Cyclacel Pharmaceuticals, Inc.
Form 424B3
May 16, 2012

PROSPECTUS SUPPLEMENT NO. 1
(TO PROSPECTUS DATED APRIL 26, 2012)

Filed pursuant to Rule 424(b)(3)
under the Securities Act of 1933
in connection with Registration
Statement No. 333-140034

3,172,168 Shares of Common Stock

Of

CYCLACEL PHARMACEUTICALS, INC.

Issuable Upon Exercise of Outstanding Warrants
Issued in Registered Direct Offerings

This Prospectus Supplement No. 1 supplements and amends the prospectus dated April 26, 2012 (the **Prospectus**), relating to the registration of 3,172,168 shares of common stock, par value $0.001 per share, which we may issue upon exercise of warrants to purchase common stock we issued as part of registered direct offerings, as follows: (i) warrants to purchase up to 1,062,412 shares of common stock at an exercise price of $8.44 per share we issued on February 16, 2007, such warrants expiring on February 16, 2014. We refer to these warrants as the February 2007 Warrants; (ii) warrants to purchase up to 692,256 shares of common stock at an exercise price of $1.00 per share we issued on July 29, 2009, such warrants expiring on July 29, 2014. We refer to these warrants as July 2009 Warrants; (iii) warrants to purchase up to 712,500 shares of common stock at an exercise price of $3.26 per share we issued on January 13, 2010, such warrants expiring on January 13, 2015. We refer to these warrants as the January 13, 2010 Warrants; and (iv) warrants to purchase up to 705,000 shares of common stock at an exercise price of $2.85 per share we issued on January 25, 2010, such warrants expiring on January 25, 2015. We refer to these warrants as the January 25, 2010 Warrants, and collectively with the February 2007 Warrants, July 2009 Warrants and the January 13, 2010 Warrants, the **outstanding registered direct warrants**.

To the extent any holder of our outstanding registered direct warrants determines to exercise its warrants, we will receive the payment of the exercise price in connection with such exercise. We will not receive any proceeds from the sale of the common stock issuable upon exercise of the outstanding registered direct warrants by the holders of the outstanding registered direct warrants.

This prospectus supplement should be read in conjunction with the Prospectus, which is to be delivered with this prospectus supplement. This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectus.

On May 15, 2012, we filed our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012. That Form 10-Q, without exhibits, is attached hereto.

Investing in our common stock involves risks. See Risk Factors beginning on page 19 of the Prospectus, as well as the section entitled Risk Factors included in our recent quarterly and annual reports filed with the Securities and Exchange Commission.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the Prospectus to which it relates are truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is May 16, 2012.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2012

OR

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

Commission file number 0-50626

CYCLACEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1707622**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

200 Connell Drive, Suite 1500

Berkeley Heights, New Jersey	**07922**
(Address of principal executive offices)	(Zip Code)

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

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

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

As of May 15, 2011 there were 59,003,301 shares of the registrant s common stock outstanding.

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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, 2011	March 31, 2012 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,449	$ 23,640
Inventory	182	109
Prepaid expenses and other current assets	1,200	1,423
Total current assets	25,831	25,172
Property, plant and equipment (net)	167	166
Total assets	$ 25,998	$ 25,338
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,763	$ 1,116
Accrued liabilities and other current liabilities	4,664	4,504
Economic rights		1,153
Other liabilities measured at fair value	71	29
Total current liabilities	6,498	6,802
Total liabilities	6,498	6,802
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2011 and March 31, 2012; 1,213,142 shares issued and outstanding at December 31, 2011 and March 31, 2012. Aggregate preference in liquidation of $13,708,505 and $13,890,476 at December 31, 2011 and March 31, 2012, respectively	1	1
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2011 and March 31, 2012; 54,220,458 and 58,993,414 shares issued and outstanding at December 31, 2011 and March 31, 2012, respectively	54	59
Additional paid-in capital	276,452	278,430
Accumulated other comprehensive loss	57	65
Deficit accumulated during the development stage	(257,064)	(260,019)
Total stockholders equity	19,500	18,536
Total liabilities and stockholders equity	$ 25,998	$ 25,338

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

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

	Three Months Ended March 31,		Period from August 13, 1996 (inception) to March 31,
	2011	2012	2012
Revenues:			
Collaboration and research and development revenue	$	$	$ 3,100
Product revenue	192	161	3,182
Grant revenue			3,648
	192	161	9,930
Operating expenses:			
Cost of goods sold	106	94	1,846
Research and development	3,080	1,347	187,146
Selling, general and administrative	1,806	1,996	91,483
Goodwill and intangible impairment			7,934
Restructuring costs			2,634
Total operating expenses	4,992	3,437	291,043
Operating loss	(4,800)	(3,276)	(281,113)
Other income (expense):			
Costs associated with aborted 2004 IPO			(3,550)
Payment under guarantee			(1,652)
Change in valuation of Economic Rights		(56)	(56)
Change in valuation of other liabilities measured at fair value	78	42	6,413
Foreign exchange (losses)/gains	(68)	114	(4,259)
Interest income	11	6	13,731
Interest expense			(4,677)
Other income		47	47
Total other income (expense)	21	153	5,997
Loss before taxes	(4,779)	(3,123)	(275,116)
Income tax benefit	191	168	18,612
Net loss	(4,588)	(2,955)	(256,504)
Dividends on preferred ordinary shares			(38,123)
Deemed dividend on convertible exchangeable preferred shares			(3,515)
Dividend on convertible exchangeable preferred shares	(182)	(182)	(3,839)
Net loss applicable to common shareholders	$ (4,770)	$ (3,137)	$ (301,981)
Net loss per share Basic and diluted	$ (0.10)	$ (0.06)	
Weighted average common shares outstanding	**46,572,180**	**54,761,620**	

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

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

	Three Months Ended March 31,		Period from August 13, 1996 (inception) to March 31,
	2011	2012	2012
Comprehensive loss	(4,611)	(2,947)	256,439

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

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

	Three Months Ended March 31,		Period from August 13, 1996 (inception) to March 31,
	2011	2012	2012
Cash flows from operating activities:			
Net loss	$ (4,588)	$ (2,955)	$ (256,504)
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 Economic Rights		56	56
Change in valuation of other liabilities measured at fair value	(78)	(42)	(6,413)
Warrant re-pricing			44
Depreciation and amortization	86	15	12,570
Amortization of intangible assets			886
Fixed asset impairment			221
Unrealized foreign exchange loss			7,747
Deferred revenue			(98)
Compensation for warrants issued to non-employees			1,215
Shares issued for IP rights			446
(Gain) loss on disposal of property, plant and equipment		(47)	53
Goodwill and intangibles impairment			7,934
Stock based compensation	251	102	19,125
Provision for restructuring			1,779
Amortization of issuance costs of Preferred Ordinary C shares			2,517
Transaction costs on sale of economic rights		33	33
Changes in operating assets and liabilities:			
Prepaid expenses, inventory and other current assets	40	(126)	(184)
Accounts payable, accrued liabilities and other current liabilities	397	(807)	(6,120)
Net cash used in operating activities	(3,892)	(3,771)	(216,890)
Investing activities:			
Purchase of ALIGN			(3,763)
Purchase of property, plant and equipment		(9)	(8,846)
Proceeds from sale of property, plant and equipment		24	187
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		15	(6,350)
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, warrants and economic rights, net of issuance costs	(80)	2,911	94,582
Net proceeds from stock options and warrants exercised	2	34	207
Payment of preferred stock dividend	(182)		(1,898)

