash to the holders of the securities to pay these potential tax liabilities.

If we automatically convert the convertible preferred stock, there is a substantial risk of fluctuation in the price of our common stock from the date we elect to automatically convert to the conversion date.

We may automatically convert the convertible preferred stock into common stock if the closing price of our common stock has exceeded $35.30. There is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred and the automatic conversion date.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend on our financial condition, results of operations, capital requirements, the outcome of the review of our strategic alternatives and other factors and will be at the discretion of our Board of Directors. Accordingly, investors will have to rely on capital appreciation, if any, to earn a return on their investment in our common stock. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends.

The number of shares of common stock which are registered, including the shares to be issued upon exercise of our outstanding warrants, is significant in relation to our currently outstanding common stock and could cause downward pressure on the market price for our common stock.

The number of shares of common stock registered for resale, including those shares which are to be issued upon exercise of our outstanding warrants, is significant in relation to the number of shares of common stock currently outstanding. If the security holder determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

If persons engage in short sales of our common stock, including sales of shares to be issued upon exercise of our outstanding warrants, the price of our common stock may decline.

Selling short is a technique used by a stockholder to take advantage of an anticipated decline in the price of a security. In addition, holders of options and warrants will sometimes sell short knowing they can, in effect, cover through the exercise of an option or warrant, thus locking in a profit. A significant number of short sales or a large volume of other sales within a relatively short period of time can create downward pressure on the market price of a security. Further sales of common stock issued upon exercise of our outstanding warrants could cause even greater declines in the price of our common stock due to the number of additional shares available in the market upon such exercise, which could encourage short sales that could further undermine the value of our common stock. You could, therefore, experience a decline in the value of your investment as a result of short sales of our common stock.

Our distribution rights to the ALIGN products are licensed from others, and any termination of that license could harm our business.

We have in-licensed from Sinclair the distribution rights to the ALIGN products. This license agreement imposes obligations on us. Although we are currently in compliance with all of our material obligations under this license, if we were to breach any such obligations, Sinclair would be permitted to terminate the license. This would restrict us from distributing the ALIGN products.

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If our supplier upon whom we rely fails to produce on a timely basis the finished goods in the volumes that we require or fails to meet quality standards and maintain necessary licensure from regulatory authorities, we may be unable to meet demand for our products, potentially resulting in lost revenues.

Our licensor and supplier Sinclair contracts with third party manufacturers to supply the finished goods to us to meet our needs. If any of Sinclair s third party manufacturers service providers do not meet our or our licensor s requirements for quality, quantity or timeliness, or do not achieve and maintain compliance with all applicable regulations, demand for our products or our ability to continue supplying such products could substantially decline. As the third party manufacturers are the sole supplier of the products any delays may impact our sales.

In all the countries where we sell or may sell our products, governmental regulations exist to define standards for manufacturing, packaging, labeling and storing. All of our suppliers of raw materials and contract manufacturers must comply with these regulations. Failure to do so could result in supply interruptions. In the United States, the FDA requires that all suppliers of pharmaceutical bulk material and all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA s Current Good Manufacturing Practice or cGMP regulations and guidelines. Failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications pre-approved by regulators for the content of the pharmaceutical product. If the operations of one or more of our manufacturers were to become unavailable for any reason, any required FDA review and approval of the operations of an alternative supplier could cause a delay in the manufacture of our products.

Our customer base is highly concentrated.

Our principal customers are a small number of wholesale drug distributors. These customers comprise a significant part of the distribution network for pharmaceutical products in the United States. Three large wholesale distributors, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation, control a significant share of the market in the United States. Our ability to distribute any product, including Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges and to recognize revenues on a timely basis is substantially dependent on our ability to maintain commercially reasonable agreements with each of these wholesale distributors and the extent to which these distributors, over whom we have no control, comply with such agreements. Our agreements with wholesaler distributors may contain terms that are not favorable, given our relative lack of market leverage as a company with only three approved products or other factors, which could adversely affect our commercialization of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. The loss of any of these customers could materially and adversely affect our ability to distribute our products, resulting in a negative impact on our operations and financial condition.

