Cyclacel Pharmaceuticals, Inc.
Form 10-Q
November 12, 2009

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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 September 30, 2009
OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Commission file number 000-50626
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 (Do not check if a smaller reporting company)	Smaller reporting filer þ

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 November 11, 2009 there were 24,433,129 shares of the registrant s common stock outstanding.

CYCLACEL PHARMACEUTICALS, INC.
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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, 2008	September 30, 2009 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	24,220	14,433
Short-term investments	1,502	
Inventory	508	140
Prepaid expenses and other current assets	2,784	1,652
Total current assets	29,014	16,225
Property, plant and equipment (net)	1,748	1,121
Deposits and other assets	195	196
Total assets	30,957	17,542
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	754	1,463
Accrued liabilities	5,186	5,228
Other current liabilities	1,615	1,336
Warrant liability	43	238
Current portion of other accrued restructuring charges	1,029	1,063
Total current liabilities	8,627	9,328
Other accrued restructuring charges, net of current	1,062	267
Other long term payables	626	
Total liabilities	10,315	9,595
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2008 and September 30, 2009; 2,046,813 shares issued and outstanding at December 31, 2008 and September 30, 2009. Aggregate preference in liquidation of $20,673,000 at December 31, 2008 and September 30, 2009	2	2
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2008 and September 30, 2009; 20,433,129, and 24,433,129 shares issued and outstanding at December 31, 2008 and September 30, 2009, respectively	20	24
Additional paid-in capital	223,377	225,864

Accumulated other comprehensive loss	(42)	5
Deficit accumulated during the development stage	(202,715)	(217,948)
Total stockholders equity	20,642	7,947
Total liabilities and stockholders equity	30,957	17,542

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 September 30,		Nine Months Ended September 30,		Period from August 13, 1996 (inception) to September 30,
	2008	2009	2008	2009	2009
Revenues:					
Collaboration and research and development revenue					3,000
Product revenue	257	223	590	688	1,526
Grant revenue	12	7	36	36	3,671
Total revenue	269	230	626	724	8,197
Operating expenses:					
Cost of goods sold	120	163	315	472	901
Research and development	4,030	1,394	15,718	7,174	167,587
Selling, general and administrative	3,218	2,188	11,337	6,703	70,011
Goodwill and intangibles impairment	6,344		6,344		7,934
Restructuring expenses	489		489	366	2,634
Total operating expenses	14,201	3,745	34,203	14,715	249,067
Operating loss	(13,932)	(3,515)	(33,577)	(13,991)	(240,870)
Other income (expense):					
Costs associated with aborted 2004 IPO					(3,550)
Payment under guarantee				(1,652)	(1,652)
Change in valuation of derivative					(308)
Change in valuation of warrants	432	101	3,321	(195)	6,512
Foreign exchange gains/(losses)	(4,776)	119	(4,638)	(129)	(4,172)
Interest income	287	7	1,184	94	13,635
Interest expense	(69)	(41)	(244)	(156)	(4,613)
Total other income (expense)	(4,126)	186	(377)	(2,038)	5,852
Loss before taxes	(18,058)	(3,329)	(33,954)	(16,029)	(235,018)

Income tax benefit	411	205	1,511	796	17,070
Net loss	(17,647)	(3,124)	(32,443)	(15,233)	(217,948)
Dividends on Preferred Ordinary shares					(38,123)
Net loss applicable to common shareholders	(17,647)	(3,124)	(32,443)	(15,233)	(256,071)
Net loss per share Basic and diluted	$ (0.86)	$ (0.13)	$ (1.59)	$ (0.71)	
Weighted average common shares outstanding	**20,433,129**	**23,172,259**	**20,433,129**	**21,356,206**	

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)

	Nine Months Ended September 30,		Period from August 13, 1996 (inception) to September 30,
	2008	2009	2009
Cash flows from operating activities:			
Net loss	(32,443)	(15,233)	(217,948)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accretion of deferred consideration payable in common stock related to the acquisition of ALIGN	29		
Accretion of interest on notes payable, net of amortization of debt premium	59	2	100
Amortization of investment premiums, net	(1,273)	20	(2,297)
Change in valuation of derivative			308
Change in valuation of warrants	(3,321)	195	(6,512)
Depreciation and amortization	1,619	501	12,576
Goodwill and intangibles impairment	6,344	151	8,085
Unrealized foreign exchange loss	5,184		7,747
Deferred revenue			(98)
Compensation for warrants issued to non employees			1,215
Shares issued for IP rights			446
Loss (gain) on disposal of property, plant and equipment		10	39
Stock based compensation	1,202	525	16,110
Provision for restructuring	383		1,779
Amortization of issuance costs of Preferred Ordinary C shares			2,517
Payment under guarantee		(796)	(796)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	1,184	1,500	(968)
Accounts payable and other current liabilities	(2,499)	507	(989)
Net cash used in operating activities	(23,532)	(12,618)	(178,686)
Investing activities:			
Purchase of ALIGN			(3,763)
Purchase of property, plant and equipment	(354)	(13)	(8,821)
Proceeds from sale of property, plant and equipment		13	39
Purchase of short-term investments	(857)		(156,657)
Redemptions of short-term investments, net of maturities	22,899	1,502	162,749
Net cash provided by (used in) investing activities	21,688	1,502	(6,450)
Financing activities:			

Payment of capital lease obligations	(10)		(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		2,867	78,850
Net proceeds from stock options and warrants exercised			163
Payment of preferred stock dividend	(921)	(307)	(3,679)
Repayment of government loan			(455)

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

	Nine Months Ended September 30,		Period from August 13, 1996 (inception) to September 30,
	2008	2009	2009
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	(931)	2,560	198,027
Effect of exchange rate changes on cash and cash equivalents	(1,489)	(1,231)	1,542
Net (decrease) increase in cash and cash equivalents	(2,775)	(9,787)	14,433
Cash and cash equivalents at beginning of period	30,987	24,220	
Cash and cash equivalents at end of period	26,723	14,433	14,433
Supplemental disclosure of cash flows information:			
Cash received during the period for:			
Interest	8448	62	11,707
Taxes	2,113	1,527	16,444
Cash paid during the period for:			
Interest	(169)		(1,681)
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

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 discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Cyclacel s strategy is focused on leading edge therapeutic management of cancer patients based on its clinical development pipeline led by sapacitabine and a portfolio of three products marketed by one of its subsidiaries ALIGN Pharmaceuticals, LLC (ALIGN).

The Company is focusing its clinical development priorities 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 Company has additional ongoing programs in clinical 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 nasopharyngeal cancer or NPC and NSCLC and CYC116.

To date, the Phase 2 AML and MDS study has enrolled 105 AML patients and 31 MDS patients. During October 2009, the Company announced top-line survival data for the primary endpoint of the Phase 2 AML study. The study was a three-arm randomized trial evaluating three dosing schedules of sapacitabine. The primary endpoint of 1-year survival was approximately 30% each on two out of the three schedules tested. Partial responses were observed in 3 out of 16 patients enrolled in the Phase 2 randomized CTCL trial which will be closed.

In September 2008, the Company announced a revision of its operating plan to concentrate its resources on the advancement of its lead drug sapacitabine. Consistent with the revised operating plan, during the second and third quarters of 2009, the Company further reduced its workforce across all locations by twenty six (26) people making a total reduction of fifty one (51) people, or 63% of the workforce, since September 2008. With these reductions and its cost-containment efforts, the Company currently anticipates that its cash and cash equivalents of approximately $14.4 million as of September 30, 2009 is sufficient to meet the Company s anticipated short-term working capital needs and fund its current operations, including on-going sapacitabine clinical trials, for the next twelve months. To continue operations beyond that time or in order to undertake further development activity, the Company would need to raise additional finance.

Subsequent Events

On October 19, 2009, the Board of Directors decided not to declare the payment of the quarterly cash dividend on the Company s 6% Convertible Exchangeable Preferred Stock (Preferred Stock) scheduled for November 1, 2009. To the extent that any dividends payable on the Preferred Stock are not paid, the unpaid dividends are accumulated. The Board of Directors will continue to evaluate the payment of a quarterly cash dividend on a quarterly basis.

On October 21, 2009, Cyclacel received a letter from The NASDAQ Stock Market notifying the Company that it had been granted an extension of time to regain compliance with the minimum $10 million stockholders equity requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(b)(1)(A). The Company previously announced on August 24, 2009, that it had received a letter from NASDAQ notifying Cyclacel that it was not in compliance with this requirement.

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Under the terms of the extension, on or before December 7, 2009, Cyclacel must furnish to the Securities and Exchange Commission and NASDAQ a publicly available filing that, among other things, evidences compliance with the minimum $10 million stockholders equity requirement. In the event the Company does not satisfy the terms of the extension, Cyclacel expects to be notified that its securities will be subject to delisting from The NASDAQ Global Market. In that event, the Company may either apply for listing on The NASDAQ Capital Market, provided it meets the continued listing requirements of that market, or appeal the decision to a NASDAQ Listing Qualifications Panel. In the event of an appeal, the Company s securities would remain listed on The NASDAQ Global Market pending a decision by the Panel following the hearing.

On October 27, 2009, the Company received a notice from The NASDAQ Stock Market indicating that the Company is not in compliance with NASDAQ Listing Rule 5450(a)(1) (the Minimum Bid Price Rule) because the closing bid price per share for its common stock has been below $1.00 per share for 30 consecutive business days. In accordance with NASDAQ Listing Rules, the Company will be provided 180 calendar days, or until April 26, 2010, to regain compliance with the Minimum Bid Price Rule. The Company can achieve compliance if at any time before April 26, 2010, its common stock closes at $1.00 per share or more for at least 10 consecutive business days. This notification has no effect on the listing of the Company s common stock at this time.

