UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

OR

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

Commission files number 0-50626

CYCLACEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ 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 ☑ 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 ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☑

As of November 14, 2011 there were 54,228,782 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, 2010	September 30, 2011 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,495	$ 27,675
Inventory	174	165
Prepaid expenses and other current assets	1,382	941
Total current assets	31,051	28,781
Property, plant and equipment (net)	408	165
Total assets	$ 31,459	$ 28,946
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,723	$ 1,101
Accrued liabilities and other current liabilities	4,132	4,797
Warrants liability	680	37
Total current liabilities	6,535	5,935
Total liabilities	6,535	5,935
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2010 and September 30, 2011; 1,213,142 shares issued and outstanding at December 31, 2010 and September 30, 2011. Aggregate preference in liquidation (including undeclared cumulative dividends) of $13,344,562 and $13,526,533 at December 31, 2010 and September 30, 2011, respectively	1	1
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2010 and September 30, 2011; 46,564,914 and 54,212,643 shares issued and outstanding at December 31, 2010 and September 30, 2011, respectively	47	55
Additional paid-in capital	266,666	276,312
Accumulated other comprehensive loss	31	49
Deficit accumulated during the development stage	(241,821)	(253,406)
Total stockholders' equity	24,924	23,011
Total liabilities and stockholders' equity	$ 31,459	$ 28,946

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

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,
	2010	2011	2010	2011	2011
Revenues:					
Collaboration and research and development revenue	$ —	$ —	$ 100	$ —	$ 3,100
Product revenue	159	164	432	524	2,846
Grant revenue	—	—	16	—	3,648
	159	164	548	524	9,594
Operating expenses:					
Cost of goods sold	76	95	310	273	1,665
Research and development	1,469	2,066	4,968	7,005	183,598
Selling, general and administrative	2,612	2,051	8,103	5,891	87,857
Goodwill and intangible impairment	—	—	—	—	7,934
Restructuring costs	—	—	—	—	2,634
Total operating expenses	4,157	4,212	13,381	13,169	283,688
Operating loss	(3,998)	(4,048)	(12,833)	(12,645)	(274,094)
Other income (expense):					
Costs associated with aborted 2004 IPO	—	—	—	—	(3,550)
Payment under guarantee	—	—	—	—	(1,652)
Change in valuation of derivative	—	—	—	—	(308)
Change in valuation of warrants	73	440	(443)	643	6,713
Warrant re-pricing	—	—	—	—	(44)
Foreign exchange (losses)/gains	(25)	28	(63)	(59)	(4,314)
Interest income	7	9	24	33	13,713
Interest expense	(7)	—	(40)	—	(4,677)
Total other income (expense)	48	477	(522)	617	5,881
Loss before taxes	(3,950)	(3,571)	(13,355)	(12,028)	(268,213)
Income tax benefit	143	126	506	443	18,322
Net loss	(3,807)	(3,445)	(12,849)	(11,585)	(249,891)
Dividends on preferred ordinary shares	—	—	—	—	(38,123)
Deemed dividend on convertible exchangeable preferred shares	—	—	(2,915)	—	(3,515)
Dividend on convertible exchangeable preferred shares	(182)	(182)	(585)	(546)	(3,475)
Net loss applicable to common shareholders	$ (3,989)	$ (3,627)	$ (16,349)	$ (12,131)	(295,004)
Net loss per share — Basic and diluted	$ (0.11)	$ (0.07)	$ (0.47)	$ (0.25)	
Weighted average common shares outstanding	**37,030,436**	**53,711,678**	**35,125,522**	**48,981,743**	

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

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,
	2010	2011	2011
Cash flows from operating activities:			
Net loss	$ (12,849)	$ (11,585)	$ (249,891)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accretion of interest on notes payable, net of amortization of debt premium	—	—	100
Amortization of investment premiums, net	—	—	(2,297)
Change in valuation of derivative	—	—	308
Change in valuation of warrants	443	(643)	(6,713)
Warrant re-pricing	—	—	44
Depreciation and amortization	351	250	12,564
Amortization of intangible assets	—	—	886
Fixed asset impairment	—	—	221
Goodwill and intangibles impairment	—	—	7,934
Unrealized foreign exchange loss	—	(29)	7,718
Deferred revenue	—	—	(98)
Compensation for warrants issued to non-employees	—	—	1,215
Shares issued for IP rights	—	—	446
(Gain) loss on disposal of property, plant and equipment	(12)	—	99
Stock based compensation	1,390	677	18,818
Provision for restructuring	—	—	1,779
Amortization of issuance costs of Preferred Ordinary “C” shares	—	—	2,517
Changes in operating assets and liabilities:			
Prepaid expenses, inventory and other current assets	675	450	218
Accounts payable, accrued liabilities and other current liabilities	(2,300)	162	(5,728)
Net cash used in operating activities	(12,302)	(10,718)	(209,860)
Investing activities:			
Purchase of ALIGN	—	—	(3,763)
Purchase of property, plant and equipment	(8)	(6)	(8,837)
Proceeds from sale of property, plant and equipment	35	—	158
Purchase of short-term investments	—	—	(156,657)
Redemptions of short-term investments, net of maturities	—	—	162,729
Net cash provided by (used in) investing activities	27	(6)	(6,370)
Financing activities:			
Payment of capital lease obligations	—	—	(3,719)
Proceeds from issuance of ordinary and preferred ordinary shares, net of issuance costs	—	—	121,678
Proceeds from issuance of common stock and warrants, net of issuance costs	16,572	9,258	91,662
Net proceeds from stock options and warrants exercised	2,710	3	173
Payment of preferred stock dividend	—	(364)	(1,898)

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,
	2010	2011	2011
Repayment of government loan	—	—	(455)
Government loan received	—	—	414
Loan received from Cyclacel Group Plc	—	—	9,103
Proceeds of committable loan notes issued from shareholders	—	—	8,883
Loans received from shareholders	—	—	1,645
Cash and cash equivalents assumed on stock purchase	—	—	17,915
Costs associated with stock purchase	—	—	(1,951)
Net cash provided by financing activities	19,282	8,897	243,450
Effect of exchange rate changes on cash and cash equivalents	(18)	7	455
Net increase (decrease) in cash and cash equivalents	6,989	(1,820)	27,675
Cash and cash equivalents at beginning of period	11,493	29,495	—
Cash and cash equivalents at end of period	$ 18,482	$ 27,675	$ 27,675
Supplemental disclosure of cash flows information:			
Cash received during the period for:			
Interest	14	20	11,735
Taxes	1,067	688	18,210
Cash paid during the period for:			
Interest	(155)	—	(1,914)
Schedule of non-cash transactions:			
Acquisitions of equipment purchased through capital leases	—	—	3,470
Issuance of common 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.

CYCLACEL PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Nature of Operations

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

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

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

On January 11, 2011, the Company opened enrollment of the SEAMLESS pivotal Phase 3 trial for the Company’s sapacitabine oral capsules as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy under a Special Protocol Assessment, or SPA, reached with the U.S. Food & Drug Administration, or FDA. SEAMLESS is a randomized study against an active control drug with the primary objective of demonstrating an improvement in overall survival. In October 2011, the independent Data Safety Monitoring Board, or DSMB, of SEAMLESS recommended that the study should enter the randomized stage as planned and, following this recommendation, the Company has implemented an improvement in the SEAMLESS trial design, converting it into a 2-arm from a 3-arm design. The Company received written confirmation from the FDA that, following the modification in the trial design, the previously agreed SPA agreement remains valid.

The Company has advanced two additional product candidates, seliciclib in Phase 2 for NSCLC and nasopharyngeal cancer or NPC, and CYC116 in Phase 1 clinical development. The combination of sapacitabine with seliciclib is also being evaluated in a Phase 1 clinical trial. The Company will determine the feasibility of pursuing further development and/or partnering these assets depending on the availability of funding and further clinical data. In addition, the Company markets directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia.

As a development stage enterprise, substantially all efforts of the Company to date have been devoted to performing research and development, conducting clinical trials, developing and acquiring intellectual property and raising capital.

Basis of Presentation

The condensed consolidated balance sheet as of September 30, 2011, the condensed consolidated statements of operations for the three and nine months ended September 30, 2011 and 2010 and for the period from August 13, 1996 (inception) to September 30, 2011, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2011 and 2010 and for the period from August 13, 1996 (inception) to September 30, 2011, and related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2010 is derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission (“SEC”). The condensed consolidated financial statements are presented on the basis of accounting principles that are generally accepted in the United States (“GAAP”) 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, 2011, the results of operations for the three and nine months ended September 30, 2011 and 2010 and for the period from August 13, 1996 (inception) to September 30, 2011, and the consolidated statements of cash flows for the nine months ended September 30, 2011 and 2010 and for the period from August 13, 1996 (inception) to September 30, 2011, have been made. The interim results for the three and nine months ended September 30, 2011 are not necessarily indicative of the results to be expected for the year ending December 31, 2011 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 included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC.

Recent Developments

July 2011 Underwritten Offering

On July 7, 2011, the Company closed an underwritten offering for an aggregate of 7,617,646 units, at an offering price of $1.36 per unit, for gross proceeds of approximately $10.4 million. Each unit consists of (i) one share of common stock and (ii) a five-year warrant to purchase 0.5 of a share of common stock at an exercise price of $1.36 per share, exercisable beginning six months after the date of issuance, or after January 7, 2012. The shares of common stock and warrants were immediately separable and were issued separately such that no units were issued. The net proceeds, after underwriting discounts and commissions and other fees and expenses, were approximately $9.3 million.

NASDAQ Notification

On September 16, 2011, the Company received a NASDAQ Staff Deficiency Letter indicating the Company was not in compliance with the minimum bid price requirement for continued listing on the NASDAQ exchange because the bid price for the Company's common stock had closed under $1.00 for 30 consecutive business days. The Company may achieve compliance if, at any time before March 14, 2012, the bid price of its common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days. Failure to achieve compliance may result in the removal of Company's common stock listing on the NASDAQ exchange.

Preferred Stock Dividend

On October 6, 2011, the Board of Directors (the "Board") decided not to declare the quarterly cash dividend on the Company's 6% Convertible Exchangeable Preferred Stock ("Preferred Stock") with respect to the third quarter of 2011 that would have otherwise been payable on November 1, 2011.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Consolidation

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

Use of Estimates

The preparation of financial statements in accordance with GAAP 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 income and expenses during the reporting period. The Company reviews its estimates on an ongoing basis. The estimates are 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 and cash equivalents are stated at cost, which is substantially the same as fair value. The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. The Company's cash equivalents generally include investments in money market funds and corporate commercial paper.