Repayment of government loan	(455)

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CYCLACEL PHARMACEUTICALS, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In $000s)
(Unaudited)

	Three Months Ended March 31,		Period from August 13, 1996 (inception) to March 31,
	2011	**2012**	**2012**
Government loan received			414
Loan received from Cyclacel Group Plc			9,103
Proceeds of committable loan notes issued from shareholders			8,883
Loans received from shareholders			1,645
Cash and cash equivalents assumed on stock purchase			17,915
Costs associated with stock purchase			(1,951)
Net cash (used in) provided by financing activities	(260)	2,945	246,404
Effect of exchange rate changes on cash and cash equivalents	7	2	476
Net increase (decrease) in cash and cash equivalents	(4,145)	(809)	23,640
Cash and cash equivalents at beginning of period	29,495	24,449	
Cash and cash equivalents at end of period	$ 25,350	$ 23,640	$ 23,640
Supplemental disclosure of cash flows information:			
Cash received during the period for:			
Interest	3	5	11,751
Taxes			18,207
Cash paid during the period for:			
Interest			(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 condensed consolidated financial statements.

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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 ar 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, an orally available, cell cycle modulating nucleoside analogue.

Sapacitabine is being evaluated in the SEAMLESS Phase 3 trial being conducted under a Special Protocol Assessment agreement with the US Food and Drug Administration (FDA) for the front-line treatment of acute myeloid leukemia in the elderly and in Phase 2 studies for myelodysplastic syndromes, non-small cell lung cancer (NSCLC) and chronic lymphocytic leukemia.

We have ongoing clinical programs in development awaiting further data. Once data becomes available and is reviewed, we will determine the feasibility of pursuing further development and/or partnering these assets, including sapacitabine in combination with seliciclib, our second clinical candidate, and seliciclib in NSCLC and nasopharyngeal cancer (NPC). In addition, we market directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. However, these activities generate a small amount of revenues. 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, raising capital and recruiting and training personnel. We currently anticipate that our cash and cash equivalents of approximately $23.6 million at March 31, 2012 are sufficient to meet our anticipated short-term working capital needs and to fund our on-going sapacitabine clinical trials for at least the next twelve months. However, we cannot be certain that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in clinical development, should they succeed.

Basis of Presentation

The condensed consolidated balance sheet as of March 31, 2012, the condensed consolidated statements of operations, comprehensive loss, and cash flows for the three months ended March 31, 2012 and 2011 and the period from August 13, 1996 (inception) to March 31, 2012, and all related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2011 is derived from the audited consolidated financial statements included in the 2011 Annual Report on Form 10-K 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 March 31, 2012, and the results of operations, comprehensive loss and cash flows for the three months ended March 31, 2012 and 2011, have been made. The interim results for the three months ended March 31, 2012 are not necessarily indicative of the results to be expected for the year ending December 31, 2012 or for any other year. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2011, included in the Company s Annual Report on Form 10-K filed with the SEC.

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Recent Developments

Sale of Common Stock and Economic Rights

On March 22, 2012, the Company entered into a purchase agreement with certain existing institutional stockholders raising approximately $2.9 million of proceeds, net of certain fees and expenses. The proceeds from the financing will be used to fund ongoing litigation-related expenses involving specified Cyclacel intellectual property and for general corporate purposes.

Under the terms of the purchase agreement, the investors purchased 4,688,079 shares of the Company s common stock at a price of $0.6476, which is equal to the 10-day average closing price of the Company s common stock for the period ending on Wednesday, March 21, 2012. The shares issued at closing are subject to a lock-up period of one year from the date of issuance.

In addition to the common stock, investors received contractual rights to receive cash equal to 10% of any future litigation settlement related to the specified intellectual property, subject to a cap. In certain defined situations, the Company may have to issue either additional shares or warrants. These collective contractual rights are referred to as Economic Rights .

See *Note 3, Fair Value Measurements* for further details.

Preferred Stock Dividend

On March 6, 2012, the Company s Board of Directors decided not to declare a quarterly cash dividend on the Company s 6% Convertible Exchangeable Preferred Stock (Preferred Stock) with respect to the first quarter of 2012 that would have otherwise been payable on May 1, 2012.

Subsequent Developments

NASDAQ Appeal

Previously, the Company received a determination letter from NASDAQ, notifying the Company that it had not regained compliance with the minimum closing bid price requirements set forth in Listing Rule 5450(a)(1) (the Rule) during the 180 calendar days allowed to regain compliance and that the Company s common stock was subject to delisting from the NASDAQ Global Market.

On April 26, 2012, the Company presented its plan to regain compliance with the Rule, which plan included the possibility of effectuating a reverse stock split, before a NASDAQ Listing Qualifications Panel (the Panel). On May 15, 2012, the Panel approved the Company s plan to regain compliance, and determined to continue the Company s listing pursuant to an exception to the Rule for a maximum of 180 calendar days from the date of the NASDAQ Staff s notification, or through September 11, 2012, provided that the Company has evidenced a closing bid price of $1.00 or more for a minimum of ten consecutive trading days prior to such date.

If the Company is unable to provide evidence of compliance with the Rule, the Company may still transfer its listing to the NASDAQ Capital Market if it meets the initial listing criteria set forth in NASDAQ Marketplace Rule 5505, except for the bid price requirement. In that case, it may have until September 11, 2012 to comply with the minimum bid price requirement. The Company currently meets these initial listing criteria, except for the bid price requirement.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Consolidation

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

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Use of Estimates

The preparation of financial statements in accordance with U.S. 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 revenues and expenses during the reporting period. Critical estimates include estimated levels of product returns, and inputs used to determine stock-based compensation expense and the fair value of financial instruments, such as Economic Rights and other liabilities measured at fair value. Cyclacel 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 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 initial purchase to be cash equivalents. The objectives of the Company s cash management policy are to safeguard and preserve funds, to maintain liquidity sufficient to meet Cyclacel s cash flow requirements and to attain a market rate of return.

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.

Trade accounts receivable are included in prepaid expenses and other current assets on the consolidated balance sheet and were $0.1 million and $0.2 million at December 31, 2011 and March 31, 2012, respectively. All trade accounts receivable were deemed collectible as of December 31, 2011 and March 31, 2012.

For the three months ended March 31, 2011 and 2012, approximately 90% and 86%, respectively, of our product sales in the United States were to three wholesalers.

Inventory

Cyclacel values inventories at the lower of cost or market. The Company determines cost using the first-in, first-out method. As of March 31, 2012 and December 31, 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. A critical input in this determination is future expected sales forecasts. The Company writes off inventory that is expected to expire before being sold. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required in future periods.

There were no inventory write-downs during the three months ended March 31, 2011 and 2012. In the future, reduced demand, quality issues or excess supply may result in write-downs, which would be recorded as adjustments to cost of sales.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, Economic Rights, and other liabilities measured at fair value. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate their respective fair values due to the nature of the accounts, notably their short maturities. Economic Rights and other liabilities measured at fair value employ applicable inputs as described in *Note 3, Fair Value Measurements* .

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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 product sales, and has considered the guidance in ASC Subtopic 605-15, *Revenue Recognition -Products* (ASC 605-15) and ASC Subtopic 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 less 5% of the current wholesale acquisition price (in accordance with our returns policy) and deferred cost of sales at the cost at which those goods were held in inventory. The Company recognizes revenue and cost of sales 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. At the time of revenue recognition, the Company also estimates a provision for returned products based on historical data and future expectations; this provision is charged against revenues.