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 September 30, 2009, the condensed consolidated statements of operations for the three and nine months ended September 30, 2009 and 2008 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2009 and 2008, and related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2008 is derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2008 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 September 30, 2009, the results of operations for the three and nine months ended September 30, 2009 and 2008 and the consolidated statements of cash flows for the three and nine months ended September 30, 2009 and 2008, have been made. The interim results for the three and nine months ended September 30, 2009 are not necessarily indicative of the results to be expected for the year ending December 31, 2009 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, 2008, included in the Company s Annual Report on Form 10-K filed with the SEC. We have evaluated all subsequent events through November 12, 2009, the date the financial statements were issued.

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.

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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 market value. The Company considers all highly liquid investments with an original maturity of three months or less at the time of initial deposit 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.

Short-term Investments

The Company invests, from time to time, in certain marketable debt securities. Debt securities, at December 31, 2008, comprised of investment-grade government and commercial securities purchased to generate a higher yield than cash equivalents. In accordance with Accounting Standards Codification (ASC) 320, *Accounting for Certain Investments in Debt and Equity Securities,* (ASC 320) such investment securities are classified as available-for-sale and are carried at fair value. Under ASC 320, unrealized gains and losses, net of tax, are reported in a separate component of stockholders equity until realized. Amortization, accretion, interest and dividends, realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in interest income. For the purpose of computing realized gains and losses, the cost of securities sold is based on the specific-identification method. Investments in securities with maturities of less than one year or which management intends to use to fund current operations are classified as short-term investments.

The Company evaluates whether an investment is other-than-temporarily impaired. This evaluation is dependent upon the specific facts and circumstances. Factors that are considered in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis; the financial condition of the issuer; and the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment.

The Company also invests its surplus cash in bank term deposits having a maturity period of between one day and one year. Accordingly, all cash resources with original maturity of three months or less have been classified as cash and cash equivalents and those with original maturity of more than three months as short term investments. 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. As of September 30, 2009, the Company did not own any short-term investments.

Inventory

Cyclacel values inventories at lower of cost or market value. The Company determines cost using the first-in, first-out method. As of September 30, 2009 and December 30, 2008, all inventories were classified as finished goods. The Company analyzes its inventory levels quarterly and writes-down inventory that becomes obsolete or that has a cost basis in excess of its expected net realizable value. Expired inventory is disposed of and the related carrying amounts 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.

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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. The Company reviews its inventory levels on a quarterly basis and adjusts accordingly. During the three and nine months ended September 30, 2009, the Company determined and recorded a reserve of approximately $48,000 and $0.1 million, respectively, based upon current inventory levels, expiration dates, and future sales. This amount was recorded within cost of sales on the condensed consolidated statement of operations. In the future, reduced demand, quality issues or excess supply may result in write-downs, which would be recorded as adjustments to cost of sales.

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.

The Company offers a general right of return on these product sales, and has considered the guidance in ASC 605-15, *Revenue Recognition When Right of Return Exists* (ASC 605-15) and ASC 605 10 Revenue Recognition (ASC 605-10). Under these pronouncements, 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 significant distributors with respect to their inventory levels and sell-through to customers.

Grant revenue

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 Trials 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) in accordance with the Company s standard operating procedures. 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 Expenses

Research and development expenses consist primarily of clinical trial costs associated with the Company s product candidates, 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.

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Foreign currency and currency translation

Average rates of exchange ruling during the period have been used to translate the statement of operations of our overseas subsidiary, Cyclacel Limited, located in the United Kingdom, from its functional currency. Transactions which do not take place in a foreign subsidiary s functional currency are converted at the rate on the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated from their functional currency at balance sheet exchange rates. The balance sheet of our overseas subsidiary is translated into United States dollars from United Kingdom pounds at rates ruling at the balance sheet.

Translation adjustments arising on consolidation due to differences between average rates and balance sheet rates and unrealized foreign exchange gains or losses arising on translation of intercompany loans which are of a long-term-investment nature are recorded as a movement in other comprehensive income. Other exchange rate differences are reported in the statements of operations for the year.

Derivative Instruments

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 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* (ASC 815). 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. The fair value of the warrants is determined at each reporting date utilizing the Black-Scholes option pricing model. All other warrants issued are being accounted for as equity in accordance with ASC 815.

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 *Share-Based Payment* (ASC 718).

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. Such value is recognized as expense over the 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. The Company considers many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. In connection with the reduction in workforce during the second and third quarters of 2009, the Company agreed to extend the option exercise term for terminated employees from thirty (30) days to nine (9) months. In accordance with ASC 718, the Company recorded a one time charge of $0.3 million during the second quarter of 2009. Actual results and future estimates may differ substantially from the Company s current estimates.

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.

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The Company accounts for income taxes in accordance with ASC 740 *Accounting for Uncertainty in Income Taxes* an interpretation of ASC 740 *Accounting for income taxes* (ASC 740). ASC 740 clarifies the accounting for uncertainty in income taxes recognized in a company s financial statements by prescribing a minimum probability threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, measurement, classification, interest and penalties and accounting in interim periods as well as disclosure and transition.

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.

Segments

The Company has determined its reportable segments in accordance with ASC 280, *Disclosure about Segments of an Enterprise and Related Information* (ASC 280) through consideration of the Company s 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, make-whole dividend payments of common stock on 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. Such excluded shares are summarized as follows:

	September 30, 2008	**September 30, 2009**
Stock options	2,743,963	3,538,933
Restricted stock and restricted stock units		141,700
Convertible preferred stock	870,980	870,980
Common stock warrants	3,809,272	7,044,363
Total shares excluded from calculation	7,424,215	11,595,976

Other Comprehensive Loss

In accordance with ASC 220, *Reporting 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 and changes in the fair value of available-for-sale securities, are reported, net of any related tax effect, to arrive at comprehensive income (loss).

	For the three months ended September 30,		**For the nine months ended September 30,**		**Period from August 13, 1996 (inception) to September 30,**
	2008	**2009**	**2008**	**2009**	**2009**
	$000	**$000**	**$000**	**$000**	**$000**
Net loss	(17,647)	(3,124)	(32,443)	(15,233)	(217,948)

Other Comprehensive income/(loss)	4,063	(113)	3,967	47	5
Comprehensive loss	(13,584)	(3,237)	(28,476)	(15,186)	(217,943)

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Restructuring Expense

The Company records costs and liabilities associated with exit and disposal activities, when certain criteria have been met in accordance with ASC 420, *Accounting for Costs Associated with Exit or Disposal Activities* (ASC 420), at fair value in the period the liability is incurred. The Company s restructuring and integration plan is subject to continued future refinement as additional information becomes available.

In September 2008, the Company announced a revision of its operating plan and that it plans to concentrate its resources on the advancement of its lead drug, sapacitabine, while maintaining the Company s core competency in drug discovery and cell cycle biology. In June 2009, the Company further reduced its workforce across all locations by 26 people making a total reduction of 51 people (or 63% of the workforce) since September 2008. At the end of September 2009, $30,000 of severance payments remained outstanding. An asset impairment amounting to $0.1 million was also charged to the consolidated statement of operations as a result of assets being identified that was no longer being utilized.

Impairment of Long-lived Assets

In accordance with the provisions of ASC 360, the Company reviews long-lived assets, including intangibles, property, plant and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Under ASC 360, impairment occurs when undiscounted estimated identifiable future cash flows expected to result from the use of the asset and its eventual dispositions are less than its carrying amount. An impairment loss, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value.

As a result of the Company s reduction in workforce in the second quarter of 2009 and third quarter of 2008, the Company identified certain research and development assets at its Scotland facility which will no longer be utilized For the three months ended June 30, 2009, the Company recorded an asset impairment of approximately $0.2 million in respect to these assets and it was included as part of restructuring costs on the consolidated statement of operations in accordance with ASC 420. During the third quarter of 2009, the Company wrote off against the impairment approximately $20,000 as a result of certain equipment not being utilized. All remaining laboratory equipment is classified as Assets for Sale within fixed assets on the balance sheet as of September 30, 2009.

3. SHORT-TERM INVESTMENTS

The following is a summary of short-term investments:

	December 31, 2008			
	Gross amortized cost $000	**Gross unrealized gains $000**	**Gross unrealized losses $000**	**Fair value $000**
Corporate bonds & commercial paper	1,501	1		1,502

	September 30, 2009			
	Gross amortized cost $000	**Gross unrealized gains $000**	**Gross unrealized losses $000**	**Fair value $000**
Corporate bonds & commercial paper				

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For investments that are in an unrealized loss position, the Company evaluated the nature of the investments, the duration of the impairments and concluded that the impairments are not other-than-temporary.

At September 30, 2009, the Company did not own any short-term investments. At December 31, 2008, the Company had marketable securities at fair value with contractual maturities of greater than one year but less than 5 years of approximately $1.5 million.

Fair value measurements

The Company adopted ASC 820, *Fair Value Measurements* (ASC 820), for its financial assets and liabilities on January 1, 2008, and for non-financial assets and non-financial liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis on January 1, 2009. The Company s adoption of ASC 820 did not materially affect the Company s financial position, results of operations or liquidity. As defined in ASC 820, 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. In order to increase consistency and comparability in fair value measurements, 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 assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

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.