We may be unable to accurately estimate demand and monitor wholesaler or retailer inventory of Xclair® Cream, Numoisyn® Liquid or Numoisyn® Lozenges. Although we attempt to monitor wholesaler or retailer inventory of Xclair® Cream, Numoisyn® Liquid or Numoisyn® Lozenges, we also rely on third party information, which is inherently uncertain and may not be accurate, to assist us in monitoring estimated inventory levels. Inaccurate estimates of the demand and inventory levels of the product may cause our revenues to fluctuate significantly from quarter to quarter and may cause our operating results for a particular quarter to be below expectations.

Inventory levels of Xclair® Cream, Numoisyn® Liquid or Numoisyn® Lozenges held by wholesalers or retailers can also cause our operating results to fluctuate unexpectedly. For the six months ended June 30, 2009 and 2010, approximately 78% and 83%, respectively, of our product sales in the United States were to three wholesalers, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen. Inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to wholesalers do not match end user demand. We have entered into inventory management agreements with these U.S. wholesalers under which they provide us with data regarding inventory levels at these wholesalers. However, these wholesalers may not be completely effective in matching inventory levels to end user demand, as they make estimates to determine end user demand. In addition, inventory is held at retail pharmacies and other non-wholesaler locations, for which we have no inventory management agreements and have no control in respect to their buying patterns. Also, the non-retail sector in the

United States, which includes government institutions and large health maintenance organizations, tends to be less consistent in terms of buying patterns, and often causes quarter-over-quarter fluctuations in inventory and ordering patterns. We attempt to monitor inventory of Xclair®, Numoisyn® Liquid or Numoisyn® Lozenges in the United States through the use of internal sales forecasts and the expiration dates of product shipped, among other factors.

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The commercialization of our products is substantially dependent on our ability to develop effective sales and marketing capabilities.

Our successful commercialization of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges in the United States will depend on our ability to establish and maintain an effective sales and marketing organization in the United States. We hired trained and deployed additional marketing personnel and a small oncology specialty sales force. We may increase or decrease the size of our sales force in the future, depending on many factors, including the effectiveness of the sales force, the level of market acceptance of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges and the results of our clinical trials. Prior to our launches of these products, we had never sold or marketed any products.

For our product candidates currently under development, our strategy is to develop compounds through the Phase 2 stage of clinical testing and market or co-promote certain of our drugs on our own. We have limited sales, marketing or distribution capabilities. We will depend primarily on strategic alliances with third parties, which have established distribution systems and sales forces, to commercialize our drugs. To the extent that we are unsuccessful in commercializing any drugs or devices ourselves or through a strategic alliance, product revenues will suffer, we will incur significant additional losses and our share price will be negatively affected.

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

On April 19, 2010, Cyclacel issued upon settlement, an aggregate of 1,416,203 shares of its common stock to several of its stockholders in exchange for such stockholders delivery to the Company of an aggregate of 710,271 shares of the Company s Preferred Stock. The shares of Common Stock were issued in reliance on the exemption from registration contained in Section 3(a)(9) of the Securities Act of 1933, as amended, for securities exchanged by an issuer and an existing security holder stockholder where no commission or other remuneration is paid or given directly or indirectly by the issuer for soliciting such exchange. These transactions settled on or before April 23, 2010, after which time, a total of 1,213,142 shares of Preferred Stock remain outstanding.

Item 3. Defaults upon Senior Securities.

On January 7, 2010, March 29, 2010 and July 16, 2010, our board of directors resolved to not declare the quarterly cash dividend on the Company s Preferred Stock scheduled for February 1, 2010, May 1, 2010 and August 1, 2010. The aggregate amount of dividends that would have been paid is $0.9 million with respect to such periods, and the total aggregate amount of dividends that are accrued but not paid is $1.0 million.

Item 4. (Removed and Reserved).

Item 5. Other Information

None.

Item 6. Exhibits

31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned.

CYCLACEL PHARMACEUTICALS, INC.

Date: August 13, 2010

By: /s/ Paul McBarron
Paul McBarron
Chief Operating Officer, Chief Financial Officer and
Executive Vice President, Finance