Deferred revenue was $0.1 million at December 31, 2011 and March 31, 2012. Deferred cost of goods sold was approximately $20,000 and $22,000 at December 31, 2011 and March 31, 2012, 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 previously recognized 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 earned and received are not refundable. The Company had deferred grant revenue of approximately $75,000 at March 31, 2012. The Company had no such deferred revenue at December 31, 2011.

Clinical Trial Accounting

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

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Research and Development Expenditures

Research and development expenses consist primarily of costs associated with developing the Company s product candidates, including upfront fees and milestones paid to parties from whom the Company licenses certain intellectual property, 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 remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange (losses)/gains in the statement of operations.

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 remeasurement of foreign-currency denominated intercompany loans that are of a long-term-investment nature, are recorded in other comprehensive income.

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 applies the guidance codified in ASC Topic 740, *Income taxes* (ASC 740) related to accounting for uncertainty in income taxes. 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.

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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 Amended and Restated Equity Incentive Plan (2006 Plan), which was approved on March 16, 2006, as amended on May 21, 2007, and subsequently amended and restated on April 14, 2008. The Company has granted various types of awards under the 2006 Plan, which is described more fully in *Note 6, Stock-Based Compensation Arrangements*. The Company accounts for these awards under ASC 718, *Compensation Stock Compensation* (ASC 718).

ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on the 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 awards 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 the Company s share price, the anticipated exercise behavior of its employees, interest rates, and dividend yields. These variables are projected based on the Company s 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.

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Net Loss per Common Share

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

	March 31, 2011	March 31, 2012
Stock options	3,347,033	3,438,679
Restricted stock and restricted stock units	52,070	344,784
Convertible preferred stock	516,228	516,228
Contingently issuable common stock and common stock warrants associated with economic rights		2,933,052
Options to purchase common stock and common stock warrants issued in connection with the October 2010 financing	6,242,398	
Common stock warrants	10,005,192	13,814,015
Total shares excluded from calculation	20,162,921	21,046,758

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 non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments, are reported, net of any related tax effect, to arrive at comprehensive income (loss). No taxes were recognized in relation to items of other comprehensive income.

Recent Accounting Pronouncements

In June 2011, the FASB issued Accounting Standards ASU 2011-05 to amend the guidance on the presentation of comprehensive income in ASC 220. ASU 2011-05 requires 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. ASU 2011-05 eliminates the alternative to present comprehensive income within the statement of equity. ASU 2011-05 does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The ASU should be applied retrospectively and is effective for annual periods beginning after December 15, 2011. In December 2011, the FASB issued ASU 2011-12, which deferred the changes in ASU 2011-05 that relate to the presentation of reclassifications out of accumulated other comprehensive income. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, which amends the guidance on fair value measurement in ASC 820 to converge the fair value measurement and disclosure requirements under GAAP and International Financial Reporting Standards (IFRS) fair value measurement and disclosure requirements. The amendments change the wording used to describe the requirements 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. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

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3. FAIR VALUE MEASUREMENTS

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

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

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

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

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

The fair value of the Company s financial assets and liabilities that are measured on a recurring basis were determined using the following inputs as of December 31, 2011:

	Level 1 $000	Level 2 $000	Level 3 $000	Total $000
Cash equivalents	19,894			19,894
Other liabilities measured at fair value:				
Warrants liability			51	51
Scottish Enterprise Agreement			20	20
Other liabilities measured at fair value			71	71
Total	19,894		71	19,965

The fair value of the Company s financial assets and liabilities that are measured on a recurring basis were determined using the following inputs as of March 31, 2012:

	Level 1 $000	Level 2 $000	Level 3 $000	Total $000

Cash equivalents	17,498		17,498
Economic rights		1,153	1,153
Other liabilities measured at fair value:			
Warrants liability		9	9
Scottish Enterprise Agreement		20	20
Other liabilities measured at fair value		29	29
Total	17,498	1,182	18,680

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The following table reconciles the beginning and ending balances of Level 3 inputs for the three months ended March 31, 2012:

	Level 3 $000
Balance as of December 31, 2011	71
Sale of Economic Rights	1,097
Change in valuation of Economic Rights	56
Change in valuation of warrants liability	(42)
Balance as of March 31, 2012	1,182

Economic Rights

On March 22, 2012, the Company entered into a financing agreement with certain existing institutional stockholders. Under the terms of the agreement, investors received contractual rights to receive cash equal to 10% of any future litigation settlement related to the specified intellectual property, subject to a cap. In certain defined situations, the Company may have to issue either additional common shares or warrants.

The Economical Rights are accounted for as a derivative financial instrument under ASC 815, *Derivative financial instruments* (ASC 815), and are measured at fair value. Changes in fair value are recognized in earnings. The fair value of the Economical Rights has been estimated using a decision-tree analysis method. This is an income-based method that incorporates the expected benefits, costs and probabilities of contingent outcomes under varying scenarios. Each scenario within the decision-tree is discounted to the present value using the company s credit adjusted risk-free rate and ascribed a weighted probability to determine the fair value.

The Company has concluded the fair value of this liability was approximately $1.1 million and $1.2 million at March 22, 2012, and March 31, 2012, respectively. The fair value of the derivative increased approximately $56,000 from March 22, 2012 to March 31, 2012. The increase in fair value was recognized as a loss in the consolidated statement of operations for the three month period ended March 31, 2012.

The most significant inputs in estimating the fair value of this liability are:

(i) The Company s credit adjusted risk-free rate, which has been derived from the observable returns on debt for more developed pharmaceuticals companies, adjusted for the Company s risk profile.

(ii) The amount of the return to the investors, which will vary depending on:

a. The outcome of the litigation, including consideration of whether the litigation may be resolved in a jury trial or settled out of court;

b. The amount of the settlement or award, which the Company has estimated predominantly based on observable royalty rates arising from the settlement of other cases of intellectual property litigation; and

c. The form of the settlement or award.

(iii) The projected timing of the cash flows to the investors, which could vary between several months to several years depending upon whether the litigation is settled, when the court may decide the case, whether any appeal is made on any court decision and the form of any settlement or award.

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(iv) The number of contingent warrants that could be issued, which is based on a formula.

The decision-tree analysis model used to calculate the fair value of the derivative requires the probability of alternative scenarios to be determined at a series of decision points. Each scenario may contain more than one decision point resulting in further scenarios. Therefore, the probability estimates made by management at each decision point are a significant input to the valuation model.

All of these inputs are unobservable inputs, which have an interrelated effect on the fair value of the derivative. It is not possible to evaluate the impact on the fair value of each factor in combination. However, generally the fair value of the derivative liability will increase, (i) the higher the value of the expected settlement or award, (ii) the lower the discount rate employed and (iii) the more likely it is that a settlement or award will be made. The fair value of the derivative liability will decrease if the timing of settlement is delayed, the expected settlement decreases, or anticipated litigation costs increase. The impact on the fair value of the derivative liability related to the probability of whether the litigation is settled prior to the court hearing or whether a settlement award is made by the court and the form of the settlement will depend on the other factors above and cannot be estimated in isolation.

The decision-tree analysis model has been performed by valuation specialists, based on inputs provided by the company and other sources. At each reporting period, the inputs to the model will be evaluated to determine whether any adjustments are appropriate, and to reflect changes in the time value of the expected cash flows.