Financial liabilities carried at fair value as of September 30, 2009 are classified in the table below in one of the three categories described above:

	Level 1 $000	**Level 2 $000**	**Level 3 $000**	**Total $000**
Warrants		238		238
Total liabilities at fair value		238		238

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4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	December 31, 2008	September 30, 2009
	($000s)	
Research and development tax credit receivable	1,530	967
Prepayments	1,017	554
Other current assets	237	131
Total prepaid expenses and other current assets	2,784	1,652

5. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES

Accrued liabilities consist of the following:

	December 31, 2008	September 30, 2009
	($000s)	
Accrued research and development	3,653	2,464
Amount payable under license agreement	594	665
Accrued payments under guarantee		796
Other accrued liabilities	939	1,523
Total accrued liabilities	5,186	5,228

Other current liabilities consist of the following:

	December 31, 2008	September 30, 2009
	($000s)	
Accrued compensation	707	132
Proposed preference dividend	307	921
Other current liabilities	601	283
Total other current liabilities	1,615	1,336

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6. STOCK BASED COMPENSATION

Stock-based compensation was reported within expense line items on the consolidated statement of operations for the three and nine months ended September 30, 2008 and 2009 as shown in the following table:

	For the three months ended September 30,		For the nine months ended September 30,	
	2008	2009	2008	2009
	($000s)		($000s)	
Research and development	127	68	548	121
General and administrative	127	289	654	404
Stock-based compensation costs before income taxes	254	357	1,202	525

The number of shares reserved under the 2006 Plan is 5,200,000 shares of the Company s common stock. 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 nine months ended September 30, 2009 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in $000s)
Options outstanding at December 31, 2008	3,674,899	$ 4.36	8.74	2
Granted	221,000	$ 0.39		
Exercised				
Expired				
Cancelled / forfeited	356,966	$ 4.31		
Options outstanding at September 30, 2009	3,538,933	$ 4.14	8.04	548
Unvested at September 30, 2009	1,997,925	$ 2.39	8.70	544
Vested and exercisable at September 30, 2009	1,541,008	$ 6.40	7.19	4

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 (and still outstanding), 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.

Effective January 1, 2006, the Company elected to recognize all share-based awards issued after the adoption of ASC 718 under the straight-line attribution method. ASC 718 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.

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The Company used the Black-Scholes option-pricing model with the following assumptions for stock option grants to employees and directors for the nine months ended September 30, 2008 and 2009:

	For the nine months ended September 30,	
	2008	2009
Expected term	1 6 Yrs	0.75 5 Yrs
Risk free interest rate	2.15 3.76%	0.325 1.84%
Expected volatility	45 75%	65 169%
Expected dividend yield over expected term		
Resulting weighted average grant fair value	$2.11	$0.39

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 as a public company, the expected volatility assumption was based on the historical volatility of peer companies over the expected term of the option awards.

Estimates of pre-vesting option forfeitures are based on the Company s experience. Currently the Company uses a forfeiture rate of 20% 75% 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. During both quarters ended September and June 30, 2009 the Company 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. For the nine months ended September 30, 2009, the Company recognized a net cumulative charge of approximately $0.5 million with respect to the revised forfeiture rates.

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.

Dividend yield has been assumed to be zero as (a) the Company has never declared or paid any dividends and (b) does not currently anticipate paying any cash dividends on its outstanding shares of common stock in the foreseeable future.

There were no exercises of stock options during the three and nine months ended September 30, 2008 and 2009. As the Company presently has tax loss carry forwards from prior periods and expects to incur tax losses in 2009, the Company is not able to benefit from the deduction for exercised stock options in the current reporting period.

No equity instruments were settled in cash for the three and nine months ended September 30, 2008 and 2009.

In accordance with the terms of a retirement agreement with a former employee, the Company agreed to extend the period during which the former employee would be entitled to exercise vested stock options to purchase Cyclacel s common stock from thirty (30) days following the effective date of his retirement, January 8, 2008, to thirty six (36) months following such effective date. The Company recorded a one time compensation expense related to the modification of the exercise period of $0.1 million for the three months ended March 31, 2008.

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Related to the workforce reduction in the second and third quarters of 2009, the Company amended the exercise period in which the employees would be able to exercise their vested stock options from thirty (30) days post termination date to nine months. In addition, the Company allowed the individuals to continue to vest stock options until November 18, 2009 as if they were still employed in recognition of past work. Per ASC 718, the Company considered the change in terms as a modification to performance condition or whereby the modification depends on the probability of achievement of the original performance condition immediately before and after the award. The modification is considered as improbable to probable or a Type III modification. As a result the Company recorded stock-based compensation expense of $0.3 million during the second quarter of 2009.

Restricted Stock

In November 2008, the Company issued restricted common stock to a senior executive of the Company 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 nine months ended September 30, 2009 is as follows:

	Restricted Common Stock	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2008	50,000	$ 0.44
Granted		
Non-vested at September 30, 2009	50,000	$ 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. There were no restricted stock unit grants prior to November 2008.

Summarized information for restricted stock grants for the nine months ended September 30, 2009 is as follows:

	Restricted Common Units	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2008	91,700	$ 0.44
Granted		
Non-vested at September 30, 2009	91,700	$ 0.44

Related to the workforce reduction in the second quarter of 2009, the Company amended the exercise period in which the employees would be able to exercise their vested stock options from thirty days post termination date to nine months. In addition, the Company allowed the individual to continue to vest the restricted stock units until November 18, 2009 as if they were still employed in recognition of past work.

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7. COMMITMENTS AND CONTINGENCIES

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 September 30, 2009, the Bothell accrued restructuring liability was $1.6 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, which is also reflected as a restructuring charge. 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 $0.1 million over the remaining term of the lease.

As a result of the Company s continual review of its operating plan additional actions were implemented further to the restructuring plan announced in September 2008. An additional restructuring accrual of $0.4 million was recorded in connection with the severance payments liability incurred during the second quarter of 2009 (see Restructuring Expense under footnote 2).

The restructuring accrual at September 30, 2009 is as follows:

	$000s
Restructuring provision at December 31, 2008	2,091
Restructuring expense for the current period	366
Payments made in the period	(1,127)
As of September 30, 2009	1,330
Less: amounts due within one year	(1,063)
Other accrued restructuring charges long term	(267)

In connection with the abandonment of the Bothell facility and the related sale of assets in late 2005, the Company has been subjected to a State sales tax audit by the Department of Revenue of the State of Washington. Based on an evaluation of the underlying asset dispositions and State tax law, the Company believes that the potential loss from the ultimate settlement of the assessment ranges from $270,000 to $1 million. Based on this evaluation the Company continues to accrue $270,000 plus related estimated interest costs of approximately $80,000 as a State tax assessment on the consolidated balance sheet as of September 30, 2009.

Guarantee

On July 28, 2005, as 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.

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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 September 30, 2009), 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 will be paid during the first quarter of 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 September 30, 2009 (see Footnote number 5).

8. ACQUISITIONS

Acquisition of ALIGN

On October 5, 2007, the Company purchased certain net assets of ALIGN Pharmaceuticals, LLC (ALIGN) including exclusive rights to sell and distribute three products in the United States, Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges used primarily to manage the effects of radiation or chemotherapy in cancer patients: The acquired business provides Cyclacel with the foundation to build a commercial organization focused on cancer that is complementary to Cyclacel s oncology/hematology products in development and is part of Cyclacel s strategy to build a diversified biopharmaceutical business.

The transaction was accounted for as a business combination and the assets and certain agreed liabilities of ALIGN were recorded, as of the closing date, at their estimated fair values. As part of the Company s annual impairment analysis during the third quarter of 2008, it was determined that the intangible assets, when treated as an asset group in accordance with ASC 360, *Accounting for the impairment or Disposal of Long-Lived Assets* (ASC 360), were not recoverable as the sum of the undiscounted cash flows was lower than the carrying value and therefore should be impaired. Consequently the fair value of these assets was determined by using the income based valuation methodology. This resulted in the requirement to recognize an impairment charge of $3.6 million. In December 2008, goodwill allocated to our ALIGN reporting unit following the ALIGN acquisition was fully written down in accordance with ASC 350, *Goodwill and Other Intangible Assets* (ASC 350) resulting in an impairment charge of approximately $1.6 million being recognized on the consolidated statement of operations. In determining the impairment charge, we considered the negative impact the current economic situation might have on sales growth expectations of the ALIGN products resulting in a downward revisions of projected net cash flows from product sales. These factors caused the discounted cash flows for the reporting unit to be less than its carrying value on December 31, 2008.

Under the terms of the asset purchase agreement, the Company paid, as part of securing long term supply arrangements, approximately $0.6 million in May 2009 with a further $0.7 million payable in June 2010. The present value of the June 2010 commitment is reported as other short term payables on the condensed consolidated balance sheet as of September 30, 2009.

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Acquisition of Xcyte Therapies Inc.

On March 27, 2006, Xcyte Therapies Inc. (Xcyte) completed a Stock Purchase Agreement with Group, a public company organized under the laws of England and Wales in which Xcyte agreed to purchase from Group all of the capital stock of Cyclacel Limited, a private limited company organized under the laws of England and Wales and a wholly-owned subsidiary of Group. For more information please see the Company s Annual Report on Form 10-K for the year ended December 31, 2006 as filed with the SEC.

9. STOCKHOLDERS EQUITY

Preferred stock

As of September 30, 2009, there were 2,046,813 6% convertible exchangeable preferred shares issued and outstanding at an issue price of $10.00 per share. Dividends on the Preferred Stock are cumulative from the date of original issue 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. Since inception through April 6, 2009, the Company paid these dividends when they have fallen due. However, as part of the Company s program to reduce expenditure, on April 6, 2009, June 22, 2009 and October 19, 2009, the Company s Board of Directors passed a resolution to suspend payment of, but continue to accumulate, the quarterly cash dividend. The Board of Directors will continue to evaluate the payment of a quarterly cash dividend on a quarterly basis.

To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are accumulated. If the Company fails to pay an aggregate amount equal to at least six quarterly dividends (whether or not consecutive) on the Preferred Stock, the size of the Company s Board of Directors will be increased by two members and the holders of the Preferred Stock, voting separately as a class, will have the right to vote to fill the two vacancies created thereby until the Company pays all accumulated but unpaid dividends, at which time the size of the Company s Board of Directors will be decreased by two members and the two directors appointed by the Preferred Stock holders will resign.

The Preferred Stock has a liquidation preference of $10 per share, plus accumulated and unpaid dividends. Each quarterly dividend distribution currently totals approximately $0.3 million.