Trade Accounts Receivable and Allowance for Doubtful Accounts

An allowance for doubtful accounts is provided, as necessary, on trade receivables based on their respective aging categories and historical collection experience, taking into consideration the type of payer, historical and projected collection outcomes, and current economic and business conditions that could affect the collectability of the Company's receivables. The allowance for doubtful accounts is reviewed, at a minimum, on a quarterly basis. Changes in the allowance for doubtful accounts are recorded as an adjustment to bad debt expense within general and administrative expenses. Material revisions to reserve estimates may result from adverse changes in collection experience. The Company writes off accounts against the allowance for doubtful accounts when reasonable collection efforts have been unsuccessful and it is likely the receivable will not be recovered. At December 31, 2010 and September 30, 2011, all receivables were deemed collectible.

For the three months ended September 30, 2010 and 2011, approximately 92% and 87%, respectively, of the Company's product sales in the United States were to three wholesalers, respectively. For the nine months ended September 30, 2010 and 2011, approximately 88% and 89%, respectively, of the Company's product sales in the United States were to three wholesalers, respectively.

Inventory

Cyclacel values inventories at the lower of cost or market value. The Company determines cost using the first-in, first-out method. As of December 31, 2010 and September 30, 2011, all inventories were classified as finished goods. The Company analyzes its inventory levels at least quarterly to identify any items that may expire prior to sale, inventory that has a cost basis in excess of net 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. An important consideration in making this determination is future sales forecasts. The Company writes down the value of inventory to the extent that inventory is expected to expire before being sold or if the cost basis is in excess of net realizable value. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required in future periods.

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 or 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 -Products*" ("ASC 605-15") and ASC 605 -10 "*Revenue Recognition — Overall*" ("ASC 605-10"). Under these guidelines, the Company accounts for all product sales using the "sell-through" method. Under the sell-through method, revenue is not recognized upon shipment of product to distributors. Instead, the Company records deferred revenue at gross invoice sales price and deferred cost of sales at the cost at which those goods were held in inventory. The Company recognizes revenue when such inventory is sold through to pharmacies. To estimate product sold through to pharmacies, the Company relies on third-party information, including information obtained from significant distributors with respect to their inventory levels and sell-through to pharmacies. The Company estimates product returns based on historical returns experience and other factors that affect demand for the Company's products as well as the amount of product subject to return.

Deferred revenue was $0.1 million at both September 30, 2010 and 2011. Deferred cost of goods sold was approximately $27,000 and $20,000 at September 30, 2010 and 2011, respectively.

Collaboration, research and development, and grant revenue

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

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

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

Clinical Trial Accounting

Data management and monitoring of all of the Company's clinical trials are performed by contract research organizations (''CROs'') or clinical research associates (''CRAs'') 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. The Company accrues unbilled clinical trial expenses based on estimates of the level of services performed each period. Costs of setting up investigational sites for participation in the Company's clinical 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 the patient data is recorded on case report forms. Any initial payment made to the clinical trial site is recognized upon execution of the clinical trial agreements and expensed as research and development expenses.

Research and Development Expenditures

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

Foreign currency and currency translation

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

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

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

Derivative Instruments

Derivative financial instruments are measured at fair value. Significant judgments and estimates are necessary in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The use of different assumptions may have a material effect on the estimated fair value amount and the Company's results of operations.

Fair Value Measurements

Inputs used to determine fair value of financial and non-financial assets and liabilities are categorized using a fair value hierarchy that prioritizes observable and unobservable inputs into three broad levels, from Level 1, which is the most reliable, to Level 3, which is the least reliable (see "Note 3 — Fair Value Measurements"). Management reviews the categorization of fair value inputs on a periodic basis and may determine that it is necessary to transfer an input from one level of the fair value hierarchy to another based on changes in events or circumstances, such as a change in the observability of an input. Any such transfer will be recognized at the end of the reporting period.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. The Company's management has established a full valuation allowance against its deferred tax assets based on the determination that it is not more likely than not that the Company will recognize the benefits of those assets.

The Company adopted the guidance related to accounting for uncertainty in income taxes, primarily codified in ASC 740, *"Income taxes"* ("ASC 740"). ASC 740 specifies 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.

The Company records income tax benefits related to research and development tax credits, which will be claimed from H. M. Revenue & Customs, the United Kingdom's taxation and customs authority, with respect to qualifying research and development costs incurred in the same accounting period.

Stock-based Compensation

The Company grants stock options, restricted stock units and restricted stock to officers, employees and directors under the 2006 Amended and Restated Equity Incentive Plan ("2006 Plan"), which was approved on March 16, 2006 and subsequently amended and restated on April 14, 2008. The Company also has outstanding options under various stock-based compensation plans for employees and directors. These plans are described more fully in "Note 6 — Stock-Based Compensation". The Company accounts for these plans under ASC 718, "*Compensation — Stock Compensation*" ("ASC 718").

ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of the Company's common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using the Black-Scholes 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 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 current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. The Company considers many factors when estimating expected forfeitures, including type of awards granted employee class, and historical experience. Actual results and future estimates may differ substantially from current estimates.

Segments

The Company has determined its reportable segments in accordance with ASC 280, "*Segment Reporting*" ("ASC 280") and related disclosures about products, services, geographic areas and major customers. After considering its business activities and geographic reach, the Company has concluded that it operates in just 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 were determined by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. The Company's potentially dilutive shares, which include outstanding common stock options, restricted stock, restricted stock units, convertible preferred stock, and common stock warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

	September 30, 2010	September 30, 2011
Stock options	3,129,177	3,538,302
Restricted stock and restricted stock units	67,700	36,440
Convertible preferred stock	516,228	516,228
Common stock warrants	5,843,597	13,814,015
Total shares excluded from calculation	9,556,702	17,904,985

See "Note 6 — Stock Based Compensation" and "Note 8 — Stockholders' Equity" for additional information.

Comprehensive Income (Loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from August 13, 1996 (inception) to September 30,
	2010	2011	2010	2011	2011
			$000		
Net loss	(3,807)	(3,445)	(12,849)	(11,585)	(249,891)
Translation adjustment	(3,699)	2,368	302	(458)	8,320
Unrealized foreign exchange (loss) gain on intercompany loans	3,627	(2,358)	(352)	476	(8,271)
Comprehensive loss	(3,879)	(3,435)	(12,899)	(11,567)	(249,842)

Recent Accounting Pronouncements

In September 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-08, which amends the guidance in ASC 350-20, Intangibles-Goodwill and Other-Goodwill ("ASC 350-20"). The guidance simplifies how companies test goodwill for impairment by allowing companies to use a qualitative approach. The amendments in the ASU permit a company to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in ASC 350-20.The ASU is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted, including for annual and interim goodwill tests performed as of a date before September 15, 2011, if a company's financial statements for the most recent annual or interim period have not yet been issued. Adoption of the guidance is not expected to have a material impact on the Company's consolidated financial statements.

In June 2011, the FASB issued Accounting Standards ASU 2011-05 to amend the guidance on the presentation of comprehensive income in ASC 220 that would require companies to present a single statement of comprehensive income or two separate but consecutive statements, a statement of operations and a statement of comprehensive income. The proposed guidance would make the financial statement presentation of comprehensive income more prominent by eliminating the alternative to present comprehensive income within the statement of equity. The ASU will be effective for annual periods beginning after December 15, 2011, although the FASB has recently issued a proposal to defer the effective date of certain aspects of ASC 2011-5 indefinitely. Nonetheless, the adoption of the guidance will not have a material impact on the Company's consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, which amends GAAP to conform to International Financial Reporting Standards ("IFRS") fair value measurement and disclosure requirements. The amendments change the wording used to describe the requirements in GAAP for measuring fair value, changes certain fair value measurement principles and enhances disclosure requirements. This guidance is effective for annual periods beginning after December 15, 2011, applied prospectively. Adoption of the guidance is not expected to have a material impact on the Company's consolidated financial statements.

3. FAIR VALUE MEASUREMENTS

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.

Financial assets and liabilities carried at fair value on a recurring basis as of December 31, 2010 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
Cash equivalents	29,066	—	—	29,066
Warrants	—	—	680	680
Total	29,066	—	680	29,746

Financial assets and liabilities carried at fair value on a recurring basis as of September 30, 2011 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
Cash equivalents	24,014	—	—	24,014
Warrants	—	—	37	37
Total	24,014	—	37	24,051

Warrants Liability

The Company issued warrants to purchase shares of common stock under the registered direct financing completed in February 2007. These warrants are classified as liabilities for accounting purposes in accordance with ASC 815, "*Derivatives and Hedging*" ("ASC 815"). At the date of the transaction, the fair value of the warrants of $6.8 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate — 4.68%, expected volatility — 85%, expected dividend yield — 0%, and a contractual life of 7 years. The fair value of the warrant is being re-measured each reporting period, with a derivative gain or loss recognized in the consolidated statement of operations. Such gains or losses will continue to be reported until the warrants are exercised or expire. The Company used the Black-Scholes option-pricing model with the following assumptions to value the warrants:

	December 31, 2010	September 30, 2011
Exercise price	$ 8.44	$ 8.44
Expected term	3.13 Yrs.	2.38 Yrs.
Risk free interest rate	1.02%	0.32%
Expected volatility	121%	106%
Expected dividend yield over expected term	—	—

During the three months ended September 30, 2010, the Company recognized the increase in the value of warrants of approximately $0.1 million as a loss on the consolidated statement of operations. During the three months ended September 30, 2011, the Company recognized the decrease in the value of warrants of approximately $0.4 million as a gain on the consolidated statement of operations. During the nine months ended September 30, 2010, the Company recognized the $0.4 million increase in the value of warrants as a loss on the consolidated statement of operations. During the nine months ended September 30, 2011, the Company recognized the $0.6 million decrease in the value of warrants as a gain on the consolidated statement of operations. The following table reconciles the beginning and ending balance of Level 3 inputs for the nine months ended September 30, 2011:

	Level 3 $000
Balance as of December 31, 2010	680
Gain from change in valuation of warrants liability reported in earnings	(643)
Balance as of September 30, 2011	37

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	December 31, 2010	September 30, 2011
	($000s)	
Research and development tax credit receivable	660	429
Prepayments	317	324
Accounts receivable	104	102
Other current assets	301	86
Total prepaid expenses and other current assets	1,382	941

5. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES

Accrued and other current liabilities consisted of the following:

	December 31, 2010	September 30, 2011
	($000s)	
Accrued research and development	2,793	3,807
Other current liabilities	1,339	990
	4,132	4,797

6. STOCK BASED COMPENSATION

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the three and nine month periods ended September 30, 2010 and 2011 as shown in the following table:

	For the three months ended September 30,		For the nine months ended September 30,	
	2010	2011	2010	2011
		($000s)		
Research and development	116	39	281	130
General and administrative	488	182	1,109	547
Stock-based compensation costs before income taxes	604	221	1,390	677

Under the 2006 Plan, 5,200,000 shares of the Company’s common stock have been reserved. The awards granted 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, 2011 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in $000s)
Options outstanding at December 31, 2010	3,489,932	$ 3.96	7.22	938
Granted	199,500	$ 1.52		
Exercised	(6,638)	$ 0.41		
Expired	—			
Cancelled / forfeited	(144,492)	$ 6.23		
Options outstanding at September 30, 2011	3,538,302	$ 3.74	6.69	8
Unvested at September 30, 2011	788,405	$ 1.79	8.74	1
Vested and exercisable at September 30, 2011	2,749,897	$ 4.30	6.10	6

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. In addition, some recent awards made to other employees vest ratably over four years, with 1/48 of the award vesting each month.