The Company used the following assumptions to calculate the value of the Economic Rights:

	March 22, 2012	**March 31, 2012**
Probability of unsuccessful/successful outcomes	25% - 75%	25% - 75%
Amount of award or settlement (1)	$10.0 million - $20.0 million	$10.0 million - $20.0 million
Discount rate	16%	16%
Timing of cash flows	0.75 2.27 years	0.75 2.27 years
Royalty rate	6%	6%
Litigation expenses	$1.0 million $3.0 million	$1.0 million $3.0 million

(1) Assumptions take into consideration the cap on the amount that the Company would have to pay investors in the event of an award or settlement.

Other Liabilities Measured at Fair Value

Warrants Liability

The Company issued warrants to purchase shares of common stock under the registered direct financing completed in February 2007. These warrants are being accounted for as a liability in accordance with ASC 815. At the date of the transaction, the fair value of the warrants of $6.8 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 4.68%, expected volatility 85%, expected dividend yield 0%, and a remaining contractual life of 7 years. The fair value of the warrant is being remeasured each reporting period, with a 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. The Company used the Black-Scholes option-pricing model with the following assumptions to value the warrants:

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	December 31, 2011	March 31, 2012
Exercise price	$8.44	$8.44
Expected term	2.13 Yrs.	1.88 Yrs.
Risk free interest rate	0.25%	0.33%
Expected volatility	121%	77%
Expected dividend yield over expected term		

The Company recognized the change in the value of warrants as a gain on the consolidated statement of operations of $0.1 million and approximately $42,000 for the three months ended March 31, 2011 and 2012, respectively.

Scottish Enterprise Agreement

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 may be obligated to pay up to £4 million to SE, which will be calculated as a maximum of £4 million (approximately $6.2 million and $6.4 million at December 31, 2011 and March 31, 2012, respectively) less the market value of the shares held by SE at the time staffing levels in Scotland fall below the prescribed minimum levels. If the Company were to have reduced staffing levels below the prescribed levels, the amount potentially payable to SE would have been approximately £3.8 million (approximately $5.9 million) and approximately £3.8 million (approximately $6.1 million) at December 31, 2011 and March 31, 2012, respectively.

This arrangement is accounted for as a liability under ASC 480, *Distinguishing Liabilities from Equity* (ASC 480), 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 approximately $20,000 at December 31, 2011 and March 31, 2012, respectively. The most significant inputs in estimating the fair value of this liability are the probabilities that staffing levels fall below the prescribed minimum and that the Company is unable or unwilling to replace such employees within the prescribed time period. At both December 31, 2011 and March 31, 2012, the Company used a scenario analysis model to arrive at the fair value of the Scottish Enterprise Agreement and assumed a 30% probability of falling below a minimum staffing level and a 1% probability that the occurrence of such an event would not be cured within the prescribed time period. At each reporting period, the inputs used to determine the fair value of the liability will be evaluated to determine whether adjustments are appropriate. Changes in the value of this liability are recorded in the consolidated statement of operations.

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4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	December 31, 2011	March 31, 2012
	($000s)	
Research and development tax credit receivable	541	734
Prepayments	321	278
Accounts receivable	116	152
Deposits	13	153
Other current assets	209	106
Total prepaid expenses and other current assets	1,200	1,423

5. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES

Accrued and other current liabilities consisted of the following:

	December 31, 2011	March 31, 2012
	($000s)	
Accrued research and development	3,471	3,334
Other current liabilities	1,193	1,170
	4,664	4,504

6. STOCK BASED COMPENSATION

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the three months ended March 31, 2011 and 2012 as shown in the following table:

	For the three months ended March 31,	
	2011	2012
	($000s)	
Research and development	50	17
General and administrative	201	85
Stock-based compensation costs before income taxes	251	102

At the Company s annual shareholder meeting on May 14, 2008, the stockholders approved and amended the number of shares reserved under the 2006 Plan to 5,200,000 shares of the Company s common stock, up from 3,000,000 shares. The 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.

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A summary of activity for the options under the Company s 2006 Plan for the three months ended March 31, 2012 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in $000s)
Options outstanding at December 31, 2011	3,515,741	$ 3.73	6.44	140
Granted				
Exercised	77,062	$ 0.44		
Expired				
Cancelled / forfeited				
Options outstanding at March 31, 2012	3,438,679	$ 3.80	6.18	233
Unvested at March 31, 2012	556,177	$ 1.72	8.59	1
Vested and exercisable at March 31, 2012	2,882,502	$ 4.20	5.71	232

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, recent awards made to rank-in-file employees vest ratably over three to four years, with 1/36 to 1/48 of the award vesting each month.

The Company estimates grant date fair value for stock option awards 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.

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

The Company estimates the expected term of stock option awards using past history of early exercise behavior and expectations about future 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.

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There were no options granted during either of the three month periods ending March 31, 2011 and 2012.

During the three months ended March 31, 2011, 5,131 stock options were exercised resulting in approximately $2,000 of cash proceeds to the Company. During the three months ended March 31, 2012, there were 77,062 stock options exercised totaling approximately $34,000 in proceeds. As the Company presently has tax loss carry forwards from prior periods and expects to incur tax losses during the year ended December 31, 2012, 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 50,000 shares of restricted common stock to an employee subject to certain forfeiture provisions. Specifically, one quarter of the award vests one year from the date of grant and 1/48 of the award effectively vests each month thereafter. This restricted stock grant was accounted for at fair value at the date of grant and an expense is recognized during the vesting term. Summarized information for the restricted stock grant for the three months ended March 31, 2012 is as follows:

	Restricted Stock		Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2011	11,450	$	0.44
Vested	(3,126)	$	0.44
Non-vested at March 31, 2012	8,324	$	0.44

Restricted Stock Units

In November 2008 and December 2011, respectively, the Company issued 91,700 and 238,000 restricted stock units to senior executives. Each unit entitles the holder to receive a share of the Company s common stock.

During the first quarter of 2012, the Company issued approximately 86,000 restricted stock units to employees as part of its annual grant.

The 2008 grants vest over four years and the 2011 and 2012 grants vest over three years. 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 over the vesting term. Summarized information for restricted stock grants for the three months ended March 31, 2012 is as follows:

	Restricted Stock Units		Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2011	255,175	$	0.80
Granted	85,974	$	0.55
Vested	(4,689)	$	0.44

Non-vested at March 31, 2011	336,460	$	0.74

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.

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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. 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, a milestone payment of $1.6 million was paid in April 2011. A further $10.0 million in aggregate milestone payments could be payable subject to achievement of all the specific contractual milestones and the Company s decision to continue with these projects. 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 upon twelve months notice after a launch of a sapacitabine-based product. The license also may be terminated 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 rate due from the Company to Daiichi Sankyo on future net sales of sapacitabine be increased between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.

In connection with the asset acquisition of ALIGN on October 5, 2007, the Company acquired distribution rights for the exclusive rights to sell and distribute three products in the United States. Each of the agreements covering the three products expires in June 2015, after which the Company has no rights to distribute these products. The Company has a minimum purchase obligation equivalent to the value of product purchased in the previous year. For the year ended December 31, 2012 this equates to $0.2 million.

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 has filed counterclaims charging Celgene with infringement of each of its four patents and seeking damages for Celgene s infringement as well as injunctive relief. The four patents directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product.