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 Since inception through September 30, 2009, holders have voluntarily converted 943,187 shares of Preferred Stock into common stock. The Company has reserved 870,980 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at September 30, 2009.

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

Common Stock

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 of (i) one share of the Company s common stock, par value $0.001 per share (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 have a seven-month 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 $1.00 per share of Common Stock. 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 will be exercisable at an exercise price of $1.00 per share of Common Stock. 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.

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As of September 30, 2009, the warrants issued to the investors have been classified as equity in accordance with ASC 840. The transaction date fair value of the Series I Warrants of $1.0 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 0.26%, expected volatility 125%, expected dividend yield 0%, and a remaining contractual life of 0.58 years. 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

In December 2007, the Company entered into a Committed Equity Financing Facility, or CEFF, with Kingsbridge Capital Limited (Kingsbridge), in which Kingsbridge committed to purchase the lesser of 4,084,590 shares of common stock from Cyclacel or $60 million of capital during the next three years. Under the terms of the agreement unless amended, Cyclacel will determine the exact timing and amount of any CEFF financings, subject to certain conditions. As of September 30, 2009, the Company had not drawn down any funds under the CEFF.

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 in accordance with ASC 840. 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, 2008 and September 30, 2009, the fair value of the warrants determined utilizing the Black-Scholes option pricing model was approximately $43,000 and $0.2 million, respectively. The fair value at September 30, 2009 reflects the increase in the Company s common stock price ($0.87 at September 30, 2009; $0.42 at December 31, 2008), risk free rate of return (2.31%) and the remaining expected term of the warrants (4.38 years). During the three and nine months ended September 30, 2008, the Company recorded a gain of approximately $0.4 million and $3.3 million, respectively, as the change in value of warrants on the consolidated statement of operations. For the three months ended September 30, 2009, the Company recorded a gain of approximately $0.1 million as the change in value of warrants on the consolidated statement of operations. For the nine months ended September 30, 2009, the Company recorded a loss of approximately $0.2 million as the change in value of warrants on the consolidated statement of operations.

The following table summarizes information about warrants outstanding at September 30, 2009:

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	2012	175,000	7.17
July 2009 Series I stock issuance	2010	2,500,000	1.00
July 2009 Series II stock issuance	2014	735,522	1.00
Total		7,044,363	4.47

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Exercise of Stock Options

There were no stock option exercises during the three and nine months ended September 30, 2009 or 2008.

10. RECENT ACCOUNTING PRONOUNCEMENTS

In September 2006, FASB issued ASC 820, *Fair Value Measurements* (ASC 820). ASC 820 defines fair value, establishes acceptable methods of measuring fair value and expands disclosures for fair value measurements required under other accounting pronouncements, but does not change existing guidance as to whether an instrument or transaction is measured at fair value. ASC 820 became partially effective for us on January 1, 2008. However, ASC 820, *Effective Date of FASB Statement No. 157* , delayed for us the effective date of ASC 820 until January 1, 2009 for nonrecurring fair value measurements of nonfinancial assets and nonfinancial liabilities. The full adoption of ASC 820 did not have a material impact on the Company s financial statements.

In December, 2007, FASB issued ASC 805, *Business Combinations* (ASC 805), which requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date. ASC 805 requires, among other things, that in a business combination achieved in stages (sometimes referred to as a step acquisition), that the acquirer recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values (or other amounts determined in accordance with ASC 805). ASC 805 also requires the acquirer to recognize goodwill as of the acquisition date, measured as a residual, which in most types of business combinations will be the excess of the consideration transferred plus the fair value of any non-controlling interest in the acquiree at the acquisition date over the fair values of the identifiable net assets acquired.

In November 2008, FASB ratified the final consensuses reached in ASC 323, *Equity Method Investment Accounting Considerations* and ASC 350, *Accounting for Defensive Intangible Assets* . ASC 323 resolves several accounting issues that arise in applying the equity method of accounting. Most of these issues arise or become more prevalent upon the effective date of ASC 805 or ASC 810. ASC 350 provides guidance on the initial and subsequent measurement of defensive assets acquired in a business combination, apart from acquired in-process research and development assets.

In April 2009, FASB issued FASB Staff Position ASC 805, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies* (ASC 805). This staff position amends ASC 805 to address application issues around the recognition, measurement, and disclosure of assets and liabilities arising from contingencies in a business combination.

ASC 805, ASC 810, ASC 323, ASC 350, and FSP ASC 805-1 all apply prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The adoption of these pronouncements did not have an impact on the Company s financial statements.

In April 2009, FASB issued ASC 320 and ASC 958, *Recognition and Presentation of Other-Than-Temporary Impairments* (ASC 320). This staff position amends the guidance in U.S. GAAP in assessing whether debt securities have experienced an other-than-temporary impairment and, if so, how to recognize the impairment loss in the financial statements. Prior to the issuance of the staff position, an other-than-temporary impairment loss was recognized for investments in debt securities unless the investor could positively assert that it had both the intent and the ability to hold the security for a period of time sufficient to allow for an anticipated recovery in its fair value to its amortized cost basis. Under ASC 320, an other-than-temporary impairment loss would only be recognized if the investor has the intent to sell the debt security, or more likely than not will be required to sell the debt security, before its anticipated recovery (for example, if its cash or working capital requirements or contractual or regulatory obligations indicate that the debt security will be required to be sold before the forecasted recovery occurs). In addition, the staff position clarifies that if the entity does not intend to sell the debt security and it is not more likely than not that the entity will be required to sell the debt security before the anticipated recovery of its remaining amortized cost basis, any credit losses (i.e., the difference between the present value of the cash flows expected to be collected and the amortized cost basis) must be recognized as a loss in the income statement, while other changes in the fair value of the debt security would be reported in other comprehensive income, a component of shareholders equity. In all other circumstances where an other-than-temporary impairment loss has been incurred, the entire change in fair value would be recognized as an impairment loss in the income statement. ASC 320 was effective for interim

and annual reporting periods ending after September 15, 2009, and was applied to existing and new investments held by an entity as of the beginning of the interim period in which it is adopted. The adoption of this staff position did not have a material effect on the Company s financial statements.

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In April 2009, FASB issued ASC 825 and ASC 270, *Interim Disclosures about Fair Value of Financial Instruments* (ASC 825 and ASC 270). This staff position amends existing U.S. GAAP to require publicly traded companies to present disclosures about fair value of financial instruments in interim reporting periods. The staff position became effective for the Company during the quarter ended September 30, 2009. The adoption of ASC 825 and ASC 270 did not have a material effect on the Company s financial statements.

In April 2009, FASB issued ASC 820, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly,* and ASC 320 and ASC 958, *Recognition and Presentation of Other-Than-Temporary Impairments.* In addition, FASB issued another ASC 825 and ASC 270, *Interim Disclosures about Fair Value of Financial Instruments,* which requires publicly traded companies to provide certain fair value disclosures in their interim reports, not just their annual reports. ASC 320 and ASC 958 are intended to provide greater clarity to investors about the credit and noncredit component of an OTTI event and to more effectively communicate when an OTTI event has occurred. The FSP applies to debt securities and requires that the total OTTI be presented in the statement of income with an offset for the amount of impairment that is recognized in other comprehensive income, which is the noncredit component. Noncredit component losses are to be recorded in other comprehensive income if an investor can assess that (a) it does not have the intent to sell or (b) it is not likely that it will have to sell the security prior to its anticipated recovery. The FSP was effective for interim and annual periods ending after September 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The FSP was applied prospectively with a cumulative effect transition adjustment as of the beginning of the period in which it is adopted. An entity early adopting this FSP must also early adopt FSP ASC 820-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* . The adoption of ASC 320 and ASC 958 did not have a material effect on the Company s condensed consolidated financial statements.

In May 2009, the FASB issued ASC 855, *Subsequent Events* (ASC 855), which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855 also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. ASC 855 is effective for interim and annual periods ending after June 15, 2009 and will be effective for the Company beginning with its interim period June 30, 2009. Since ASC 855 at most requires additional disclosures, the Company does not expect the adoption to have a material impact on its consolidated financial position, results of operations or cash flows.

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In June 2009, the FASB issued FAS 168, *The FASB Accounting Standards Codification* and *the Hierarchy of Generally Accepted Accounting Principles*, which establishes the FASB Accounting Standards Codification (Codification) as the source of authoritative US GAAP recognized by the FASB to be applied to nongovernmental entities. Codification does not change current U.S. GAAP but is intended to simplify user access to all authoritative US GAAP by providing all the authoritative literature related to a particular topic in one place. All existing accounting standard documents will be superseded and all other accounting literature not included in the Codification will be considered non-authoritative. Rules and interpretive releases of the SEC under authority of federal securities laws are also included in the Codification as sources of authoritative US GAAP for SEC registrants. FAS 168 and the Codification are effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification is effective for the Company during its interim period ending September 30, 2009 and did not have an impact on its financial condition or results of operations.

11. SUBSEQUENT EVENT

On October 19, 2009, the Board of Directors decided not to declare the payment of the quarterly cash dividend on the Preferred Stock scheduled for November 1, 2009. To the extent that any dividends payable on the Preferred Stock are not paid the unpaid dividends are accumulated. The Board of Directors will continue to evaluate the payment of a quarterly cash dividend on a quarterly basis. If the Company fails to pay an aggregate amount equal to at least six quarterly dividends (whether or not consecutive) on the Preferred Stock, the size of the Company s Board of Directors will be increased by two members and the holders of the Preferred Stock, voting separately as a class, will have the right to vote to fill the two vacancies created thereby until the Company pays all accumulated but unpaid dividends, at which time such the size of the Company s Board of Directors will be decreased by two members and the Directors appointed by the Preferred Stock holders will resign.