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 performed quarterly and the forfeiture rate adjusted as necessary. Ultimately, the actual expense recognized over the vesting period is based on only those shares that vest.

The Company used the Black-Scholes option-pricing model with the following assumptions for stock option grants to employees and directors for the nine months ended September 30, 2010 and 2011:

	For the nine months ended September 30,	
	2010	2011
Expected term	5 – 6Yrs	5 – 6Yrs
Risk free interest rate	2.37 – 2.96%	1.47 – 2.29%
Expected volatility	90 – 100%	93 – 99%
Expected dividend yield over expected term	—	—
Resulting weighted average grant fair value	$1.80	$1.15

There were 199,500 options granted during the nine months ended September 30, 2011. For grants made during the nine months ended September 30, 2010 and September 30, 2011, the expected term assumption was estimated using past history of early exercise behavior and estimated expectations of future exercise behavior. Starting with the December 2010 annual grants to the Company's employees, the Company relied exclusively on its historical volatility as an input to the option pricing model as the Company's management believes that this rate will be representative of future volatility over the expected term of the options. Prior to December 2010, because the Company had been publicly traded for a limited period, 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. For outstanding options, the Company uses a forfeiture rate of 0 — 50% depending on when and to whom the options are granted. The Company adjusts its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and may impact the amount of compensation expense to be recognized in future periods.

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.

During the nine months ended September 30, 2011, 6,638 stock options were exercised resulting in approximately $3,000 of cash proceeds to the Company. During the nine months ended September 30, 2010, there were 149,313 stock options exercised for proceeds of approximately $0.1 million. As the Company presently has tax loss carry forwards from prior periods and expects to incur tax losses in 2011, the Company is not able to benefit from the deduction for exercised stock options in the current reporting period.

Restricted Stock

In November 2008, the Company issued restricted common stock to an employee subject to certain forfeiture provisions. Specifically, one quarter of the award vested 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 ratably over the vesting term. Summarized information for the restricted stock grant for the nine months ended September 30, 2011 is as follows:

	Restricted Stock	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2010	23,954	$ 0.44
Vested	(9,378)	$ 0.44
Non-vested at September 30, 2011	14,576	$ 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, 2011 is as follows:

	Restricted Stock Units	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2010	35,931	$ 0.44
Vested	(14,067)	$ 0.44
Non-vested at September 30, 2011	21,864	$ 0.44

7. COMMITMENTS AND CONTINGENCIES

Licensing Agreements

The Company has entered into licensing agreements with academic and research organizations. Under the terms of these agreements, the Company has received licenses to technology and patent applications. The Company is required to pay royalties on future sales of product employing the technology or falling under claims of patent applications.

Pursuant to the Daiichi Sankyo license under which the Company licenses certain patent rights for sapacitabine, its lead drug candidate, the Company is under an obligation to use reasonable endeavors to develop a product and obtain regulatory approval to sell a product and has agreed to pay Daiichi Sankyo an up-front fee, reimbursement for Daiichi Sankyo's enumerated expenses, milestone payments and royalties on a country-by-country basis. Under this agreement, aggregate milestone payments totaling $11.7 million could be payable subject to achievement of all the specific contractual milestones and the Company's decision to continue with these projects. The up-front fee and certain past reimbursements have been paid and, as a result of the SEAMLESS trial entering Phase 3 during the first quarter of 2011, $1.6 million was paid in July 2011. Following these milestone payments, a further $10.0 million in aggregate milestone payments could be payable. Royalties are payable in each country for the term of patent protection in the country or for ten years following the first commercial sale of licensed products in the country, whichever is later. Royalties are payable on net sales. Net sales are defined as the gross amount invoiced by the Company or its affiliates or licensees, less discounts, credits, taxes, shipping and bad debt losses. The agreement extends from its commencement date to the date on which no further amounts are owed under it. If the Company wishes to appoint a third party to develop or commercialize a sapacitabine-based product in Japan, within certain limitations, Daiichi Sankyo must be notified and given a right of first refusal to develop and/or commercialize in Japan. In general, the license may be terminated by the Company for technical, scientific, efficacy, safety, or commercial reasons on six months notice, or twelve months, if after a launch of a sapacitabine-based product, or by either party for material default. Effective July 11, 2011, the license agreement was amended to irrevocably waive a termination right Daiichi Sankyo possessed under a provision of the agreement that required the Company to obtain regulatory approval to sell sapacitabine in at least one country by September 2011, and releases the Company from all claims and liability of any kind arising under such provision. The amendment further provides that the royalty due from the Company to Daiichi Sankyo on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.

Guarantee

On June 22, 2009, the Company amended the Agreement with Scottish Enterprise ("SE") (the "Amendment"), 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 December 31, 2009), which SE had previously entered into with the Company. The Agreement provided for repayment of up to £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 million (approximately $0.8 million) was paid and the remaining amount of £0.5 million (approximately $0.8 million) was paid on January 6, 2010. In addition, should a further reduction below current minimum staff levels be effectuated before July 2014 without SE's prior consent, the Company will guarantee approximately £4 million, the amount potentially due to SE, which will be calculated as a maximum of £4 million less the market value of the shares held by SE at the time of any further reduction in research facilities.

This arrangement is accounted for as a liability and is measured at fair value. Changes in fair value are recognized in earnings. Due to the nature of the associated contingency and the likelihood of occurrence, the Company has concluded the fair value of this liability was immaterial as of December 31, 2010 and September 30, 2011.

Legal proceedings

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

8. STOCKHOLDERS' EQUITY

Preferred Stock

As of September 30, 2011, there were 1,213,142 shares of Preferred Stock issued and outstanding at an issue price of $10.00 per share. Dividends on the Preferred Stock are cumulative from the date of original issuance at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of February, May, August and November, commencing February 1, 2005. Any dividends must be declared by the Company's Board of Directors and must come from funds that are legally available for dividend payments. The Preferred Stock has a liquidation preference of $10 per share, plus accrued and unpaid dividends. Accrued and unpaid dividends on Preferred Stock were $1.4 million, or $1.15 per each share of Preferred Stock, as of September 30, 2011.

The Preferred Stock is convertible at the option of the holder at any time into the Company's shares of common stock at a conversion rate of approximately 0.42553 shares of common stock for each share of Preferred Stock based on a price of $23.50. During 2010, 833,671 shares of Preferred Stock were converted into 1,655,599 shares of the Company's common stock, which is described in more detail below. Since inception through September 30, 2011, holders have voluntarily converted 1,776,858 shares of Preferred Stock into common stock. The Company has reserved 516,228 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at September 30, 2011. The converted shares of Preferred Stock have been retired and canceled and shall upon cancellation be restored to the status of authorized but unissued shares of preferred stock, subject to reissuance by the Board of Directors as shares of Preferred Stock of one or more series.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded $35.25, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

The Certificate of Designations governing the Preferred Stock provides that if the Company fails to pay dividends on its Preferred Stock for six quarterly periods, holders of Preferred Stock are entitled to nominate and elect two directors to the Company's Board of Directors. This right accrued to the holders of Preferred Stock as of August 2, 2010 and two directors were nominated and elected at the annual meeting held on May 24, 2011.

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

From November 6, 2007, the Company may, at its option, redeem the Preferred Stock in whole or in part, out of funds legally available at the redemption prices per share stated below, plus an amount equal to accrued and unpaid dividends up to the date of redemption:

Year from November 1, 2010 to October 31, 2011	$	10.24
Year from November 1, 2011 to October 31, 2012	$	10.18
Year from November 1, 2012 to October 31, 2013	$	10.12
Year from November 1, 2013 to October 31, 2014	$	10.06
November 1, 2014 and thereafter	$	10.00

The Preferred Stock is exchangeable, in whole but not in part, at the option of the Company on any dividend payment date beginning on November 1, 2005 (the "Exchange Date") for the Company's 6% Convertible Subordinated Debentures ("Debentures") at the rate of $10 principal amount of Debentures for each share of Preferred Stock. The Debentures, if issued, will mature 25 years after the Exchange Date and have terms substantially similar to those of the Preferred Stock.

Conversion of Convertible Preferred Stock

During the nine months ended September 30, 2010, Cyclacel entered into agreements to exchange shares of the Company's Preferred Stock into shares of common stock. There were no such conversions during the three months ended September 30, 2010 or during the nine months ended September 30, 2011. The table below provides details of the aggregate activities in 2010:

	For the nine months ended September 30, 2010
Preferred shares exchanged	833,671
Common shares issued:	
At stated convertible option	354,752
Incremental shares issued under an inducement offer	1,300,847
Total common shares issued	1,655,599

ASC 260, EITF Topic D-42, "*The Effect of the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock*" ("ASC 260") requires that if convertible preferred stock is converted to other securities pursuant to an inducement offer, the Company should record the excess of (1) the fair value of all securities and other consideration transferred to the holders of the convertible preferred stock and (2) the fair value of securities issuable to the original conversion terms as an increase to net loss to arrive at a net loss attributable to common shareholders. The stockholder received more shares of the Company's common stock than would have been delivered pursuant to the original conversion terms of the Preferred Stock, pursuant to a short term inducement offer. The excess of the fair value of the common stock transferred to the stockholder over the carrying amount of the preferred stock in the Company's balance sheet at the time of the transfer was considered to be an additional return to the holder of the Preferred Stock. Specifically, the Company recorded deemed dividends related to the additional shares issued under the exchange transactions of approximately $2.9 million for the nine months ended September 30, 2010. There were no conversions during the three months ended September 30, 2011or during the nine months ended September 30, 2011.

Common Stock

July 2011 Underwritten Offering

On July 7, 2011, the Company closed an underwritten offering for an aggregate of 7,617,646 units, at an offering price of $1.36 per unit, for gross proceeds of approximately $10.4 million. Each unit consists of (i) one share of common stock and (ii) a five-year warrant to purchase 0.5 of a share of common stock at an exercise price of $1.36 per share, exercisable beginning six months after the date of issuance. The shares of common stock and warrants were immediately separable and were issued separately such that no additional units were issued. As of September 30, 2011, all warrants issued to the investors were outstanding and have been classified as equity. The transaction date fair value of the warrants was $3.5 million. Net proceeds of approximately $9.3 million, after underwriting discounts and commissions and other fees and expenses of approximately $1.1 million, were allocated based on relative transaction date fair values in the following manner: $6.8 million ($0.89 per share) and $2.5 million ($0.66 per warrant) to common shares and warrants, respectively.