A Scheduling Order was entered February 2, 2012, at which time the court set the following significant dates: March 22, 2012 (amendment of pleadings/joinder of parties); September 24, 2012 (teleconference with the court exploring possibility of Alternative Dispute Resolution); March 14, 2013 (claim construction hearing); August 14, 2013 (summary judgment briefing); and June 2, 2014 (7 day jury trial start date). Discovery is currently ongoing.

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8. STOCKHOLDERS EQUITY

Preferred stock

As of March 31, 2012, 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.

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. The Company has reserved 516,228 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at March 31, 2012.

During 2010, 833,671 shares of Preferred Stock were converted into 1,655,599 shares of the Company s common stock. Since inception through March 31, 2012, holders have voluntarily converted 1,776,858 shares of Preferred Stock into common stock. 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, 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.

On March 6, 2012, the Company s Board of Directors decided not to declare a quarterly cash dividend on the Company s 6% Convertible Exchangeable Preferred Stock (Preferred Stock) with respect to the first quarter of 2012 that would have otherwise been payable on May 1, 2012.

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Common Stock

March 2012 Sale of Common Stock and Economic Rights

On March 22, 2012, the Company entered into a purchase agreement with certain existing institutional stockholders, raising approximately $2.9 million of proceeds, net of certain fees and expenses. The proceeds from the financing will be used to fund ongoing litigation-related expenses on certain intellectual property and for general corporate purposes.

Under the terms of the purchase agreement, the investors purchased 4,688,079 shares of the Company s common stock at a price of $0.6476, which is equal to the 10-day average closing price of the Company s common stock for the period ending on Wednesday, March 21, 2012. In addition to the common stock, investors received contractual rights to receive cash equal to 10% of any future litigation settlement related to the specified intellectual property, subject to a cap. In certain defined situations, the Company may have to issue either additional shares or warrants. The shares issued at closing are subject to a lock-up period of one year from the date of issuance.

See *Note 3, Fair Value Measurements* for further details.

Common Stock Warrants

The following table summarizes information about warrants outstanding at March 31, 2012:

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	2015	3,808,823	$	1.36
Total		13,814,015	$	3.28

There were no exercises of warrants during the three months ended March 31, 2011 and 2012.

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward looking statements due to a number of factors, including those set forth in Part I, Item 1A, entitled Risk Factors, of our Annual Report on Form 10-K for the year ended December 31, 2011, as updated and supplemented by Part II, Item 1A, entitled Risk Factors, of our Quarterly Reports on Form 10-Q, and elsewhere in this report. These factors as well as other cautionary statements made in this Quarterly Report on Form 10-Q, should be read and understood as being applicable to all related forward-looking statements wherever they appear herein. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our judgment as of the date hereof. We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements. In this report, Cyclacel, the Company, we, us, and our refer to Cyclacel Pharmaceuticals, Inc.

Overview

We are a development-stage biopharmaceutical company dedicated to the development and commercialization of small-molecule drugs that target the various phases of the cell cycle for the treatment of cancer and other serious diseases, particularly those of high unmet medical need.

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 have generated several families of anticancer drugs that act on the cell cycle including nucleoside analogues, cyclin dependent kinase, or CDK, inhibitors and Aurora kinase/Vascular Endothelial Growth Factor Receptor 2 or AK/VEGFR 2 inhibitors and Plk inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitor and AK inhibitor drugs, we believe that our drug candidates are differentiated in that they are orally-available and interact with unique target profiles and mechanisms. For example we believe that our sapacitabine is the only orally-available nucleoside analogue presently being tested in a Phase 3 trial in AML and in Phase 2 for MDS and NSCLC and seliciclib is the most advanced orally-available CDK inhibitor currently in Phase 2 trials. Our resources are primarily directed towards advancing our lead drug candidate sapacitabine through in-house development activities although we are also progressing our earlier stage novel drug series through working with external collaborators but with limited investment by us.

We have worldwide rights to commercialize sapacitabine and seliciclib and our business strategy is to enter into selective partnership arrangements with these programs. Taken together, our pipeline covers all four phases of the cell cycle, which we believe will improve the chances of successfully developing and commercializing novel drugs that work on their own or in combination with approved conventional chemotherapies or with other targeted drugs to treat human cancers.

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Sapacitabine is being evaluated in the SEAMLESS Phase 3 trial being conducted under a Special Protocol Assessment agreement with the US Food and Drug Administration for the front-line treatment of acute myeloid leukemia in the elderly and in Phase 2 studies for myelodysplastic syndromes, lung cancer and chronic lymphocytic leukaemia. Additionally, sapacitabine has been shown to have increased activity in cancer cells with BRCA- or Homologous Recombinant repair-deficient backgrounds, including ovarian cancer cell lines.

We have ongoing clinical programs in development awaiting further data. Once data becomes available and is reviewed, we will determine the feasibility of pursuing further development and/or partnering these assets, including sapacitabine in combination with seliciclib and seliciclib in NSCLC and nasopharyngeal cancer, or NPC. In addition, we market directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia.

From our inception in 1996 through March 31, 2012, 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 March 31, 2012, our accumulated deficit during the development stage was $260.0 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and pre-clinical drug candidates. Our operating expenses are comprised of research and development expenses and selling, general and administrative expenses.

To date, we have not generated significant product revenue but have financed our operations and internal growth through private placements, registered direct financings, licensing revenue, collaborations, interest on investments, government grants and research and development tax credits. We have recognized revenues from inception through March 31, 2012, totaling $9.9 million, of which $3.1 million is derived from fees under collaborative agreements, $3.7 million of grant revenue from various United Kingdom and European government grant awards, and $3.2 million from product sales. We have also recognized $18.6 million in research and development tax credits, which are reported as income tax benefits on the consolidated statements of operations, from the United Kingdom s tax authority, H.M. Revenue & Customs since inception.

Research and development expenditures for the three months ended March 31, 2012 decreased $1.7 million, or 56%, from $3.1 million for the three months ended March 31, 2011 to $1.3 million for the three months ended March 31, 2012. This is because during the three months ended March 31, 2011, we incurred a contractual milestone amount of $1.6 million payable to Daiichi Sankyo under the sapacitabine licensing agreement. We expect that for the year ended December 31, 2011, research and development expenses will increase compared to those incurred for the year ended December 31, 2011, excluding the contractual obligation payment made to Daiichi Sankyo, as we continue to enroll the randomized portion of the SEAMLESS pivotal Phase 3 trial.

Recent Developments

Sale of Common Stock and Economic Rights

On March 22, 2012, we entered into a purchase agreement with certain existing institutional stockholders, raising $2.9 million of proceeds, net of certain fees and expenses. The proceeds from the financing will be used to fund ongoing litigation-related expenses involving specified intellectual property and for general corporate purposes.

Under the terms of the purchase agreement, the investors purchased 4,688,079 shares of our common stock at a price of $0.6476, which is equal to the 10-day average closing price of our common stock for the period ended on Wednesday, March 21, 2012. The shares issued at closing are subject to a lock-up period of one year from the date of issuance.

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In addition to the common stock, investors received contractual rights to receive cash equal to 10% of any future litigation settlement related to the specified intellectual property, subject to a cap. In certain defined situations, we may have to issue either additional shares or warrants.

Preferred Stock Dividend

On March 6, 2012, our Board of Directors decided not to declare a quarterly cash dividend on our 6% Convertible Exchangeable Preferred Stock (Preferred Stock) with respect to the first quarter of 2012 that would have otherwise been payable on May 1, 2012.