On October 21, 2009, Cyclacel received a letter from The NASDAQ Stock Market notifying the Company that it had been granted an extension of time to regain compliance with the minimum $10 million stockholders equity requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(b)(1)(A). The Company previously announced on August 24, 2009, that it had received a letter from NASDAQ notifying Cyclacel that it was not in compliance with this requirement.

Under the terms of the extension, on or before December 7, 2009, Cyclacel must furnish to the Securities and Exchange Commission and NASDAQ a publicly available filing that, among other things, evidences compliance with the minimum $10 million stockholders equity requirement. In the event the Company does not satisfy the terms of the extension, Cyclacel expects to be notified that its securities will be subject to delisting from The NASDAQ Global Market. In that event, we may either apply for listing on The NASDAQ Capital Market, provided it meets the continued listing requirements of that market, or appeal the decision to a NASDAQ Listing Qualifications Panel. In the event of an appeal, our securities would remain listed on The NASDAQ Global Market pending a decision by the Panel following the hearing.

On October 27, 2009, the Company received a notice from The NASDAQ Stock Market indicating that the Company is not in compliance with NASDAQ Listing Rule 5450(a)(1) (the Minimum Bid Price Rule) because the closing bid price per share for its common stock has been below $1.00 per share for 30 consecutive business days. In accordance with NASDAQ Listing Rules, the Company will be provided 180 calendar days, or until April 26, 2010, to regain compliance with the Minimum Bid Price Rule. The Company can achieve compliance if at any time before April 26, 2010, its common stock closes at $1.00 per share or more for at least 10 consecutive business days. This notification has no effect on the listing of the Company s common stock at this time.

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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, 2008, as updated and supplemented by Part II, Item 1A, entitled Risk Factors, of our Quarterly Reports on Form 10-Q, and elsewhere in this 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 discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Our strategy is focused on leading edge therapeutic management of cancer patients based on our clinical development pipeline led by sapacitabine and a portfolio of three products marketed by our subsidiary, ALIGN Pharmaceuticals, LLC.

We are focusing our clinical development priorities on sapacitabine and in particular the following indications:

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

We have additional ongoing programs in clinical development which are currently pending availability of clinical data. Once these 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 nasopharyngeal cancer or NPC, NSCLC and CYC116.

To date, the Phase 2 AML and MDS study has enrolled 105 AML patients and 31 MDS patients. During October 2009, we announced top-line survival data for the primary endpoint of the Phase 2 AML study. The study was a three-arm randomized trial evaluating three dosing schedules of sapacitabine. The primary endpoint of 1-year survival was approximately 30% each on two out of the three schedules tested. A Phase 2 randomized trial in CTCL will be closed.

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In September 2008, we announced a revision of our operating plan and that we plan to concentrate our resources on the advancement of our lead drug sapacitabine. Consistent with the operating plan during the second quarter of 2009, we further reduced our workforce across all locations by twenty six (26) people making a total reduction of fifty one (51) people, or 63% of the workforce since September 2008. With these reductions and its cost-containment efforts, we currently anticipate that our cash and cash equivalents of approximately $14.4 million as of September 30, 2009, are sufficient to meet the Company s anticipated short-term working capital needs and fund its current operations, including on-going sapacitabine clinical trials, for the next twelve months. To continue operations beyond that time or in order to undertake further development activity, the company would need to raise additional finance

Our pipeline and expertise in cell cycle biology

Our core area of expertise is in cell cycle biology or the processes by which cells divide and multiply. 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. Our pipeline includes three clinical-stage anticancer drugs that act on the cell cycle including sapacitabine, a nucleoside analogue, seliciclib, a cyclin dependent kinase or CDK inhibitor and CYC116, an Aurora kinase/Vascular Endothelial Factor Receptor 2 or AK/VEGFR2 inhibitor. 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 seliciclib is the only orally available CDK inhibitor currently in Phase 2 trials. We have also discovered several additional molecules which are in preclinical stages. We have retained rights to commercialize our clinical development candidates and our business strategy is to enter into selective partnership arrangements with these programs.

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 September 30, 2009, 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 September 30, 2009, our accumulated deficit during the development stage was approximately $217.9 million. We expect to continue incurring substantial losses for the next several years as we continue to focus our clinical development efforts on sapacitabine. Our operating expenses comprise research and development expenses and selling, 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 September 30, 2009 totaling approximately $8.2 million of which approximately $1.5 million is derived from product sales, approximately $3.0 million from fees under collaborative agreements and approximately $3.7 million of grant revenue from various United Kingdom government grant awards.

Subsequent Events

On October 19, 2009, our Board of Directors decided not to declare the quarterly cash dividend on our 6% Convertible Exchangeable Preferred Stock, or Preferred Stock, with respect to the third quarter of 2009 that would have otherwise been payable on November 1, 2009. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are accumulated. In addition, if we fail to pay an aggregate amount equal to at least six quarterly dividends (whether or not consecutive) on the Preferred Stock, the size of our Board of Directors will be increased by two members and the holders of the Preferred Stock, voting separately as a class, will have the right to fill the two vacancies created thereby until we pay all accumulated but unpaid dividends, at which time the size of our Board of Directors will be decreased by two members and the directors appointed by the Preferred Stock holders will resign. The Board of Directors also did not declare the quarterly cash dividend with respect to the first and second quarters of 2009. Our Board of Directors will continue to evaluate the payment of the cash dividend on a

quarterly basis.

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On October 21, 2009, we received a letter from The NASDAQ Stock Market notifying us that we had been granted an extension of time to regain compliance with the minimum $10 million stockholders equity requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(b)(1)(A). We previously announced on August 24, 2009, that we had received a letter from NASDAQ notifying us that we were not in compliance with this requirement.

Under the terms of the extension, on or before December 7, 2009, we must furnish to the Securities and Exchange Commission and NASDAQ a publicly available filing that, among other things, evidences compliance with the minimum $10 million stockholders equity requirement. In the event we do not satisfy the terms of the extension, we expect to be notified that our securities will be subject to delisting from The NASDAQ Global Market. In that event, we may either apply for listing on The NASDAQ Capital Market, provided we meet the continued listing requirements of that market, or appeal the decision to a NASDAQ Listing Qualifications Panel. In the event of an appeal, our securities would remain listed on The NASDAQ Global Market pending a decision by the Panel following the hearing.

On October 27, 2009, we received a notice from The NASDAQ Stock Market indicating that the Company is not in compliance with NASDAQ Listing Rule 5450(a)(1) (the Minimum Bid Price Rule) because the closing bid price per share for our common stock has been below $1.00 per share for 30 consecutive business days. In accordance with NASDAQ Listing Rules, we will be provided 180 calendar days, or until April 26, 2010, to regain compliance with the Minimum Bid Price Rule. We can achieve compliance if at any time before April 26, 2010, our common stock closes at $1.00 per share or more for at least 10 consecutive business days. This notification has no effect on the listing of our common stock at this time.

Intangibles

As part of the acquisition of ALIGN, on October 5, 2007, we acquired rights to a license agreement with Sinclair as well as to various customer relationships which allowed us to exclusively sell and distribute Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges in the United States. We also assumed all rights to the ALIGN trade name, as well as non-compete agreements signed between ALIGN and its senior managers and a beneficial contract pricing arrangement. Following our annual impairment review of these assets, they were fully written down and an impairment charge of approximately $3.6 million was recognized in the consolidated statement of operations for the year ended December 31, 2008.

Goodwill

The Company recognized goodwill arising on the purchase transactions related to Xcyte Therapies, Inc., (Xcyte) on March 27, 2006, and ALIGN on October 5, 2007 in accordance with ASC 805 *Business Combinations* (ASC 805). We are organized as a single operating segment with two reporting units; ALIGN and Xcyte. We performed an impairment analysis of goodwill for both Xcyte and ALIGN at September 30, 2008 and of ALIGN at December 31, 2008. In September 2008, the goodwill acquired in the Xcyte transaction was written down in full and in December 2008, goodwill allocated to our ALIGN reporting unit following the ALIGN acquisition was fully written down in accordance with ASC 350. As a result, we recognized an impairment charge of approximately $4.3 million in accordance with ASC 350 in the consolidated statement of operations for the year ended December 31, 2008.

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Results of Operations

The results of operations for the three and nine months ended September 30, 2008 and 2009 and balance sheet data at December 31, 2008 and September 30, 2009 reflect our operations and our subsidiaries.

Three Months Ended September 30, 2008 and 2009

Revenues

The following table summarizes the components of our revenues for the three months ended September 30, 2008 and 2009:

	Three months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Product revenue	257	223	(34)	(13)
Grant revenue	12	7	(5)	(42)
Total revenue	269	230	(39)	(14)

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. Product revenue decreased by $34,000 from $257,000 for the three months ended September 30, 2008 to $223,000 for the three months ended September 30, 2009. 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. Grant revenue decreased from $12,000 for the three months ended September 30, 2008 to $7,000 for the three months ended September 30, 2009.

The future

We expect that grant revenue will decrease as we focus our expenditure on the advancement of sapacitabine, which is currently in Phase 2 clinical trials, and away from grant qualifying research expenditure.

Cost of goods sold

	Three months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Cost of goods sold	120	163	43	36

Total cost of sales represented 47% and 73% of product revenue for the three months ended September 30, 2008 and 2009, respectively. The increase in the cost of goods for the three months ended September 30, 2009 included an inventory provision of approximately $48,000 based upon current inventory levels, expiration dates, and future sales. Excluding the inventory provision the cost of sales for the three months ended September 30, 2009 represented 52% of product revenues. In the future, we expect to maintain these margins.