October 2010 Private Placement

On October 7, 2010, the Company completed a private placement pursuant to which it sold approximately $15.2 million of its units to several institutional investors, for net proceeds of approximately $14.0 million. The units consist of one share of common stock and 0.5 of a warrant, with each whole warrant representing the right to purchase one share of common stock at an exercise price of $1.92 per share for a period of five years. As of September 30, 2011, all options and warrants issued to the investors are outstanding and have been classified as equity. The investors purchased a total of 8,323,190 units at a price of $1.82625 per unit. The investors also have the right to acquire up to 4,161,595 additional units at a price of $1.67 per unit (for $6.9 million in gross proceeds) at any time up to nine months after closing or by July 6, 2011. As of September 30, 2011, none of the additional units had been exercised and, as of July 6, 2011, the right to acquire the additional units lapsed. The transaction date fair value of the warrants and additional optional units was $5.1 million and $2.8 million, respectively. Net proceeds of approximately $14.0 million were allocated based on relative transaction date fair values in the following manner: $8.9 million ($1.07 per share), $3.3 million ($0.79 per warrant) and $1.8 million ($0.43 per optional unit) to common shares, warrants and the additional optional units, respectively.

In connection with the October 2010 private placement, the Company granted to the investors certain registration rights pursuant to a Registration Rights Agreement, dated October 7, 2010, in which the Company agreed, among other things, to register all of the shares of common stock acquired from the Company (including upon exercise of the warrants and/or the options) within thirty calendar days after the Company becomes eligible to use a registration statement on Form S-3, and use commercially reasonable efforts to have the registration statement declared effective as promptly as practicable thereafter. Upon the Company's failure to comply with the terms of the Registration Rights Agreement and certain other conditions, the Company will be required to make pro rata payments to each investor, as liquidated damages, in an amount equal to 1.5% of the aggregate purchase price paid by such investor. The Company also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the registration statement. The Company is currently in compliance with the applicable terms of the Registration Rights Agreement, and the securities that were registrable under the terms of the Registration Rights Agreement are currently subject to an effective registration statement.

January 2010 Registered Direct Financings

On January 25, 2010, the Company completed the sale of 2,350,000 units in a "registered direct" offering at a purchase price of $2.50 per unit to certain institutional investors of the Company for gross proceeds of approximately $5.9 million. Each unit consisted of one share of the Company's common stock and one warrant to purchase 0.30 of one share of its common stock. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance at an exercise price of $2.85 per share of common stock. As of September 30, 2011, warrants issued to the investors have been classified as equity. The transaction date fair value of the warrants of $1.0 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate — 2.39%, expected volatility - 90%, expected dividend yield — 0%, and a remaining contractual life of 5.00 years. As of September 30, 2011, all the warrants are outstanding. Net proceeds of approximately $5.4 million were allocated based on relative transaction date fair values in the following manner: $4.5 million ($1.93 per share) to common shares and $0.9 million ($1.29 per warrant) to the warrants.

On January 13, 2010, the Company completed the sale of 2,850,000 units in a "registered direct" offering to certain institutional investors. Each unit was sold at a purchase price of $2.51 per unit and consists of one share of the Company's common stock and one warrant to purchase 0.25 of one share of its common stock for gross proceeds of approximately $7.2 million. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance at an exercise price of $3.26 per share of common stock. As of September 30, 2011, warrants issued to the investors have been classified as equity. The transaction date fair value of the warrants of $1.3 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate — 2.55%, expected volatility — 90%, expected dividend yield — 0%, and a remaining contractual life of 5.00 years. As of September 30, 2011, all the warrants are outstanding. Net proceeds of approximately $6.5 million were allocated based on relative transaction date fair values in the following manner: $5.6 million ($1.95 per share) to common shares and $0.9 million ($1.32 per warrant) to the warrants.

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 at a purchase price of $0.85 per unit. Each unit consisted of (i) one share of the Company's common stock, (ii) one warrant to purchase 0.625 of one share of common stock (a "Series I Warrant") and (iii) one warrant to purchase 0.1838805 of one share of common stock (a "Series II Warrant"). The Series I Warrants had a seven-month term from the date of issuance, were exercisable beginning six months from the date of issuance at an exercise price of $1.00 per share of common stock. During the first quarter of 2010, all of the Series I Warrants were exercised for $2.5 million. The Series II Warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance at an exercise price of $1.00 per share of common stock. During the first quarter of 2010, 43,266 common shares were issued upon exercise of Series II Warrants with proceeds of $43,266. There were no exercises during the nine months ended September 30, 2011.

The net proceeds to the Company from the sale of the units, after deducting for the placement agent's fees and offering expenses, were approximately $2.9 million. As of September 30, 2011, the remaining Series II Warrants outstanding and exercisable into 692,256 of the Company's shares of common stock have been classified as equity. The transaction date fair value of the Series II Warrants of $0.6 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate — 2.69%, expected volatility — 90%, expected dividend yield — 0%, and a remaining contractual life of 5.00 years.

December 2007 Committed Equity Financing Facility

On December 10, 2007 and as amended on November 24, 2009, Cyclacel entered into a Committed Equity Financing Facility, or CEFF, with Kingsbridge, in which Kingsbridge committed to purchase the lesser of 4,084,590 shares of common stock or $60 million of common stock from Cyclacel over a three-year period. The CEFF lapsed on December 10, 2010.

During March 2010, the Company sold 1,563,208 shares of its common stock to Kingsbridge under the CEFF, in consideration of aggregate proceeds of $3.1 million. During December 2009 and January 2010, the Company sold an aggregate of 1,583,626 shares of its common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of $1.3 million, of which approximately $1.0 million was received in 2009, with the balance of $0.3 million in respect of common shares subscribed but unissued at December 31, 2009, received by the Company in January 2010.

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 classified as liabilities for accounting purposes. 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 is being remeasured each reporting period as a derivative gain or loss on the consolidated statement of operations until exercised or expiration. See "Note 3 — Fair Value" for further details.

The following table summarizes information about warrants outstanding at September 30, 2011:

Issued in Connection With	Expiration Date	Common Shares Issuable	Weighted Average Exercise Price
April 2006 stock issuance	2013	2,571,429	$ 7.00
February 2007 stock issuance	2014	1,062,412	$ 8.44
December 2007 CEFF	2013	100,000	$ 1.40
July 2009 Series II stock issuance	2014	692,256	$ 1.00
January 2010 stock issuance	2015	712,500	$ 3.26
January 2010 stock issuance	2015	705,000	$ 2.85
October 2010 stock issuance	2015	4,161,595	$ 1.92
July 2011 stock issuance	2016	3,808,823	$ 1.36
Total		13,814,015	$ 3.28

Exercise of Stock Options

During the nine months ended September 30, 2011, there were 6,638 stock option exercises totaling approximately $3,000. There were no exercises of stock options during three months ended September 30, 2011.

9. SUBSEQUENT EVENTS

Preferred Stock Dividend

On October 6, 2011, the Board of Directors decided not to declare the quarterly cash dividend on the Preferred Stock with respect to the third quarter of 2011 that would have otherwise been payable on November 1, 2011.

The Board also did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009, the first, second and third quarters of 2010, and the second quarter of 2011. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are added to the liquidity preference of the Preferred Stock. As the Company elected not to pay in 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 was increased by two members and the holders of the Preferred Stock, voting separately as a class, voted on May 24, 2011 and elected two directors to fill the vacancies created thereby, which directorships shall terminate when the Company pays all accrued but unpaid dividends.

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, 2010, as updated and supplemented by Part II, Item 1A, entitled "Risk Factors," of our Quarterly Reports on Form 10-Q and other reports we publicly file with the Securities and Exchange Commission, or the SEC. 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 biopharmaceutical company dedicated to the development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious diseases. Our strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates.

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

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

On January 11, 2011, we opened enrollment of the SEAMLESS pivotal Phase 3 trial for sapacitabine oral capsules as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy. SEAMLESS is a registration-directed clinical trial and is conducted under a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA. SEAMLESS is a randomized study against an active control drug with the primary objective of demonstrating an improvement in overall survival. In October 2011, the independent Data Safety Monitoring Board, or DSMB, of SEAMLESS recommended that the study should enter the randomized stage as planned and, following this recommendation, we have implemented an improvement in the SEAMLESS trial design converting it into a 2-arm from the original 3-arm design. We received written confirmation from the FDA that, following the modification in the trial design, the previously agreed SPA agreement remains valid.

We have advanced two additional product candidates, seliciclib in Phase 2 for NSCLC and nasopharyngeal cancer or NPC, and CYC116 in Phase 1 clinical development. The combination of sapacitabine with seliciclib is also being evaluated in a Phase 1 clinical trial. We will determine the feasibility of pursuing further development and/or partnering these assets depending on the availability of funding and further clinical data. In addition, we market directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia.

Recent Developments

Clinical

On October 13, 2011, we announced that the DSMB of SEAMLESS recommended that the study should enter the randomized stage as planned. The DSMB reviewed available data from a total of 46 patients receiving oral sapacitabine capsules, the Company's lead product candidate, administered in alternating cycles with decitabine. The DSMB noted that no safety or efficacy concerns were identified. The DSMB review was mandated in the SPA agreement that Cyclacel entered into with the FDA with regard to the SEAMLESS study protocol. Of the 46 patients reviewed by the DSMB, 21 were enrolled in the lead-in phase of SEAMLESS and 25 in an earlier pilot Phase 1/2 study using an identical treatment regimen.

The regimen of the lead-in phase is considered tolerable, as the rate of dose-limiting toxicity was 9.5% and the 8-week mortality rate was 14.3%. The criteria, as specified in the SPA, are a dose-limiting toxicity less than 33% and an 8-week mortality rate of less than 37%.

Interim data from the pilot Phase 1/2 study, which was presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2011, showed thirty-day mortality from all causes was 4.5%; 60-day mortality from all causes was 9.5%. The overall response rate was 34.8%. An additional 26.1% of patients stayed on study for more than 4 cycles with a decrease in bone marrow blast counts despite not meeting criteria of response. Approximately 60.9% of patients received 4 or more cycles of the regimen. As reported at ASCO, no dose-limiting toxicities were observed in 21 patients treated with the regimen who have had at least 60 days of follow-up. The median age in the group is 76 years (range 72-88). Common adverse events regardless of cause included anemia, anorexia, dehydration, diarrhea, dyspnea, edema, hypocalcemia, nausea, febrile neutropenia, neutropenia, pneumonia, thrombocytopenia, and weakness, which were mostly moderate in intensity. On October 13, 2011, we announced updated data from 25 patients treated with the regimen and at least 60 days follow-up that showed no dose-limiting toxicities and an 8-week mortality rate of 12.0%.

Financial

On September 16, 2011, we received a NASDAQ Staff Deficiency Letter indicating that we were not in compliance with the minimum bid price requirement for continued listing on the NASDAQ exchange because the bid price for our common stock had closed under $1.00 for 30 consecutive business days. We may achieve compliance if, at any time before March 14, 2012, the bid price of our stock closes at $1.00 per share or more for a minimum of 10 consecutive business days. Failure to achieve compliance may result in the removal of our common stock listing on the NASDAQ exchange.