Subsequent Events

NASDAQ Appeal

Previously, we received a determination letter from NASDAQ notifying us that we had not regained compliance with the minimum closing bid price requirements set forth in Listing Rule 5450(a)(1) (the Rule) during the 180 calendar days allowed to regain compliance and that our common stock was subject to delisting from the NASDAQ Global Market.

On April 26, 2012, we presented our plan to regain compliance with the Rule, which plan included the possibility of effectuating a reverse stock split, before a NASDAQ Listing Qualifications Panel (the Panel). On May 15, 2012, the Panel approved our plan to regain compliance, and determined to continue our listing pursuant to an exception to the Rule for a maximum of 180 calendar days from the date of the NASDAQ Staff s notification, or through September 11, 2012, provided that we have evidenced a closing bid price of $1.00 or more for a minimum of ten consecutive trading days prior to such date.

If we are unable to provide evidence of compliance with the Rule, we may still transfer our listing to the NASDAQ Capital Market if we meet the initial listing criteria set forth in NASDAQ Marketplace Rule 5505, except for the bid price requirement. In that case, we may have until September 11, 2012 to comply with the minimum bid price requirement. We currently meet these initial listing criteria, except for the bid price requirement.

Results of Operations

Three Months Ended March 31, 2011 and 2012

Revenues

The following table summarizes the components of our revenues for the three months ended March 31, 2011 and 2012:

	Three months ended March 31,			
	2011	2012	Difference	Difference
		($000s)		%
Product revenue	192	161	(31)	(16)
Total revenue	192	161	(31)	(16)

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. During each of the three months ended March 31, 2011 and 2012, we recognized revenue of approximately $0.2 million in accordance with our revenue recognition policy.

We may also recognize, from time to time, revenue from collaboration and research and development and from grant awards. We had no collaboration and research and development revenue or grant revenue for each of the three months periods ended March 31, 2011 and 2012.

The future

We expect to continue to maintain the sales of ALIGN products for the year ended December 31, 2012 through the support of a small sales and marketing infrastructure. We also expect to recognize approximately $0.2 million in grant revenue over the next twelve to eighteen months in connection with an award from the European Union to study ovarian cancer therapies.

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Cost of goods sold

	Three months ended March 31,			
	2011	**2012**	**Difference**	**Difference**
		($000s)		**%**
Cost of goods sold	106	94	(12)	(11)

Total cost of sales represented 55% and 58% of product revenue for the three months ended March 31, 2011 and 2012, respectively.

Research and development expenses

We expense all research and development expenses 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 March 31, 2011 and 2012:

	Three months ended March 31,			
	2011	**2012**	**Difference**	**Difference**
		($000s)		**%**
Sapacitabine	2,971	1,237	(1,734)	(58)%

Other research and development costs	109	110	1	0%
Total research and development expenses	3,080	1,347	(1,733)	(56)%

Total research and development expenses represented 62% and 40% of our operating expenses for the three months ended March 31, 2011 and 2012, respectively.

Research and development expenditures decreased by $1.7 million to $1.3 million for the three month period ended March 31, 2012 from $3.1 million for the three month period ended March 31, 2011. The decrease was primarily due to $1.6 million of contractual expenses recognized during the three months ended March 31, 2011, resulting from an achievement of a milestone triggered by the opening of enrollment in the lead-in portion our SEAMLESS trial, pursuant to the Daiichi-Sankyo license under which we license certain patent rights for sapacitabine, and a $0.2 million decrease in sapacitabine capsule manufacturing costs, partially offset by a $0.1 million increase in clinical trial costs.

The future

We will continue to concentrate our resources on the development of sapacitabine. We anticipate that overall research and development expenditures for the year ended December 31, 2012 will increase compared to the year ended December 31, 2011, excluding the milestone payment to Daiichi-Sankyo, as we enroll the randomized portion of the SEAMLESS pivotal Phase 3 trial.

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Selling, general and administrative expenses

Selling, general and administrative expenses include costs for sales and marketing and administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the selling, general and administrative expenses for the three months ended March 31, 2011 and 2012:

	Three months ended March 31,			
	2011	**2012**	**Difference**	**Difference**
		($000s)		**%**
Total selling, general and administrative expenses	1,806	1,996	190	11

Total selling, general and administration expenses represented 36% and 58% of our operating expenses for the three months ended March 31, 2011 and 2012, respectively.

Our selling, general and administrative expenditure increased by approximately $0.2 million from $1.8 million for the three months ended March 31, 2011, to $2.0 million for the three months ended March 31, 2012. The increase in expenses was primarily attributable to a net increase in professional and consultancy costs of $0.2 million.

The future

We expect our selling, general and administrative expenditures for the year ended December 31, 2012 to remain at the same level as our expenditures for the year ended December 31, 2011.

Other income (expense)

The following table summarizes other income (expense) for the three months ended March 31, 2011 and 2012:

	Three months ended March 31,			
	2011	**2012**	**Difference**	**Difference**
		($000s)		**%**
Change in valuation of Economic Rights		(56)	(56)	
Change in valuation of other liabilities measured at fair value	78	42	(36)	(46)
Foreign exchange gains (losses)	(68)	114	182	268
Interest income	11	6	(5)	(45)

Other income		47	47	
Total other income (expense)	21	153	132	629

Total other income and expense, net, increased by approximately $0.1 million, from income of approximately $21,000 for the three months ended March 31, 2011, to income of $0.2 million for the three months ended March 31, 2012. The increase was primarily because of the $0.2 million increase in foreign exchange gains, mostly due to the increase in exchange rate of the British Pound Sterling relative to the U.S. Dollar and an approximately $47,000 gain on sale of equipment.

The change in valuation of Economic Rights related to the sale of Economic Rights in connection with the purchase agreement completed in March 2012. These collective rights are classified as liabilities and will be marked to market each reporting period. For the three months ended March 31, 2012, we recognized a loss of approximately $56,000 due to the change in the value of Economic Rights from the transaction date of March 22, 2012 to March 31, 2012.

The change in valuation of other liabilities measured at fair value relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007 and our liability under an agreement with the Scottish Enterprise, or SE, that would require us to make a payment to SE should staffing levels in Scotland fall below prescribed minimum levels. The warrants and agreement are classified as liabilities. The value of the warrants is being marked to market each reporting period as a gain or loss. Such gains or losses will continue to be reported for the warrants until they are exercised or expired. Gains of losses on the SE Agreement will be reported until the agreement expires in July 2014. For the three months ended March 31, 2011 and 2012, the change in the valuation of other liabilities measured at fair value was a decrease of $78,000 and $42,000, respectively.

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Foreign exchange gains (losses) increased by $0.2 million to a gain of $0.1 million for the three months ended March 31, 2012 compared to a loss of approximately $68,000 for the three months ended March 31, 2011. Foreign exchange gains (losses) are reported in the consolidated statement of operations as a separate line item within other income (expense).

We recognized approximately $47,000 in other income from the sale of laboratory equipment during the three months ended March 31, 2012. We did not recognize any such income during the three months ended March 31, 2011.