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Research and development expenses

To date, we have focused on drug discovery and development programs, with particular emphasis on orally available anticancer agents. Research and development expenses represent costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for sapacitabine, seliciclib, sapacitabine in combination with seliciclib and CYC116, the advancement of product candidates toward clinical and pre-clinical trials and the development of in-house research to advance our biomarker program and technology platforms. During 2008 and subsequently during the second and third quarters of 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. We expect that the full benefit of these cost reductions will be realized in 2009 and 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;
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 September 30, 2008 and 2009:

	Three months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Sapacitabine	1,299	1,426	127	10
Seliciclib	797	(244)	(1,041)	(131)
CYC116	183	21	(162)	(89)
Other research and development costs	1,751	191	(1,560)	(89)
Total research and development expenses	4,030	1,394	(2,636)	(65)

Total research and development expenses represented 28% and 37% of our operating expenses for the three months ended September 30, 2008 and 2009, respectively.

Research and development expenditure decreased by $2.6 million from $4.0 million for the three months ended September 30, 2008 to $1.4 million for the three months ended September 30, 2009. The reduction in costs of $2.6 million was primarily associated with the cost containment measures implemented in September 2008 and June 2009 which reduced our overall headcount and focused resources on sapacitabine. Sapacitabine costs increased by $0.1 million to $1.4 million for the three months ended September 30, 2009 from $1.3 million for the three months ended September 30, 2008, primarily due to the level of product manufacturing costs incurred in the three months to September 30, 2009 in preparation of advancing the AML indication to a Phase 3 trial. Seliciclib costs showed a net credit of $0.2 million as a result of accrued costs associated with the APPRAISE trial, which completed enrolment in the third quarter of 2008, being reversed in the current quarter as the trial sites are closed and final costs determined. In the CYC116 program, expenditures were lower by $0.2 million as costs in 2008 included higher employment related costs and costs associated with reformulation of the drug. Other research and development costs were reduced by approximately $1.6 million from $1.8 million for the three months ended September 30, 2008 to $0.2 million for three months ended September 30, 2009 due to lower employment related and overhead costs.

The future

Following our reduction of expenditure in September 2008 and September 2009 in our non-core research and development programs, we have concentrated our resources on the development of sapacitabine in three indications. We therefore expect our overall research and development expenditure in 2009 to remain lower than that in 2008. During the fourth quarter of 2009, we expect to announce Phase 2 clinical data for sapacitabine and also provide further details on our pivotal Phase 3 randomized trial plans for sapacitabine.

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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 September 30, 2008 and 2009:

	Three months ended September 30,			
	2008	2009	Difference	Difference
		($000s)		%
Total selling, general and administrative expenses	3,218	2,188	(1,030)	(32)

Total selling, general and administration expenses represented 23% and 58% of our operating expenses for the three months ended September 30, 2008 and 2009, respectively.

Our selling, general and administrative expenditure decreased by $1.0 million from $3.2 million for the three months ended September 30, 2008 to $2.2 million for the three months ended September 30, 2009. The decrease of $1.0 million in expenses was primarily attributable to a reduction in salary costs of $0.5 million, patent and license fees of $0.3 million and amortization of intangibles of $0.2 million.

The future

Following our reduction in expenditure in September 2008 and September 2009, we expect our selling, general and administrative expenditure to remain lower in 2009 than in 2008.

Goodwill and intangible asset impairment

In accordance with ASC 350, we recorded an impairment charge related to the goodwill acquired in the Xcyte transaction of approximately $2.7 million during the three months ended September 30, 2008 as a result of our market capitalization being lower than the book value of its constituent assets and liabilities as a result of our reduced common stock price. In accordance with ASC 360, we recorded an impairment charge related to the intangible assets ascribed in the ALIGN transaction of approximately $3.6 million during the three months ended September 30, 2008 as a result of the sum of the undiscounted cash flows being less than the carrying amount of the intangible assets on September 30, 2008.

Restructuring expense

As of September 30, 2009, the restructuring liability associated with exiting the Bothell facility was $1.3 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 three months ended September 30, 2009.

For the three months ended September 30, 2008 and 2009, we recorded accretion expense associated with the Bothell restructuring lease of approximately $48,000 and $29,000, respectively, on the consolidated statement of operations as interest expense. A further $0.1 million of accretion expense will be recognized over the remaining life of the lease to December 2010.

Other income (expense)

The following table summarizes other income (expense) for the three months ended September 30, 2008 and 2009:

	Three months ended September 30,			
	2008	2009	Difference	Difference
		($000s)		%
Change in valuation of warrants	432	101	(331)	(77)
Foreign exchange gain/(losses)	(4,776)	119	4,895	102
Interest income	287	7	(285)	(98)
Interest expense	(69)	(41)	28	41
Total other income (expense)	(4,126)	186	(4,312)	(105)

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Total other income and expense, increased by approximately $4.3 million from a net loss of $4.1 million for three months ended September 30, 2008 to an income of $0.2 million for the three months ended September 30, 2009. The most significant impact of other income and expense was the accounting treatment for the foreign exchange gain or losses on the intercompany loans (see below).

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 840 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.* (ASC 840). 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 September 30, 2008 and 2009, the change in the value of warrants amounted to a gain of approximately $0.4 million and $0.1 million, respectively.

The nature of intercompany funding was re-considered in September 2008 and it was concluded that, as repayment of intercompany loans 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 have been recognized in other comprehensive income. Future unrealized foreign exchange gains or losses arising on the intercompany loans will be recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable.

For the three months ended September 30, 2009, there were realized foreign exchange movements of approximately $0.1 million recorded on the consolidated statement of operations within the separate line item foreign exchange gains/(losses), within other income (expense). Unrealized foreign exchange losses of approximately $2.4 million arising on intercompany loans in the three months to September 30, 2009 due to the decrease in the strength of the United States dollar against the British pound have been recognized in other comprehensive income.

For the three months ended September 30, 2008, we recorded a loss of $4.8 million on our intercompany loans due to the strength of the United States dollar against the British pound during those three months. This was reclassified from selling, general and administrative expense for comparative purposes.

Interest income decreased by approximately $280,000 from $287,000 for the three months ended September 30, 2008 to $7,000 for the three months to September 30, 2009. This has been due to the redemption of short-term investments into cash and cash equivalents during the third quarter of 2009 and a reduction in the average balance of cash and cash equivalents for the three months ended September 30, 2009, compared to the equivalent period in 2008, and the significant reduction in interest rates.

Interest expense decreased by $28,000 from $69,000 for the three months ended September 30, 2008 to $41,000 for the three months ended September 30, 2009. In May 2009, we paid a portion of our note payable to Sinclair earlier than the contractual terms resulting in three months of interest based upon $0.7 million of principal during the three months ended September 30, 2009 compared to interest on a principal balance of $1.3 million for the three months ended September 30, 2008. During the three months ended September 30, 2009 and 2008, interest expenses included accretion expenses associated with the Bothell lease restructuring provision.

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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As the nature of funding advanced through inter-company loans is that of a long-term investment in nature, unrealized foreign exchange gains and losses on such funding are being recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable and it will have no impact on earnings.

A further accretion expense of approximately $0.1 million associated with the Bothell lease restructuring charge will be recognized over the remaining life of the lease through November 2010.

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 September 30, 2008 and 2009:

	Three months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Total income tax benefit	411	205	(206)	(50)

Research and development tax credits recoverable decreased by $0.2 million from $0.4 million for three months ended September 30, 2008 to $0.2 million for the three months ended September 30, 2009. 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 decrease is a reflection of decreased income taxes available for recovery as a consequence of the lower eligible research and development payroll expenses in the United Kingdom following the workforce reductions in September 2008 and September 2009.

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.

Nine Months Ended September 30, 2008 and 2009

Revenues

The following table summarizes the components of our revenues for the nine months ended September 30, 2008 and 2009:

	Nine months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Product revenue	590	688	98	17
Grant revenue	36	36		
Total revenue	626	724	98	16

Collaboration and research and development revenue was derived from several agreements under which we provide compounds for evaluation for an agreed consideration.

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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 as a result of the asset acquisition of ALIGN on October 5, 2007. During the nine months ended September 30, 2008 and 2009, we recorded sales of $0.6 million and $0.7 million, respectively.

Cost of goods sold

	Nine months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Cost of goods sold	315	472	157	50

Total cost of sales represented 53% and 68% of product revenue for the nine months ended September 30, 2008 and 2009, respectively. The increase in the cost of goods for the nine months ended September 30, 2009 is due to an inventory provision of $0.1 million based upon current inventory levels, expiration dates, and future sales. Excluding the inventory provision the cost of sales for the nine months ended September 30, 2009 represented 51% of product revenues.

Research and development expenses

The following table provides information with respect to our research and development expenditure for the nine months ended September 30, 2008 and 2009:

	Nine months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Sapacitabine	4,940	4,980	40	1
Seliciclib	2,408	(133)	(2,541)	(106)
CYC116	1,578	160	(1,418)	(90)
Other research and development costs	6,792	2,167	(4,625)	(68)
Total research and development expenses	15,718	7,174	(8,544)	(54)

Total research and development expenses represented 46% and 49% of our operating expenses for the nine months ended September 30, 2008 and 2009, respectively.

Research and development expenditures decreased by $8.5 million from $15.7 million for the nine months ended September 30, 2008 to $7.2 million for the nine months ended September 30, 2009. Sapacitabine costs remained stable in the nine months ended September 30, 2009 compared to the same period in 2008. Seliciclib costs decreased by $2.5 million in the nine months ended September 30, 2009 compared to the same period in 2008 primarily due to lower costs associated with the APPRAISE study as patient enrollment was completed in the third quarter of 2008 and final trial sites costs being less than originally expected. In the CYC116 program expenditure was lower by $1.4 million as costs in 2008 included higher employment related costs and costs associated with reformulation of the drug. Other research and development costs were reduced by approximately $4.6 million from $6.8 million for the nine months ended September 30, 2008 to $2.2 million for the nine months ended September 30, 2009 due to lower employment related and overhead costs.

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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 nine months ended September 30, 2008 and 2009:

	Nine months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Total selling, general and administrative expenses	11,337	6,703	(4,634)	(41)

Total selling, general and administration expenses represented 33% and 46% of our operating expenses for each of the nine months ended September 30, 2008 and 2009, respectively.