Our pipeline and expertise in cell cycle biology

Our core area of expertise is in cell cycle biology and we focus primarily on the development of orally-available anticancer agents that target the cell cycle with the aim of slowing the progression or shrinking the size of tumors, and enhancing the quality of life and improving survival rates of cancer patients. We are generating several families of anticancer drug candidates that act on the cell cycle including nucleoside analogues, cyclin dependent kinase, or CDK inhibitors and Aurora kinase/Vascular Endothelial Growth Factor Receptor 2, or AK/VEGFR2 inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitor and AK inhibitor drugs, we believe that our drug candidates are differentiated in that they are orally-available and interact with unique target profiles and mechanisms. For example we believe that our sapacitabine is the only orally-available nucleoside analogue to be tested in a Phase 3 trial for AML and in a Phase 2 trial in MDS and seliciclib is the most advanced orally-available CDK inhibitor in Phase 2 trials.

Although our resources are primarily directed towards advancing our anticancer drug candidate sapacitabine through in-house development activities we are also progressing, but with minimal investment, our other novel drug series which are at earlier stages. As a consequence of our progress in sapacitabine clinical development, research and development expenditures for the nine months ended September 30, 2011 increased by $2.0 million, or approximately 40%, to $7.0 million, compared to $5.0 million for the nine months ended September 30, 2010.

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 Dundee, Scotland.

From our inception in 1996 through September 30, 2011, 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, 2011, our accumulated deficit during the development stage was approximately $253.4 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates. Our operating expenses are comprised of research and development expenses and selling and general and administrative expenses.

To date, we have not generated significant product revenue but have financed our operations and internal growth through, among other things, public and private equity offerings, 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, 2011 totaling approximately $9.6 million, of which approximately $2.8 million is derived from product sales, approximately $3.1 million from fees under collaborative agreements and approximately $3.6 million of grant revenue from various United Kingdom government grant awards.

Subsequent Events

Preferred Stock Dividend

On October 6, 2011, our Board of Directors, or Board, decided not to declare the quarterly cash dividend on our 6% Convertible Exchangeable Preferred Stock, or Preferred Stock, with respect to the second quarter of 2011 that would have otherwise been payable on November 1, 2011.

The Board also did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009, the first, second and third quarters of 2010, and the second quarter of 2011. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are added to the liquidity preference of the Preferred Stock. As we elected not to pay in an aggregate amount equal to at least six quarterly dividends (whether or not consecutive) on the Preferred Stock, the size of the our Board was increased by two members and the holders of the Preferred Stock, voting separately as a class, voted on May 24, 2011 and elected two directors to fill the vacancies created thereby, which directorships shall terminate when we pay all accrued but unpaid dividends.

Results of Operations

Three Months Ended September 30, 2011 and 2010

Revenues

The following table summarizes our revenue for the three months ended September 30, 2010 and 2011:

	Three Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
	($000s)			
Product revenue	$ 159	$ 164	$ 5	3%
Total revenue	$ 159	$ 164	$ 5	3%

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges following the ALIGN asset acquisition on October 5, 2007. During each of the three months ended September 30, 2010 and 2011, we recognized revenue of approximately $0.2 million.

We had no collaboration and research and development revenue or grant revenue for the three months ended September 30, 2011.

The future

We expect to continue to maintain the sales of ALIGN products in 2011 through the support of a small sales and marketing infrastructure. We do not expect to earn any grant revenue during the remainder of year, as no awards are expected during the year ended December 31, 2011.

Cost of goods sold

The following table summarizes cost of goods sold for the three months ended September 30, 2010 and 2011:

	Three Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
	($000s)			
Cost of goods sold	$ 76	$ 95	$ 19	25%

Total cost of sales represented 48% of product revenue for the three months ended September 30, 2010 and 58% of product revenue for the three months ended September 30, 2011.

Research and development expenses

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, 2010 and 2011:

	Three Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
		($000s)		
Sapacitabine	$ 1,189	$ 1,848	$ 659	55%
Seliciclib	(12)	47	59	492%
Other research and development costs	292	171	(121)	(41)%
Total research and development costs	$ 1,469	$ 2,066	$ 597	41%

Total research and development expenses represented 35% and 49% of our operating expenses for the three months ended September 30, 2010 and 2011, respectively.

Research and development expenditure increased by $0.6 million to $2.1 million for the three month period ended September 30, 2011 from $1.5 million for the three month period ended September 30, 2010. The increase in costs of $0.6 million is mostly due to a $0.7 million increase in sapacitabine-related expenses, primarily a $0.3 million increase in clinical trial expenses and a $0.4 million increase in clinical trial supplies as a result of the SEAMLESS trial entering Phase 3. Seliciclib costs increased $59,000, from a net credit of $12,000 for the three months ended September 30, 2010, to $47,000 for the three months ended September 30, 2011, because accrued liabilities were released in 2010 as we reconciled certain final study costs. Other research and development costs decreased $0.1 million from approximately $0.3 million for the three months ended September 30, 2010 to approximately $0.2 million for three months ended September 30, 2011 as we have continued to concentrate financial resources on the development of sapacitabine and only selectively invest in other compounds.

The future

We will continue to concentrate our resources on the development of sapacitabine. We anticipate that overall research and development expenditures in 2011 will increase as we enroll the SEAMLESS pivotal Phase 3 trial.

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, 2010 and 2011:

	Three Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
		($000s)		
Selling, general and administrative	$ 2,612	$ 2,051	$ (561)	(21)%

Total selling, general and administrative expenses represented 63% and 49% of our operating expenses for the three months ended September 30, 2010 and 2011, respectively. Our selling, general and administrative expenditure decreased by $0.6 million from $2.6 million for the three months ended September 30, 2010 to $2.0 million for the three months ended September 30, 2011. The decrease of $0.6 million in expenses was primarily attributable to a net decrease in professional and consultancy costs of $0.2 million, a decrease in stock compensation of $0.3 million, a decrease in rent expense of $0.1 million, and a decrease in patent costs of $0.1 million.

The future

We expect our selling, general and administrative expenditures in 2011 to remain at lower levels than our expenditures in 2010.

Other income (expense)

The following table summarizes other income (expense) for the three months ended September 30, 2010 and 2011:

	Three Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
		($000s)		
Other income (expense):				
Change in valuation of warrants	$ 73	$ 440	$ 367	503%
Foreign exchange (losses)/gains	(25)	28	53	212%
Interest income	7	9	2	29%
Interest expense	(7)	—	7	(100)%
Total other income (expense)	$ 48	$ 477	$ 429	894%

Total other income and expense, net, increased by approximately $0.4 million, from $48,000 for the three months ended September 30, 2010, to $0.5 million for the three months ended September 30, 2011. The most significant impact is the change in the valuation of the warrant liability described 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 815, "*Derivatives and Hedging*". The fair value of the warrants is re-measured each reporting period with a derivative gain or loss recognized in the consolidated statement of operations. Such gains or losses will continue to be reported until the warrants are exercised or expired. For the three months ended September 30, 2010 and 2011, we recorded gains as a result of the change in the value of warrants of $73,000 and a $0.4 million, respectively.

Foreign exchange gains (losses) increased by $53,000 to a gain of $28,000 for the three months ended September 30, 2011 compared to a loss of $25,000 for the three months ended September 30, 2010. Foreign exchange gains/(losses) are reported in the consolidated statement of operations as a separate line item within other income (expense).

Interest income increased by approximately $2,000 to $9,000 for the three months to September 30, 2010 from $7,000 for the three months ended September 30, 2010. This is mostly attributed to a higher average daily balance of cash and cash equivalents during the three months ended September 30, 2011 compared to the same period in 2010.

Interest expense was $7,000 for the three months ended September 30, 2010. We did not record interest expense for three months ended September 30, 2011. This reduction was due to the elimination of the accretion expense associated with the restructured Bothell lease, which expired in December 2010.

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.

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, 2010 and 2011:

	Three Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
		($000s)		
Income tax benefit	$ 143	$ 126	$ (17)	(12)%

Research and development tax credits recoverable decreased by $17,000 to $0.1 million for the three months ended September 30, 2011 from $0.1 million for three months ended September 30, 2010. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year, but restricted to payroll taxes paid by us in the United Kingdom in that same year. The $17,000 decrease between the three months ended September 30, 2010 and 2011 is due to lower payroll taxes paid as a result of lower headcount in 2011.

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.

Nine Months Ended September 30, 2010 and 2011

Revenues

The following table summarizes the components of our revenues for the nine months ended September 30, 2010 and 2011:

	Nine Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
		($000s)		
Collaboration and research and development revenue	$ 100	$ —	$ (100)	(100)%
Product revenue	432	524	92	21%
Grant revenue	16	—	(16)	(100)%
Total revenue	$ 548	$ 524	$ (24)	(4)%

We recognized $0.1 million of collaboration and research and development revenue for the nine months ended September 30, 2010 derived from an agreement with a pharmaceutical company under which we provided one of our compounds for evaluation in the field of eye care. We had no collaboration and research and development revenue for the nine months ended September 30, 2011.

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. During the nine months ended September 30, 2010 and 2011, we recognized product revenue of approximately $0.4 and $0.5 million, respectively, in accordance with our revenue recognition policy. Product revenue was lower by $0.1 million for the nine months ended September 30, 2010 compared to the same period in 2011 due to $0.2 million in product returns during nine month ended September 30, 2010.

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 European Union and United Kingdom government grant awards. We recognized $16,000 in grant revenue for the nine months ended September 30, 2010. We did not recognize any grant revenue for the nine months ended September 30, 2011 as our last grant was finalized in the first quarter of 2010.

Cost of goods sold

The following table summarizes cost of goods sold for the nine months ended September 30, 2010 and 2011:

	Nine Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
		($000s)		
Cost of goods sold	$ 310	$ 273	$ (37)	(12)%

Total cost of sales represented 72% and 52% of product revenue for the nine months ended September 30, 2010 and 2011, respectively. The high percentage for the nine months ended September 30, 2010 is the result of lower product revenue driven by $0.2 million of product returns as described in “Revenues” above.

Research and development expenses

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 nine months ended September 30, 2010 and 2011:

	Nine Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
		($000s)		
Sapacitabine	$ 3,992	$ 6,579	$ 2,587	65%
Seliciclib	121	72	(49)	(40)%
Other research and development costs	855	354	(501)	(59)%
Total research and development expenses	$ 4,968	$ 7,005	$ 2,037	41%

Total research and development expenses represented 37% and 53% of our operating expenses for the nine months ended September 30, 2010 and 2011, respectively.