The future

The valuation of the Economic Rights, warrants liability, and SE Agreement will continue to be re-measured at the end of each reporting period. The change in valuation of the Economic Rights is dependent on a number factors, including our stock price, and other management assumptions, including, the probability of success of the underlying litigation, amount of award or settlement, discount rate, royalty rate, and timing of cash flows, and may fluctuate significantly, which may have a significant impact on our statement of operations. The valuation of the warrant is dependent upon many factors, including our stock price, interest, and remaining term of the instrument and may fluctuate significantly, which may have a significant impact on our statement of operations. The valuation of the SE Agreement is dependent on a number of factors, including our stock price and the probability of the occurrence of certain events that would give rise to a payment. We do not expect the valuation of fair value of the SE Agreement to fluctuate significantly.

As the nature of funding advanced through intercompany loans is that of a long-term investment in nature, future unrealized foreign exchange gains and losses on such funding will be recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable. This will minimize the future impact of unrealized foreign exchange fluctuations on earnings.

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 March 31, 2011 and 2012:

	Three months ended March 31,			
	2011	**2012**	**Difference**	**Difference**
		($000s)		**%**
Total income tax benefit	191	168	(23)	(12)

Research and development tax credits recoverable decreased by $23,000 to $0.2 million for the three months ended March 31, 2012 relative to the three-month period ended March 31, 2011. The level of tax credits recoverable is linked directly to qualifying research and development

expenditure incurred in any one year but is restricted to the payroll taxes paid by us to HMRC in that same year. The decrease is a consequence of lower payroll taxes in the period.

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. If legislation is passed that eliminates the restriction of the amount recoverable to the payroll taxes paid in a period, we expect the amount of tax credits we will be able to recover to increase for the year ended December 31, 2012.

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Liquidity and Capital Resources

The following is a summary of our key liquidity measures at December 31, 2011 and March 31, 2012:

	December 31, 2011	March 31, 2012	$ Difference	% Difference
		($000s)		
Cash and cash equivalents	$ 24,449	$ 23,640	$ (809)	(3)%
Working capital:				
Current assets	$ 25,831	$ 25,172	$ (659)	(3)%
Current liabilities	(6,498)	(6,802)	(304)	5%
Working capital	$ 19,333	$ 18,370	$ (963)	(5)%

At March 31, 2012, we had cash and cash equivalents of $23.6 million as compared to $24.5 million at December 31, 2011. The decrease in balance was primarily due to normal cash outflows required to operate our business, offset by $2.9 million proceeds, net of certain expenses, received from a sale of common stock and Economic Rights completed in March 2012. 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 income on our investments, licensing revenue, government grants and research and development tax credits. We have incurred significant losses since our inception. As of March 31, 2012, we had an accumulated deficit during the development stage of $260.0 million.

We currently anticipate that our cash and cash equivalents are sufficient to meet our anticipated short-term working capital needs and to fund our on-going sapacitabine clinical trials for at least the next twelve months. However, we cannot be certain that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in clinical development, should they succeed.

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

Cash provided by (used in) operating, investing and financing activities for the three months ended March 31, 2011 and 2012, is summarized as follows:

	Three months ended March 31, 2011	2012
	($000s)	
Net cash used in operating activities	(3,892)	(3,771)
Net cash provided by investing activities		15
Net cash (used in) provided by financing activities	(260)	2,945

Operating activities

Net cash used in operating activities decreased slightly from $3.9 million for the three months ended March 31, 2011 to $3.8 million for the three months ended March 31, 2012. Net cash used in operating activities during the three months ended March 31, 2012 resulted from our net operating loss of $2.9 million and a net decrease in working capital of $0.9 million due to an increase in prepaid expenses combined with a decrease in accounts payable and other current liabilities.

Investing activities

Net cash provided by investing activities for the three months ended March 31, 2012 was $15,000 as a result of the sale of laboratory equipment. There were no cash flows from investing activities during the three months ended March 31, 2011.

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Financing activities

Net cash used in financing activities for the three months ended March 31, 2011 was $0.3 million as a result of paying a cash dividend of approximately $0.2 million to our Preferred stockholders. Net cash provided by financing activities was $2.9 million for the three months ended March 31, 2012. During the three months ended March 31, 2012, we completed a sale of stock and Economic Rights for proceeds of approximately $2.9 million, net of certain expenses.

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur substantial operating losses in the future. Although we have generated a limited amount of product revenues from ALIGN product sales from October 2007 through March 31, 2012, we cannot guarantee that we will generate any significant product revenues until a product candidate has been approved by the US Food and Drug Administration, or 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.

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 factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. We believe the judgments and estimates required by the following accounting policies to be critical in the preparation of our consolidated financial statements.

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Revenue Recognition

Product sales

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

We offer a general right of return on these product sales and 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 less 5% of the current wholesale acquisition price in accordance with our returns policy 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 product 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 also record against revenue a provision for product returns which is calculated based on the historical return rate for each product.

Stock-based Compensation

We grant stock options, restricted stock units and restricted stock to officers, employees, directors and consultants under the Company s Amended and Restated Equity Incentive Plan, which was amended and restated as of April 14, 2008. We measure compensation cost for all stock-based awards at fair value on date of grant and recognize compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of our common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, the anticipated exercise behavior of our employees, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments.

The fair 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 are 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.

Economic Rights

The Economic Rights are accounted for as a derivative financial instrument and measured at fair value. Changes in fair value are recognized in earnings. The fair value of the Economic Rights has been estimated using a decision-tree analysis method. This is an income-based method that incorporates the expected benefits, costs and probabilities of contingent outcomes under varying scenarios. Each scenario within the

decision-tree is discounted to the present value using the company s credit adjusted risk-free rate and ascribed a weighted probability to determine the fair value. Changes in any of these assumptions could result in material adjustments to the expense recognized for changes in the valuation of the Economic Rights.

The Company has concluded the fair value of this liability was approximately $1.1 million and $1.2 million at March 22, 2012, and March 31, 2012, respectively. We recognized approximately $56,000 as a loss on our consolidated statement of operations for the three months ended March 31, 2012 as a result of an increase in the value of the Economic Rights from the transaction date to March 31, 2012.

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Other Liabilities Measured at Fair Value

Warrants Liability

The accounting guidance on derivatives and hedging requires freestanding contracts that are settled in our own stock, including common stock warrants to be designated as equity instruments, assets or liabilities. Under the provisions of this guidance, a contract designated as an asset or a liability must be carried at fair value until exercised or expired, with any changes in fair value recorded in the results of operations. A contract designated as an equity instrument must be included within equity, and no subsequent fair value adjustments are required. We review the classification of the contracts at each balance sheet date. 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. We recorded income of approximately $78,000 and $42,000 to reflect the change in fair value for the years ended March 31, 2011 and 2012, respectively. Fair value is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrants liability.

Scottish Enterprise Agreement

The accounting guidance on distinguishing liabilities and equity requires freestanding financial instruments that meet certain criteria to be accounted for as liabilities and carried at fair value until exercised or expired, with any changes in fair value recorded in the results of operations. We entered into an agreement with SE in 2009 that would require us to pay SE £4 million (approximately $6.4 million at March 31, 2012) less the market value of the shares held by SE if staffing levels in Scotland fall below minimum levels stipulated in the Agreement. Due to the nature of the associated contingency and the likelihood of occurrence, we concluded the fair value of this liability was approximately $20,000 at March 31, 2012. The most significant inputs in estimating the fair value of this liability are the probabilities that staffing levels fall below the prescribed minimum levels and that we are unable or unwilling to replace such employees within the prescribed time period. As of March 31, 2012, we concluded the probability of the combination of these events occurring is minimal. We record changes in fair value in the consolidated statement of operations. There were no changes to the fair value for either the three months ended March 31, 2012 or 2011.