Our selling, general and administrative expenditure decreased by $4.6 million from $11.3 million for the nine months ended September 30, 2008 to $6.7 million for the nine months ended September 30, 2009. The decrease of $4.6 million in expenses was primarily attributable to patent and license fees of $1.1 million, $0.7 million of amortization charges, $1.6 million of employment costs, professional fees of $0.3 million and $0.3 million of stock-based compensation costs.

Goodwill and intangible asset impairment

In accordance with ASC 350, we recorded an impairment charge related to the goodwill acquired in the Xcyte transaction of approximately $2.7 million during the three months ended September 30, 2008 as a result of our market capitalization being lower than the book value of its constituent assets and liabilities as a result of our reduced common stock price. In accordance with ASC 360, we recorded an impairment charge related to the intangible assets ascribed in the ALIGN transaction of approximately $3.6 million during the three months ended September 30, 2008 as a result of the sum of the undiscounted cash flows are less than the carrying amount of the intangible assets on September 30, 2008.

Restructuring charge

As of September 30, 2009, the restructuring liability associated with exiting the Bothell facility was $1.3 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 nine months ended September 30, 2009.

For the nine months ended September 30, 2009, 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 $0.1 million of accretion expense will be recognized over the remaining life of the lease to December 2010.

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 nine months ended September, 2008 and 2009:

	Nine months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Payment under guarantee		(1,652)	(1,652)	100
Change in valuation of warrants	3,321	(195)	(3,516)	(106)
Foreign exchange gains/(losses)	(4,638)	(129)	4,509	97
Interest income	1,184	94	(1,090)	(92)
Interest expense	(244)	(156)	88	36
Total other income (expense)	(377)	(2,038)	(1,661)	(441)

The payment under guarantee is payable to Scottish Enterprise as a result of a reduction in our research operations (see footnote 7).

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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 840. 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 nine months ended September 30, 2008 and 2009, we recognized the change in the value of warrants as a gain of approximately $3.3 million and an expense of $0.2 million, respectively, as other income (expense) in the consolidated statement of operations.

Interest income decreased by $1.1 million from $1.2 million for the nine months ended September 30, 2008 to $0.1 million for the nine months ended September 30, 2009. The decrease is primarily attributable to lower average balances of cash and cash equivalents and short-term investments in 2009 compared to 2008.

Interest expense decreased by $88,000 from $244,000 for the nine months ended September 30, 2008 to $156,000 for the nine months ended September 30, 2009. In May 2009, we paid a portion of our note payable to Sinclair earlier than the contractual terms resulting in three months of interest based upon $0.7 million of principal during three months ended September 30, 2009 compared to interest on a principal balance of $1.3 million for the three months ended September 30, 2008.

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 nine months ended September 30, 2008 and 2009:

	Nine months ended September 30,			
	2008	**2009**	**Difference**	**Difference**
		($000s)		**%**
Total income tax benefit	1,511	796	(715)	(47)

Research and development tax credits recoverable decreased by $0.7 million from $1.5 million for the nine months ended September 30, 2008 to $0.8 million for the nine months ended September 30, 2009. 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 2009.

Liquidity and Capital Resources

The following is a summary of our key liquidity measures at December 31, 2008 and September 30, 2009:

	December 31, 2008	**September 30, 2009**	**$ Difference**	**% Difference**
		($000s)		
Cash and cash equivalents	24,220	14,433	(9,787)	(40)
Short-term investments, available for sale	1,502		(1,502)	(100)
Total cash and cash equivalents and short-term investments	25,722	14,433	(11,289)	(44)
Current assets	29,014	16,225	(12,789)	(44)
Current liabilities	8,627	9,328	(701)	(8)
Working capital	20,387	6,897	(13,490)	(66)

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At September 30, 2009, we had cash and cash equivalents and short-term investments of $14.4 million as compared to $25.7 million at December 31, 2008. The lower balance at September 30, 2009 was primarily due to the ongoing research and development of our product candidates. Since our inception, we have not generated any significant product 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 September 30, 2009, we had an accumulated deficit of $217.9 million. We currently anticipate that our cash and cash equivalents of approximately $14.4 million as of September 30, 2009 is sufficient to meet our anticipated short-term working capital needs and fund its current operations, including on-going sapacitabine clinical trials, for the next twelve months. To continue operations beyond that time or in order to undertake further development activity, we would need to raise additional financing.

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

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2009 and 2008, is summarized as follows:

	Nine months ended September 30,	
	2008	**2009**
	($000s)	
Net cash used in operating activities	(23,532)	(12,618)
Net cash provided by investing activities	21,688	1,502
Net cash (used in) provided by financing activities	(931)	2,560

Operating activities

Net cash used in operating activities decreased by $10.9 million, from $23.5 million in 2008 to $12.6 million in 2009. Net cash used in operating activities during the nine months ended September 30, 2009 of $12.6 million resulted from our net operating loss of $15.2 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 $1.4 million, a net increase in working capital of $2.0 million due to a decrease in prepaid expenses and other current assets combined with a net increase in accounts payable and other current liabilities. During the nine months ended September 30, 2009, we also paid Scottish Enterprise $0.8 million as partial payment under a guarantee to them.

The net decrease of $10.9 million in net cash used in operations was primarily due to the cessation of expenditures on development activities outside of our core projects of approximately $8.5 million and savings on selling, general and administration expenses of approximately $4.6 million and a reduction in our working capital movement.

Investing activities

Net cash provided by investing activities for the nine months ended September 30, 2009 and 2008 was approximately $1.5 million and approximately $21.7 million, respectively. For the nine months ended September 30, 2009, we redeemed all of our short-term investments of $1.5 million and did not purchase any during 2009. The decrease in investing activities of approximately $20.2 million is primarily due to us having securities totaling $27.8 million classified as short-term investment at December 31, 2007, compared to only $1.5 million at December 31, 2008. During the nine months ended September 30, 2009 and 2008, we purchased fixed assets of approximately $13,000 and $0.4 million, respectively.

Financing activities

For the nine months ended September 30, 2009 and 2008, the cash outflows for financing activities primarily related to the payment of our Preferred Stock dividend of $0.3 million and $0.9 million, respectively. On April 6, 2009 and June 22, 2009, our Board of Directors decided not to declare the quarterly cash dividend on the Company s Preferred Stock that would have otherwise been payable on May 1, 2009, August 1, 2009, respectively totaling $0.6 million. The cash inflow of $2.9 million relates to the net proceeds received from the Registered Direct financing in July 2009.

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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 to September 30, 2009, 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, cash equivalents and short-term investments will be sufficient to fund our anticipated short-term working capital needs and fund its current operations, including on-going sapacitabine clinical trials, for the next twelve months. To continue operations beyond that time or in order to undertake further development activity, we would need to raise additional finance.

We cannot 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 and timing of seeking and obtaining FDA and other regulatory approvals;
- the costs associated with establishing manufacturing and commercialization capabilities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the costs of acquiring or investing in businesses, product candidates and technologies; 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. 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.

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.

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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.

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.

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. 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 quarter 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.

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Warrants Liability

February 2007 Financing

ASC 840 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 840, 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 840, 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. The change in fair value recognized in the financial statements during the three months ended September 30, 2008 and 2009 was a gain of $0.4 million and $0.1 million, respectively, with regards to the February 2007 financing. For the nine months ended 2008 and 2009, we recorded a gain of approximately $3.3 million and a loss of approximately $0.2 million, respectively. 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.

Off-Balance Sheet Arrangements

As of September 30, 2009, we had no off-balance sheet arrangements.

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 the Company to interest rate risk consist principally of cash and cash equivalents and short-term investments. As of September 30, 2009, our cash and cash equivalents of approximately $14.4 million are invested in highly liquid money market accounts.

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 10% of the total portfolio. To minimize our exposure to adverse shifts in interest rates, we invest in short-term instruments and, at September 30, 2009, 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 September 30, 2009 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 September 30, 2009, 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.

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 re-measured into United States dollars using the average currency rate in effect for the period and assets and liabilities are re-measured into United States dollars using either historical rates or the exchange rate in effect at the end of the period. Intercompany loans with this subsidiary are denominated in United States dollars and unrealized foreign exchange gains and losses arising on these loans were recorded in the consolidated statement of operations within the separate line item foreign exchange

gains/(losses) within other income (expense) up to September 30, 2008.

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In September 2008, we reviewed the nature of the intercompany funding and concluded that the repayment of intercompany loans is not expected in the foreseeable future and that 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 have been recognized in other comprehensive income. Future unrealized foreign exchange gains or losses arising on the intercompany loans will be recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable.

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 three and nine months ended September 30, 2009, we recognized a realized loss of $9,000 and $126,000 respectively, on such transactions. Other differences on foreign currency translation arising on consolidation of $5.7 million for the nine months ended September 30, 2009 are also recorded as a movement in other comprehensive loss.

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. 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, we entered into a Committed Equity Financing Facility, or CEFF, with Kingsbridge, in which Kingsbridge committed to provide us up to $60 million of capital during the next three years. Under the terms of the CEFF unless amended, we may access capital from Kingsbridge in tranches with Kingsbridge purchasing newly issued shares of our common stock with each tranche being priced at a discount to the average market price of the common stock during an eight-day pricing period. As of September 30, 2009, we have not drawn down any funds under the CEFF.

In July 2009, we issued common stock and warrants in a registered direct offering (the Offering). Each investor received two warrants. One warrant to purchase 0.625 of one share of Common Stock (a Series I Warrant) and one warrant to purchase 0.1838805 of one share of Common Stock (a Series II Warrant . The Series I Warrants have a seven-month 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 $1.00 per share of Common Stock. 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 will be exercisable at an exercise price of $1.00 per share of Common Stock.

Item 4T. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Spiro Rombotis, our President and Chief Executive Officer, and Paul McBarron, our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Securities Exchange Act Rule 13a-15(e) and 15d-15(e)), have concluded that, based on such evaluations as of September 30, 2009, our disclosure controls and procedures are effective in ensuring that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified by the Securities and Exchange Commission s rules and regulations, and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting for the third quarter of 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting as such term is defined in Rule 13a and 15d-15 of the Exchange Act.

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PART II. OTHER INFORMATION

Item 1. Legal proceedings.

None.

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, 2008. 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 may not accept our proposed registration pathways based on Phase 2 data and therefore, we may 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 at least drugs submitted for approval as treatments for patients with acute myeloid leukemia. Therefore, we believe that to gain regulatory approval from the FDA we may 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.

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.

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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.

On October 21, 2009, Cyclacel received a letter from The NASDAQ Stock Market notifying the Company that it had been granted an extension of time to regain compliance with the minimum $10 million stockholders equity requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(b)(1)(A). The Company previously announced on August 24, 2009, that it had received a letter from NASDAQ notifying Cyclacel that it was not in compliance with this requirement.

Under the terms of the extension, on or before December 7, 2009, Cyclacel must furnish to the Securities and Exchange Commission and NASDAQ a publicly available filing that, among other things, evidences compliance with the minimum $10 million stockholders equity requirement. In the event the Company does not satisfy the terms of the extension, Cyclacel expects to be notified that its securities will be subject to delisting from The NASDAQ Global Market. In that event, we may either apply for listing on The NASDAQ Capital Market, provided we meet the continued listing requirements of that market, or appeal the decision to a NASDAQ Listing Qualifications Panel. In the event of an appeal, our securities would remain listed on The NASDAQ Global Market pending a decision by the Panel following the hearing.

On October 27, 2009, we received a notice from The NASDAQ Stock Market indicating that the Company is not in compliance with NASDAQ Listing Rule 5450(a)(1) (the Minimum Bid Price Rule) because the closing bid price per share for our common stock has been below $1.00 per share for 30 consecutive business days. In accordance with NASDAQ Listing Rules, we will be provided 180 calendar days, or until April 26, 2010, to regain compliance with the Minimum Bid Price Rule. We can achieve compliance if at any time before April 26, 2010, our common stock closes at $1.00 per share or more for at least 10 consecutive business days. This notification has no effect on the listing of our common stock at this time.

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

Economic conditions remain difficult with the continuing deterioration 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. CYC116 is currently in a Phase 1 clinical trial. 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 September 30, 2009, our accumulated deficit was $217.9 million. Our net loss for the three and nine months ended September 30, 2009 was $3.1 million and $15.2 million, respectively. Our net loss attributable to common shareholders from inception through September 30, 2009 was $256.1 million. Our initial drug candidates are in the early 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 initial 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.

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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.

Due to restrictions under United States securities laws, we have limited ability to utilize our existing shelf registration statement to raise additional capital for a period of up to one year unless the market value of our common stock increases substantially, which would delay or prevent us from raising capital under our existing shelf registration statement. There can be no assurance that our efforts to raise additional funds will be successful, or that sufficient funds will be available on satisfactory terms.

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

On December 10, 2007, 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 the lesser of 4,084,590 shares of our common stock or $60 million of our common stock, during the next three years, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock of $2.50 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; effectiveness of the registration statement; and the continued listing of our stock on The NASDAQ Global Market. As the price of our common stock has traded for some months below the minimum price required under the CEFF agreement and we have no certainty that the price of our common stock will exceed the minimum price requirements, we may never be able to access the funds available to us under the CEFF.

In addition, 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.

If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, or if the CEFF is amended, the terms may be worse than those in effect then we may be unable to access capital on favorable terms or at all.

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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 agreement, 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 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 10% 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.

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. 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 costs of acquiring or investing in businesses, products and technologies;
- 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.

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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, such as the one we announced in September 2008 and in June 2009, our operating results and financial conditions could be negatively impacted.

In September 2008 and in 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. In addition, if we should further reduce our workforce below current minimum staff levels at our research facility in Scotland before July 2014 without prior consent from the Scottish Enterprise, we may owe additional money to the Scottish Enterprise.

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 be distracting to our management.

Further workforce and expense reductions additional to those carried out in September 2008 and in 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. 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. In addition, 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. 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.

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 and CYC116. 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.

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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 U.S. 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.

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;

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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 extensive 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 extensive 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.

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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;
- 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.

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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. With the acquisition of ALIGN, the success of the commercialization of those 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.

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.

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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 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 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.

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.

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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.

We are engaged in a rapidly changing and highly competitive field. We are seeking to develop and market products that will compete with other products and drugs that currently exist or are being developed. We compete with companies that are developing small molecule drugs, as well as companies that have developed drugs or are developing alternative drug candidates for cancer or other serious disorders where there is abnormal cell proliferation. We believe that several companies are developing drugs targeting cancer that may compete with our candidates. A large number of drug candidates are in development for the treatment of leukemias, lymphomas, lung cancer and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs on the market or in clinical trials for oncology indications, including Eli Lilly, Genzyme, GlaxoSmithKline and Mayne Pharma. We believe that we are currently the only company that has an orally available CDK inhibitor in Phase 2 clinical trials. We believe that a number of companies, including AstraZeneca, Bayer-Schering, Bristol-Myers Squibb, Eisai, Pfizer, and Roche 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 is continuing to enroll patients in a Phase 2 trial and that Sanofi-Aventis has reinitiated development of alvocidib in Phase 3 clinical trials 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, Merck, jointly with Vertex, Merck KGaA, Takeda-Millennium and Sunesis and have commenced Phase 2 or Phase 1 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 and Onconova have commenced Phase 1 or Phase 2 clinical trials with Plk inhibitor candidates for oncology indications. We believe that Beiersdorf, Daiichi-Sankyo, Johnson & Johnson, MPM Medical and other companies market products for radiation dermatitis or 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.

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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 its 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. 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.

Following the acquisition of ALIGN, we now market commercialized products, and consequently 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.

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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.

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.

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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 our two lead drug candidates have composition of matter patents that expire at the earliest case in 2016 and 2014. 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.

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. 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.

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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, seliciclib, sapacitabine 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;
- 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.

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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. With respect to seliciclib we hold a license from CNRS and Institut Curie. 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. Under the CNRS/Institut Curie license, 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. 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 would be permitted 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.

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 have completed a formal process to evaluate our internal controls for purposes of Section 404, and we concluded that as of December 31, 2008, our internal control over financial reporting is effective. 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.

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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, among other things, to maintain a minimum closing bid price of $1.00 per share. 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;
- 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.

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.

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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.

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.

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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 to suspend the payment of dividends. If that was to happen, holders of preferred stock would be granted certain additional rights until such dividends were repaid.

If we continue to suspend payment of the quarterly dividends on our 6% Convertible Exchangeable Preferred Stock for a total of six quarterly dividend periods, we will have to grant additional rights to our holders of Preferred Stock with respect to the management of the Company.

On April 6, 2009, September 22, 2009 and October 19, 2009, our Board of Directors decided not to declare payment of the quarterly cash dividend on the Company s 6% Convertible Exchangeable Preferred Stock, or the Preferred Stock, scheduled for May 1, 2009, August 1, 2009 and November 1, 2009, respectively. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are accumulated. However, if we fail to pay dividends on the Preferred Stock for six quarterly dividend periods (whether or not consecutive), the size of our Board of Directors will be increased by two and the holders of the Preferred Stock will have the right to vote to fill the two vacancies created thereby until we pay all accumulated and unpaid dividends. Although our Board of Directors will continue to evaluate the payment of a quarterly cash dividend on a quarterly basis, we cannot assure you that we will be able to continue to pay the dividends and that holders of our Preferred Stock will not be granted additional rights with respect to our management.

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.

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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 Risk Factor: *Our common stock may have a volatile public trading price.*

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

If our common or convertible preferred stockholders sell substantial amounts of its stock in the public market, or the market perceives that such sales may occur, the market price of our common and convertible preferred stock could fall.

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 U.S. 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.

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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.

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.

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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 inventory of Xclair®, Numoisyn® Liquid or Numoisyn® Lozenges. Although we attempt to monitor wholesaler inventory of Xclair®, 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 and prescription trends. 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®, Numoisyn® Liquid or Numoisyn® Lozenges held by wholesalers can also cause our operating results to fluctuate unexpectedly. For the year ended December 31, 2008 and the nine months ended September 30, 2009, approximately 85% and 80%, respectively, of our product sales in the United States were to two wholesalers, Cardinal Health, Inc. and McKesson Corp. 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. We also rely on third party data to assist us in monitoring estimated pharmacy and other non-wholesaler inventory levels and prescription trends. The information provided by third parties to quantify inventory levels and prescriptions trends is inherently uncertain and may not be accurate. Because the methodology behind the third party information is proprietary, we are unable to quantify why third party estimates of inventory and of prescription trends for Xclair®, Numoisyn® Liquid or

Numoisyn® Lozenges may be accurate or inaccurate quarter to quarter.

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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 national 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.

We may not be able to obtain approval in Canada to market Numoisyn® Liquid.

Numoisyn® Liquid is currently approved for marketing in the United States and we own the rights to market the drug in Canada. There is no guarantee that we will be able to obtain approval to market Numoisyn® Liquid in Canada and hence market the drug and earn potential sales revenue in Canada.

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

None.

Item 3. Defaults upon Senior Securities.

On October 19, 2009, our Board of Directors decided not to declare the quarterly cash dividend on the Company s 6% Convertible Exchangeable Preferred Stock scheduled for November 1, 2009. The aggregate amount of dividends that would have been paid is $307,022.

Item 4. Submissions of Matters to a Vote of Security Holders.

None.

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

CYCLACEL PHARMACEUTICALS, INC.

Dated: November 12, 2009.

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