Research and development expenditure increased by $2.0 million to $7.0 million for the nine month period ended September 30, 2011 from $5.0 million for the nine month period ended September 30, 2010. The increase in costs of $2.0 million is primarily due to a $2.6 million increase in sapacitabine related costs and a $0.6 million decrease in other research and development costs, respectively, as we continue to focus on the development of sapacitabine. The $2.6 million increase in sapacitabine expenditures was primarily due to $1.6 million of contractual expenses, resulting from an achievement of a milestone triggered by the opening of enrollment in our SEAMLESS trial, pursuant to the Daiichi Sankyo license under which we license certain patent rights for sapacitabine, a $0.8 million increase related to clinical trial supplies, and a $0.4 million increase in clinical trial expenses. Seliciclib costs decreased by $49,000 from $121,000 for the nine months ended September 30, 2010 to $72,000 for nine months ended September 30, 2011 primarily due to the completion of clinical trials. Other research and development costs decreased $0.5 million to $0.4 million for the nine months ended September 30, 2011 from $0.9 million for the nine months ended September 30, 2010, as we have concentrated financial resources on the development of sapacitabine and reduced investment in other compounds.

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, 2010 and 2011:

	Nine Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
		($000s)		
Selling, general and administrative	$ 8,103	$ 5,891	$ (2,212)	(27)%

Total selling, general and administrative expenses represented 61% and 45% of our operating expenses for the nine months ended September 30, 2010 and 2011, respectively. Our selling, general and administrative expenditure decreased by $2.2 million from $8.1 million for the nine months ended September 30, 2010 to $5.9 million for the nine months ended September 30, 2011. The decrease of $2.2 million in expenses was primarily attributable to a net decrease in professional and consultancy costs of $1.3 million, a decrease in salaries of $0.3 million, a decrease in rent of $0.3 million as a result of the expiration our lease on a facility in Bothell, Washington in December 2010, and a decrease in stock compensation of $0.6 million. These amounts were partially offset by a $0.2 million increase in patent-related costs.

Other income (expense)

The following table summarizes other income (expense) for the three months ended September 30, 2010 and 2011:

	Nine Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
	($000s)			
Other income (expense):				
Change in valuation of warrants	$ (443)	$ 643	$ 1,086	(245)%
Foreign exchange (losses)/gains	(63)	(59)	4	6%
Interest income	24	33	9	38%
Interest expense	(40)	—	40	(100)%
Total other income (expense)	$ (522)	$ 617	$ 1,139	(218)%

Total other income and expense, net, increased by approximately $1.1 million, from an expense of $0.5 million for the nine months ended September 30, 2010, to income of $0.6 million for the nine months ended September 30, 2011. The most significant impact is the $1.1 million increase in the change in the valuation of the warrant liability, mostly due to the decrease in our common share price.

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 are classified as liabilities in accordance with ASC 815, "*Derivatives and Hedging*". The fair value of the warrants is re-measured each reporting period with a derivative gain or loss recognized in the consolidated statement of operations. Such gains or losses will continue to be reported until the warrants are exercised or expired. For the nine months ended September 30, 2010 and 2011, the change in the valuation of warrants was a $0.5 million decrease and a $0.6 million increase, respectively.

Foreign exchange gains (losses) increased by $4,000 to a loss of $59,000 for the nine months ended September 30, 2011 compared to a loss of $63,000 for the nine months ended September 30, 2010. Foreign exchange gains/(losses) are reported in the consolidated statement of operations as a separate line item within other income (expense).

Interest income increased by approximately $9,000 to $33,000 for the nine months ended September 30, 2010 from $24,000 for the nine months ended September 30, 2010. This is mostly attributed to a higher average daily balance of cash and cash equivalents during the three months ended September 30, 2011 compared to the same period in 2010.

Interest expense was $40,000 for the nine months ended September 30, 2010. We did not record any interest expense for the nine months ended September 30, 2011. This reduction was due to the elimination of the accretion expense associated with the restructured Bothell lease, which expired in December 2010.

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.

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 nine months ended September 30, 2010 and 2011:

	Nine Months Ended September 30,		Increase (Decrease)	
	2010	2011	$	%
		($000s)		
Income tax benefit	$ 506	$ 443	$ (63)	(12)%

Research and development tax credits recoverable decreased $0.1 million, from $0.5 million for the nine months ended September 30, 2010, to $0.4 million for the nine months ended September 30, 2011. 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 $0.1 million decrease between the nine months ended September 30, 2010 and 2011 is due to lower payroll taxes paid as a result of lower headcount in 2011.

Liquidity and Capital Resources

The following is a summary of our key liquidity measures at December 31, 2010 and September 30, 2011:

	December 31, 2010	September 30, 2011	$ Difference	% Difference
		($000s)		
Cash and cash equivalents	$ 29,495	$ 27,675	$ (1,820)	(6)%
Working capital:				
Current assets	$ 31,051	$ 28,781	$ (2,270)	(7)%
Current liabilities	(6,535)	(5,935)	600	(9)%
Working capital	$ 24,516	$ 22,846	$ (1,670)	(7)%

The objectives of our cash management policy are to safeguard and preserve funds, to maintain liquidity sufficient to meet our cash flow requirements and to attain a market rate of return. At September 30, 2011, we had cash and cash equivalents of $27.7 million as compared to $29.5 million at December 31, 2010. The decrease in balance was primarily due to normal cash outflows required to operate our business, offset by net proceeds of $9.3 million from the July 2011 underwritten offering. Since our inception, we have not generated any significant revenue and have relied primarily on the proceeds from sales of equity and preferred securities to finance our operations and internal growth. Additional funding has come through interest on investments, licensing revenue, government grants and research and development tax credits. We have incurred significant losses since our inception. As of September 30, 2011, we had an accumulated deficit during the development stage of $253.4 million. We believe that existing funds together with cash generated from operations and recent financing activities are sufficient to satisfy our planned working capital, capital expenditures, debt service and other financial commitments for at least the next twelve months. Current business and capital market risks could have a detrimental effect on the availability of sources of funding and our ability to access them in the future which may delay or impede our progress of advancing our drugs currently in the clinic to approval by the FDA for commercialization.

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

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2010 and 2011, is summarized as follows:

	Nine months ended September 30,	
	2010	2011
	($000s)	
Net cash used in operating activities	(12,302)	(10,718)
Net cash provided by (used in) investing activities	27	(6)
Net cash provided by (used in) financing activities	19,282	8,897

Operating activities

Net cash used in operating activities decreased $1.6 million, from $12.3 million for the nine months ended September 30, 2010 to $10.7 million for the nine months ended September 30, 2011. The decrease in cash outflow is primarily the result of better management of selling, general and administrative expenses as the result of our continued focus on sapacitabine.

Investing activities

Net cash provided by investing activities decreased $33,000, from an inflow of $27,000 for the nine months ended September 30, 2010, as a result of the sale of laboratory equipment, to an outflow of $6,000 during the nine months ended September 30, 2011 as a result of equipment purchases.

Financing activities

Net cash used in financing activities for the nine months ended September 30, 2011 was $8.9 million. Net cash provided by financing activities was $19.3 million for the nine months ended September 30, 2010. During the nine months ended September 30, 2010, we completed two registered direct offerings in January 2010 for gross proceeds of approximately $13.0 million, drew down the Kingsbridge CEFF totaling approximately $2.8 million and had investors exercising warrants totaling $2.7 million. During the nine months ended September 30, 2011, we received $9.3 million in net financing proceeds and paid a cash dividend to our holders of the Preferred Stock of approximately $0.4 million.

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur substantial operating losses in the future. While we have generated modest product revenues from ALIGN product sales from October 2007 through September 30, 2011, we do not expect to generate any significant product revenues until a product candidate has been approved by the FDA or similar regulatory agencies in other countries and successfully commercialized.

We currently anticipate that our cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. We 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 associated with establishing manufacturing and commercialization capabilities;
- the costs of acquiring or investing in businesses, product candidates and technologies;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the effect of competing technological and market developments; and
- the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter.

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

Off-Balance Sheet Arrangements

As of September 30, 2011, we have no off-balance sheet arrangements.

Critical Accounting Policies

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

Revenue Recognition

Product sales

We have adopted the following revenue recognition policy related to the sales of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. We recognize revenue from these product sales when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the selling 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 Topic 605. Under these guidelines, 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 pharmacies. To estimate products sold through to pharmacies, we rely on third-party information, including information obtained from significant distributors with respect to their inventory levels and sell-through to pharmacies. We estimate product returns based on historical returns experience and other factors that affect the demand for our products as well as the amount of product subject to return.

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 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.

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. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period.

Warrants Liability

With respect to warrants issued in February 2007 as part of a financing and pursuant to ASC 815, since we are unable to control all the events or actions necessary to settle the warrants in registered shares the warrants have been recorded as a current liability at fair value. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the consolidated statements of operations. During the three months ended September 30, 2010 and 2011, the Company recognized gains from the change in the value of warrants of approximately $73,000 and $0.4 million, respectively. During the nine months ended September 30, 2010, the Company recognized the change in the value of warrants as a loss of approximately $0.4 million. During the nine months ended September 30, 2011, the Company recognized the change in the value of warrants as a gain of approximately $0.6 million. 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.

Recently Issued Accounting Pronouncements

In September 2011, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2011-08, which amends the guidance in ASC 350-20, Intangibles-Goodwill and Other-Goodwill (“ASC 350-20”). The guidance simplifies how companies test goodwill for impairment by allowing companies to use a qualitative approach. The amendments in the ASU permit a company to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in ASC 350-20.The ASU is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted, including for annual and interim goodwill tests performed as of a date before September 15, 2011, if a company’s financial statements for the most recent annual or interim period have not yet been issued. Adoption of the guidance is not expected to have a material impact on our consolidated financial statements.

In June 2011, the FASB issued Accounting Standards ASU 2011-05 to amend the guidance on the presentation of comprehensive income in ASC 220 that would require companies to present a single statement of comprehensive income or two separate but consecutive statements, a statement of operations and a statement of comprehensive income. The proposed guidance would make the financial statement presentation of comprehensive income more prominent by eliminating the alternative to present comprehensive income within the statement of equity. The ASU will be effective for annual periods beginning after December 15, 2011, although the FASB has recently issued a proposal to defer the effective date of certain aspects of ASC 2011-5 indefinitely. Nonetheless, the adoption of the guidance will not have a material impact on our consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, which amends GAAP to conform to International Financial Reporting Standards (“IFRS”) fair value measurement and disclosure requirements. The amendments change the wording used to describe the requirements in GAAP for measuring fair value, changes certain fair value measurement principles and enhances disclosure requirements. This guidance is effective for annual periods beginning after December 15, 2011, applied prospectively. Adoption of the guidance is not expected to have a material impact on our consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to fluctuations in foreign currency exchange rates.

Foreign Currency Risk

We are exposed to foreign currency rate fluctuations related to the operation of our subsidiary in the United Kingdom. At the end of each reporting period, income and expenses of the subsidiary are translated into U.S. dollars using the average currency rate in effect for the period and assets and liabilities are translated into U.S. 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 U.S. dollars and unrealized foreign exchange gains and losses arising on these loans have been 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.

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. We realized losses of $25,000 and gains of $28,000 for the three months ended September 30, 2010 and 2011, respectively. During the nine months ended September 30, 2010 and 2011, we realized losses of $63,000 and $59,000, respectively.

Common Stock Price Risk

In February 2007, we issued common stock and warrants. Pursuant to ASC 815, we recorded the fair value of the warrants as a current liability. The fair value of the outstanding warrants is remeasured at each reporting period with any resulting change in the fair value being reflected in the condensed consolidated statements of operations. We recognized gains of $73,000 and $0.4 million on the consolidated statement of operations for the three months ended September 30, 2010 and 2011, respectively, related to the change in the value of warrants. We recognized a loss of $0.4 million and a gain of $0.6 million on the consolidated statement of operations for the nine months ended September 30, 2010 and 2011, respectively, related to the change in the value of warrants. Fair value of the warrants 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.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of September 30, 2011, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. The purpose of this evaluation was to determine whether as of the evaluation date our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the SEC under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, management has concluded that as of September 30, 2011, our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weaknesses in our internal controls described in the amendment to our Annual Report on Form 10-K for the year ended December 31, 2010 in the section captioned "Item 9A — Controls and Procedures — Management's Annual Report on Internal Control Over Financial Reporting" that remain present.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than those described below.

In response to the material weaknesses in our internal controls noted in our Annual Report on Form 10-K for the year ended December 31, 2010, filed on March 31, 2011, management presented a proposed remediation plan to our audit committee concerning our internal controls over financial reporting, and the audit committee adopted management's remediation plan. We have implemented the plan by hiring qualified finance professionals and retaining outside consultants. Remediation of the material weaknesses will require management time and attention over the coming quarters and will likely result in additional incremental expenses. Any failure on our part to remedy our identified weaknesses or any additional errors or delays in our financial reporting would have a material adverse effect on our business and results of operations and could have a substantial adverse impact on the trading price of our common stock.

Subject to oversight by our board of directors, our chief executive officer will be responsible for implementing management's internal control remediation plan, adopted by our audit committee and approved by our board of directors.

Specifically, the remediation plan consists of strengthening the financial reporting function through the hiring of qualified finance personnel, with experience in the interpretation and application of accounting principles generally accepted in the United States, or GAAP, and designing and placing into operation appropriate controls to prevent or detect on a timely basis any potential material misstatements in the accounting, presentation and disclosure of cumulative preferred dividends. It is anticipated that the remediation plan, once implemented, will materially affect our internal control over financial reporting.

We anticipate that the actions described above will remediate the material weakness described in our Annual Report on Form 10-K for the year ended December 31, 2010.

Inherent Limitation on the Effectiveness of Internal Controls

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

PART II. OTHER INFORMATION

Item 1. Legal proceedings.

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

Item 1A. Risk Factors.

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2010. 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.

Risks Associated with Development and Commercialization of Our Drug Candidates

Clinical trial designs that were discussed with the authorities prior to their commencement may subsequently be considered insufficient for approval at the time of application for regulatory approval. Thus, our SPA regarding our SEAMLESS trial does not guarantee marketing approval or approval of our sapacitabine oral capsules for the treatment of acute myeloid leukemia.

On September 13, 2010, we reached agreement with the FDA regarding an SPA on the design of a pivotal Phase 3 trial for our sapacitabine oral capsules as a front-line treatment in elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia, or AML, who are not candidates for intensive induction chemotherapy, or the SEAMLESS trial. An SPA provides trial sponsors with an agreement from the FDA that the design and analysis of the trial adequately address objectives in support of a submission for a marketing application if the trial is performed according to the SPA. The SPA may only be changed through a written agreement between the sponsor and the FDA or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. On January 11, 2011, we opened enrollment of the SEAMLESS trial.

An SPA, however, neither guarantees approval nor provides any assurance that a marketing application would be approved by the FDA. There are companies that have been granted SPAs but have ultimately failed to obtain final approval to market their drugs. The FDA may revise previous guidance or decide to ignore previous guidance at any time during the course of clinical activities or after the completion of clinical trials. The FDA may raise issues relating to, among other things, safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Even with successful clinical safety and efficacy data, including such data from a clinical trial conducted pursuant to an SPA, we may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

The development program for our lead drug candidate sapacitabine is based, in part, on intellectual property rights we license from others and any termination of this license could seriously harm our business.

Effective July 11, 2011, the Daiichi Sankyo license under which we license certain patent rights for sapacitabine, our lead drug candidate, was amended to irrevocably waive a termination right Daiichi Sankyo possessed under a provision of the agreement that required the Company to obtain regulatory approval to sell sapacitabine in at least one country by September 2011, and releases the Company from all claims and liability of any kind arising under such provision. The amendment further provides that the royalty due from the Company to Daiichi Sankyo on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.

In general, the license may be terminated by us for technical, scientific, efficacy, safety, or commercial reasons on six months notice, or twelve months if after a launch of a sapacitabine-based product, or by either party for material default.

Although we are currently in compliance with all of our material obligations under this license, if we were to breach any such obligations, our counterparty may be entitled to terminate the license. This would restrict or delay or eliminate our ability to develop and commercialize these drug candidates, which could adversely affect our business.

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.

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

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

- delays in securing clinical investigators or trial sites for our clinical trials;
- delays in obtaining institutional review board, or IRB, and other regulatory approvals to commence a clinical trial;
- slower than anticipated rates of patient recruitment and enrollment, or reaching the targeted number of patients because of competition for patients from other trials or other reasons;
- negative or inconclusive results from clinical trials;

- unforeseen safety issues;
- uncertain dosing issues may or may not be related to suboptimal pharmacokinetic and pharmacodynamic behaviors;
- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unavailability of clinical trial supplies.

If we suffer any significant delays, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue development of our drug candidates or generate revenue and our development costs could increase significantly. Adverse events have been observed in our clinical trials and may force us to stop development of our product candidates or prevent regulatory approval of our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

- we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;
- our collaborators may experience financial difficulties;
- 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 cannot rely upon Sinclair to continue to supply the products. We anticipate future reliance on a limited number of third party manufacturers until we are able, or decide to, expand our operations to include manufacturing capacities. Any performance failure on the part of manufacturers could delay late stage clinical development or regulatory approval of our drug, the commercialization of our drugs or our ability to sell our commercial products, producing additional losses and depriving us of potential product revenues.

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

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

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

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

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

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

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

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

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

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

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

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

With regard to our ALIGN products and our drug candidates, if any, approved by the FDA or by another regulatory authority, we are held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the product or drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug or device, and could include withdrawal of the drug or device from the market.

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

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

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

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

A large number of drug candidates are in development for the treatment of leukemia, lung cancer, lymphomas and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs or other products on the market or in clinical trials which may be competitive to sapacitabine in both hematological and oncology indications. These include Celgene, Cephalon, Eisai, Johnson & Johnson, Eli Lilly, Genzyme, GlaxoSmithKline, Hospira, Onconova, Pfizer, Seattle Genetics and Sunesis. There are two other orally available CDK inhibitors in Phase 2 clinical trials. PD-0332991 (Pfizer/Onyx) and PHA-848125 (Nerviano Medical Sciences) target different subsets of kinase enzymes and have a different mechanism of action from seliciclib. We believe that seliciclib is currently the most advanced orally available CDK-specific agent in Phase 2 clinical trials but that there are a number of companies, including AstraZeneca, Astex Pharmaceuticals, Bayer-Schering, Eisai, Merck, Nerviano Medical Sciences, Pfizer, Piramal Life Sciences, and Roche that are developing CDK inhibitors in early stage clinical trials in cancer patients. Although Aventis, a predecessor of Sanofi-Aventis, had previously announced that it has ceased Phase 2 development of alvocidib or flavopiridol, a CDK inhibitor, we believe that the National Cancer Institute's Cancer Therapy Evaluation Program, or CTEP, is continuing to enroll patients in a CTEP sponsored trial in patients with chronic leukemia. A number of companies are pursuing discovery and research activities in each of the other areas that are the subject of our research and drug development programs. We believe that Amgen, Astex Pharmaceuticals, AstraZeneca, Entremed, Merck, jointly with Vertex, Nerviano Medical Sciences, Pfizer, Rigel, Sunesis and Takeda-Millennium have commenced Phase 1, Phase 2, or Phase 3 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, Merck, Nerviano Medical Sciences, Takeda-Millennium and Tekmira Pharmaceuticals Corporation have commenced Phase 1 or Phase 2 clinical trials with Plk inhibitor candidates for oncology indications. For our ALIGN products, we believe that Beiersdorf, Daiichi Sankyo, Eisai, Johnson & Johnson, MPM Medical and other companies market products for radiation dermatitis and xerostomia.

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

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

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

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

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

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

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

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

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

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

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

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.

Intellectual property rights and distribution rights for our drug candidate seliciclib and ALIGN products are licensed from others, and any termination of these licenses could harm our business.

We have in-licensed certain patent rights in connection with the development program of our drug candidate seliciclib. Pursuant to the CNRS and Institut Curie license under which we license seliciclib, we are obligated to pay license fees, milestone payments and royalties and provide regular progress reports. We are also obligated to use reasonable efforts to develop and commercialize products based on the licensed patents.

We have in-licensed from Sinclair the distribution rights to the ALIGN products. This license agreement imposes obligations on us and expires in 2015. 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. In addition, if we are unable to extend the term of the license agreement, it would prevent us from distributing the ALIGN products.

Although we are currently in compliance with all of our material obligations under these licenses, if we were to breach any such obligations our counterparties may be entitled to terminate the licenses. This would restrict or delay or eliminate our ability to develop and commercialize the seliciclib or sell the ALIGN products, which could adversely affect our business.

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

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

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

We may be 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.

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

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

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

Our customer base is highly concentrated.

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

We may be unable to accurately estimate demand and monitor wholesaler inventory of Xclair® Cream, Numoisyn® Liquid or Numoisyn® Lozenges. Although we attempt to monitor wholesaler inventory of Xclair® Cream, Numoisyn® Liquid or Numoisyn® Lozenges, we also rely on third party information, which is inherently uncertain and may not be accurate, to assist us in monitoring estimated inventory levels 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® Cream, Numoisyn® Liquid or Numoisyn® Lozenges held by wholesalers can also cause our operating results to fluctuate unexpectedly. For the three months ended September 30, 2010 and 2011, approximately 92% and 87%, respectively, of our product sales in the United States were to three wholesalers, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen. For the nine months ended September 30, 2010 and 2011, approximately 88% and 89%, respectively, of our product sales were to the three wholesalers. Inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to wholesalers do not match customer 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 customer demand, as they make estimates to determine customer 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.

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 effective sales and marketing initiatives in the United States. Although we launched the ALIGN products with a small specialty oncology sales force, we now sell and market our products via unique sales and marketing strategies in order to reduce costs. We contracted, trained and deployed additional telemarketing personnel to call on specialists who prescribe ALIGN products. We also utilize mailings, print advertising, sampling, trade show attendance and other unique marketing programs to reach our customer base. We may increase or decrease the size of our telemarketing 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.

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.

Risks Related to Our Business and Financial Condition

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

Economic conditions remain difficult with the continuing uncertainty in the global credit markets, the European Union, 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. If these circumstances persist or continue to worsen, our future operating results could be adversely affected, particularly relative to our current expectations.

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, our most advanced drug candidates for the treatment of cancer, is currently in Phase 3 for AML and Phase 2 for MDS. Seliciclib is currently in Phase 2 clinical trials. A combination trial of sapacitabine and seliciclib 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 December 31, 2010 and September 30, 2011, our accumulated deficit was $241.8 million and $253.4 million, respectively. Our net loss for the nine months ended September 30, 2010 and 2011 was $12.8 million and $11.6 million, respectively. Our net loss applicable to common stockholders from inception through September 30, 2011 was $294.9 million. Our drug candidates are in the mid-stages of clinical testing and we must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of our drugs. We expect to incur continued losses for several years, as we continue our research and development of our drug candidates, seek regulatory approvals, commercialize any approved drugs and market and promote the ALIGN products: Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. If our drug candidates are unsuccessful in clinical trials or we are unable to obtain regulatory approvals, or if our drugs are unsuccessful in the market, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, particularly in light of the current economic conditions, you could lose all or part of your investment.

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

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

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

Our common stock is currently listed for trading on the NASDAQ Global Market. We must satisfy NASDAQ's continued listing requirements, including among other things, a minimum stockholders' equity of $10.0 million and a minimum bid price for our common stock of $1.00 per share, or risk delisting, which would have a material adverse effect on our business. A delisting of our common stock from the NASDAQ Global Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. During 2009, Cyclacel received notification from the NASDAQ Stock Market that the Company was not in compliance with the minimum $10 million stockholders' equity requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(b)(1)(A). On January 27, 2010, NASDAQ notified the Company that it regained compliance with the minimum $50 million market value of listed securities requirement and that it currently complies with all other applicable standards for continued listing on The NASDAQ Global Market. Accordingly, the Company's shares of common and preferred stock will continue to trade on The NASDAQ Global Market. In September 2011, Cyclacel received a NASDAQ Staff Deficiency Letter indicating that it was not in compliance with the minimum bid price requirement for continued listing on the NASDAQ exchange because the bid price for the common stock had closed under $1.00 for 30 consecutive business days. We may achieve compliance if, at any time before March 14, 2012, the bid price of our stock closes at $1.00 per share or more for a minimum of 10 consecutive business days. If we are not able to comply with the bid price requirement by March 14, 2012, or in subsequent 180 day period as allowed by NASDAQ, the NASDAQ staff may begin the process to have our securities delisted.

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.

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

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

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

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs associated with establishing sales and marketing capabilities;
- the 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.

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.

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

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

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

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

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

Some of our costs and expenses are denominated in foreign currencies. Most of our foreign expenses are associated with our research and development operations of our United Kingdom-based wholly-owned subsidiary. When the United States dollar weakens against the British pound or other foreign currency, the United States dollar value of the foreign currency denominated expense increases, and when the United States dollar strengthens against the British pound or other foreign currency, 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

Risks Related to our Intellectual Property

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.

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

Our commercial success depends in large part on obtaining and maintaining patent and trade secret protection for our drug candidates, the methods used to manufacture those drug candidates and the methods for treating patients using those drug candidates.

Specifically, sapacitabine is covered in granted, composition of matter patents that expire in 2014 in the United States and 2012 outside the United States. Sapacitabine is further protected by additional granted, composition of matter patents claiming certain, stable crystalline forms of sapacitabine and their pharmaceutical compositions and therapeutic uses that expire in 2022 and also patent applications claiming the combination of sapacitabine with decitabine which is being tested as one of the arms of the SEAMLESS Phase 3 trial . In early development, amorphous sapacitabine was used. We have used one of the stable, crystalline forms of sapacitabine in nearly all our Phase 1 and in all of our Phase 2 clinical studies. We have also chosen this form for commercialization. Additional patents claim certain medical uses and formulations of sapacitabine which have emerged in our clinical trials. Seliciclib is protected by granted, composition of matter patents that expire in 2016. Additional patents claim certain medical uses which have emerged from our research programs.

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

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

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.

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

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

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

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

Risks Related to Securities Regulations and Investment in Our Securities

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

During March 2011, we identified a deficiency in respect of our internal controls over financial reporting, specifically our controls over the accounting for cumulative preferred stock dividends, that constitutes a material weakness as described in the SEC's guidance regarding Management's Report on Internal Control Over Financial Reporting as of December 31, 2010. As a result of this deficiency, the financial statements included in our Form 10-K for the year ended December 31, 2009, filed on March 29, 2010, as amended by Amendment No. 1 to our Annual Report on Form 10-K/A for the year ended December 31, 2009 filed on May 17, 2010 and, as further amended by Amendment No. 2 to our Annual Report on Form 10-K/A for the year ended December 31, 2009 filed on May 19, 2010, included errors related to the presentation and disclosure of undeclared cumulative preferred stock dividends in the consolidated balance sheet and in the statement of stockholders' equity. Unaudited balance sheets for the each of the first three quarters of 2009 and 2010 also contained errors. In addition, in May 2010, we filed an amendment to our Annual Report on Form 10-K for the year ended December 31, 2009, to report a restatement of our financial statements and report a material weakness in our internal control over financial reporting as of December 31, 2009, specifically related to the operational failure of the controls in place to ensure the correct computation of net loss per share and presentation of preferred stock dividends in the consolidated statement of cash flows. In March 2011, our auditors identified a further error in respect of the accounting, presentation and disclosure of cumulative undeclared preferred stock dividends, specifically the inclusion of undeclared cumulative preferred stock dividends as a current liability in its consolidated financial statements, which resulted from the same material weakness as described above. This has resulted in the restatement of our consolidated balance sheets as of March 31, 2009, June 30, 2009, September 30, 2009, December 31, 2009, March 31, 2010, June 30, 2010, and September 30, 2010 and consolidated statement of stockholders' equity for the year ended December 31, 2009 and selected financial data as of and for the year ended December 31, 2009.

If we fail to maintain our internal controls or fail to implement required new or improved controls, as such control standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting. Effective internal controls are necessary for us to produce reliable financial reports and are important in the prevention of financial fraud. If we cannot produce reliable financial reports or prevent fraud, our business and operating results could be harmed.

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, 2010, our internal control over financial reporting was ineffective. As our business grows and changes, there can be no assurances that we can maintain the effectiveness of our internal controls over financial reporting.

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

Our common stock may have a volatile public trading price.

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

- disclosure of actual or potential clinical results with respect to product candidates we are developing;
- regulatory developments in both the United States and abroad;
- developments concerning proprietary rights, including patents and litigation matters;

- public concern about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;
- 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.

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.

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 subsequently amended, most recently as of January 1, 2011), 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.

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

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

In addition, in the event a third party seeks to acquire our company or acquire control of our company by way of a merger, but the terms of such offer do not provide for our preferred stock to remain outstanding or be converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our preferred stock, the terms of the Certificate of Designation of our preferred stock provide for an adjustment to the conversion ratio of our preferred stock such that, depending on the terms of any such transaction, preferred stockholders may be entitled, by their terms, to receive up to $10.00 per share in common stock, causing our common stockholders not to receive as favorable a price as the price at which such shares may be trading at the time of any such transaction. As of September 30, 2011, there were 1,213,142 shares of our preferred stock issued and outstanding. If the transaction were one in which proceeds were received by the Company for distribution to stockholders, and the terms of the Certificate of Designation governing the preferred stock were strictly complied with, approximately $13,344,563 would be paid to the preferred holders before any distribution to the common stockholders, although the form of transaction could affect how the holders of preferred stock are treated. In such an event, although such a transaction would be subject to the approval of our holders of common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time. Thus, the terms of our preferred stock might hamper a third party's acquisition of our company.

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

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

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

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

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

We may have limited ability to pay cash dividends on our preferred stock, and there is no assurance that future quarterly dividends will be declared.

Delaware law may limit our ability to pay cash dividends on our preferred stock. Under Delaware law, cash dividends on our 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 our preferred stock, we may not have sufficient cash to pay dividends on the preferred stock or we may choose not to declare the dividends.

On July 8, 2011, the Board of Directors decided not to declare the quarterly cash dividend on the preferred stock with respect to the second quarter of 2011 that would have otherwise been payable on August 1, 2011. In addition, the Board of Directors also did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009 and the first, second and third quarters of 2010.

We have granted additional rights to our holders of preferred stock with respect to the management of the Company as a result of having not declared quarterly dividends on our preferred stock for a total of six quarterly dividend periods.

As a result of having not declared quarterly dividends on our preferred stock for a total of six quarters, the size of the Company's Board was increased by two members and the holders of the preferred stock, voting separately as a class, voted on May 24, 2011 and elected two directors to fill the vacancies created thereby. The directors elected by the holders of the preferred stock will have the ability to participate in the management of the Company until all accrued but unpaid dividends have been paid in full.

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

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

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

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

The future sale of our common and preferred stock and future issuances of our common stock upon conversion of our preferred stock could negatively affect our stock price and cause dilution to existing holders of our common stock.

If our common or preferred stockholders sell substantial amounts of our stock in the public market, or the market perceives that such sales may occur, the market price of our common and preferred stock could fall. For example, we were approached by a preferred stockholder that elected to convert 123,400 of its shares of preferred stock, which shares were converted into 239,396 shares of common stock in the first quarter of 2010. In addition, 710,271 shares of preferred stock were converted to 1,416,203 shares of common stock during the second quarter of 2010. If additional holders of preferred stock elect to convert their shares to shares of common stock at renegotiated prices, such conversion as well as the sale of substantial amounts of our common or preferred stock, could cause dilution to existing holders of our common stock, thereby also negatively affecting the price of our common stock.

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

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

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

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

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

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

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

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

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

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

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.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. (Removed and Reserved).

Item 5. Other Information.

None.

Item 6. Exhibits.

31.1*	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101***	The following materials from Cyclacel Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Income, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

* Filed herein.

** Furnished herewith.

*** XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

SIGNATURES

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

CYCLACEL PHARMACEUTICALS, INC.

Date: November 14, 2011

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

EXHIBIT 31.1

Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Spiro Rombotis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2011 of Cyclacel Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting: and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2011

/s/ Spiro Rombotis

Spiro Rombotis
President & Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Certification of Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Paul McBarron, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2011 of Cyclacel Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2011

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

EXHIBIT 32.1

Certification of Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. s 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Cyclacel Pharmaceuticals, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the Quarterly Report on Form10-Q of the Company for the period ended September 30, 2011 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2011

/s/ Spiro Rombotis
Spiro Rombotis
President & Chief Executive Officer

EXHIBIT 32.2

Certification of Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. s 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Cyclacel Pharmaceuticals, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the Quarterly Report on Form10-Q of the Company for the period ended September 30, 2011 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2011

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