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 remeasured into U.S. dollars using the average currency rate in effect for the period and assets and liabilities are remeasured into U.S. dollars using either historical rates or the exchange rate in effect at the end of the period.

From October 1, 2008, foreign exchange gains and losses arising from U.S. dollar denominated intercompany loans with this subsidiary have been recorded have been recorded as a component of other comprehensive income.

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 approximately $68,000 and gains of $0.1 million for the three months ended March 31, 2011 and 2012, respectively.

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Common Stock Price Risk

In February 2007, we issued common stock and warrants and recorded the fair value of the warrants as a current liability. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the consolidated statements of operations. During the three months ended March 31, 2012, we recognized the change in the value of warrants of approximately $42,000 as a gain on the consolidated statement of operations. During the three months ended March 31, 2011, we recognized the change in the value of warrants as a gain of approximately $78,000 on the consolidated statement of operations. Fair value of the derivative instruments will be affected by estimates of various factors that may affect the respective instrument, including our stock price, the risk free rate of return and expected volatility in the fair value of our stock price. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

Item 4. Controls and Procedures

Under the supervision and with the participation of our management, including our chief executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of March 31, 2012, 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. Based upon such evaluation, our chief executive officer and principal financial and accounting officer have concluded that, as of March 31, 2012, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended March 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Controls

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

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PART II. Other Information

Item 1. Legal proceedings

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.

A scheduling Order was entered February 2, 2012, at which time the court set the following significant dates: March 22, 2012 (amendment of pleadings/joinder of parties); September 24, 2012 (teleconference with the court exploring possibility of Alternative Dispute Resolution); March 14, 2013 (claim construction hearing); August 14, 2013 (summary judgment briefing); and June 2, 2014 (7 day jury trial start date). Discovery is currently ongoing.

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, 2011. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed above in Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this Quarterly Report on Form 10-Q. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

We have grouped risks into several categories in order of their potential impact on our results of operations, financial condition, and cash flows.

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 AML.

On September 13, 2010, and as amended on October 11, 2011, 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 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. In January 2011, we opened enrollment in the lead-in portion of the SEAMLESS trial and in October 2011, we opened enrollment in the randomized portion of the 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.

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

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

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

Clinical trials are expensive, time consuming, subject to delay and may be required to continue beyond our available funding and we cannot be certain that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in clinical development, should they succeed.

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 more years 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 IRB and other regulatory approvals to commence a clinical trial;

- slower than anticipated rates of patient recruitment and enrollment, or not reaching the targeted number of patients because of competition for patients from other trials, or if there is limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors for the use of agents used in our clinical trials, such as Dacogen® (decitabine) in SEAMLESS, 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;

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- 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.

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.

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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.

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 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. 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. 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. We depend upon a third party, Sinclair, to manufacture the commercial products sold by our ALIGN subsidiary and we cannot assure that Sinclair will be able to continue to supply the products.

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

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

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

We are highly dependent on our senior management and key clinical development, 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, clinical development, scientific, technical or sales and 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 clinical development, scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant clinical development, scientific and technical expertise, and this competition is likely to continue. The inability to attract and retain sufficient clinical development, 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.

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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 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.

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

- those discussed in the risk factor which immediately follows;

- the fact that the FDA or other regulatory officials may not approve our or our third party manufacturer s processes or facilities; or

- the fact that new regulations may be enacted by the FDA or other regulators may change their approval policies or adoption of new regulations requiring new or different evidence of safety and efficacy for the intended use of a drug candidate.

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

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

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

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

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

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

A large number of drug candidates are in development for the treatment of leukemia, lung cancer, lymphomas and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs or other products on the market or in clinical trials which may be competitive to sapacitabine in both hematological and oncology indications. See Competition under *Item 1. Business* for further details.

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

If our drug candidates are approved, or approved in combination with another agent such as Dacogen® (decitabine) in SEAMLESS, by the FDA or by another regulatory authority, the resulting drugs, if any, must still gain market acceptance among physicians, healthcare providers and payors, patients and the medical community, as would our distribution partners products, including Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. The degree of market acceptance of any of our approved drugs or devices will depend on a variety of factors, including:

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- 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 drug candidates or distribution partners products 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.

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 believe 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. Any attempts to terminate our distribution rights could have adverse consequences on the ALIGN business. This could restrict our ability to sell the ALIGN products.

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 or if the amount of the insurance coverage is insufficient to meet any liabilities resulting from any claims.

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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.

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

If any third party manufacturer 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 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. Sales to three wholesale distributors represented 90% and 86% of our product sales in the United States for the three months ended March 31, 2011 and 2012, respectively. 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, 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 three wholesalers, Cardinal Health, Inc., McKesson Corporation and Amerisource Bergen, 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. 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. Although we attempt to monitor inventory of Xclair®, Numoisyn® Liquid or Numoisyn® Lozenges in the United States through the use of internal sales forecasts and the expiration dates of product shipped, among other factors, we may have quarter-over-quarter fluctuations in inventory and ordering patterns, which can cause our operating results for a particular quarter to be below expectations.

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

Our successful commercialization of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges in the United States will depend on our ability to establish and maintain 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. 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 may suffer, we may 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

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. We may have insufficient public equity available for issue to raise the required

additional substantial funds to implement our operating plan and we may not be able to obtain the appropriate stockholder approvals necessary to increase our available public equity for issuance within a time that we may require additional funding. 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.

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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.

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, NSCLC and CLL. 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.

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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, 2011 and March 31, 2012, our accumulated deficit was $257.1 million and $260.0 million, respectively. Our net loss for the three months ended March 31, 2011 and 2012 was $4.6 million, $2.9 million, respectively. Our net loss applicable to common stockholders from inception through March 31, 2012 was $302.0 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.

If we fail to comply with the continued listing requirements of the NASDAQ Global Market, our common stock 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.

In September 2011, we received a NASDAQ Staff Deficiency Letter indicating that were 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. On March 15, 2012, we were notified by the NASDAQ Staff that we did not comply with the minimum bid price set forth in NASDAQ Listing Rule 5450(a)(1) (the Rule) and that our securities are subject to delisting from The NASDAQ Global Market unless we request a hearing before a NASDAQ Listing Qualifications Panel (the Panel). We timely requested a hearing before the Panel, which automatically stays the delisting of our securities pending the issuance of the Panel s decision after a hearing.

On April 26, 2012, we presented our plan, which could include effectuating a reverse stock split, to regain compliance with the Rule before the Panel. On May 15, 2012, the Panel approved the Company s plan to regain compliance, and determined to continue our listing pursuant to an exception to the Rule for a maximum of 180 days from the date of the Staff s notification or through September 11, 2012, provided that we have evidenced a closing bid price of $1.00 or more for a minimum of ten consecutive trading days prior to such date.

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If we are unable to provide evidence of compliance with the Rule, we may transfer our listing to The NASDAQ Capital Market if we meet the initial listing requirements set forth in NASDAQ Marketplace Rule 5505, except for the bid price requirement, which requirements include, among other things, the following criteria: (i) our stockholders equity must be at least $5,000,000; (ii) the market value of our publicly held shares must be at least $15,000,000; and (iii) the market value of our shares held by non-affiliates must be at least $1,000,000. In that case, we may have until September 11, 2012 to regain compliance. The Company currently meets these initial listing criteria of the NASDAQ Capital Market, except for the bid price requirement.

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: