Cyclacel Pharmaceuticals, Inc.
Form 10-Q
August 14, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2013

OR

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 August 13, 2013 there were 17,715,113 shares of the registrant s common stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

CYCLACEL PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In $000s, except share amounts)

	December 31, 2012	June 30, 2013 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,412	$ 33,668
Prepaid expenses and other current assets	1,599	2,670
Current assets of discontinued operations	861	817
Total current assets	18,872	37,155
Property, plant and equipment (net)	129	169
Long-term assets of discontinued operations	353	186
Total assets	$ 19,354	$ 37,510
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,259	$ 2,437
Accrued and other current liabilities	5,601	3,797
Economic Rights measured at fair value	1,120	
Other liabilities measured at fair value	20	20
Current liabilities of discontinued operations	335	325
Total current liabilities	9,335	6,579
Total liabilities	9,335	6,579
Commitments and contingencies (Note 7)		
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2012 and June 30, 2013; 1,213,142 and 420,682 shares issued and outstanding at December 31, 2012 and June 30, 2013, respectively. Aggregate preference in liquidation of $14,436,390 and $5,006,116 at December 31, 2012 and June 30, 2013, respectively	1	
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2012 and June 30, 2013; 8,686,484 and 17,715,113 shares issued and outstanding at December 31, 2012 and June 30, 2013, respectively	9	17
Additional paid-in capital	280,211	311,125
Accumulated other comprehensive income (loss)	48	(5)
Deficit accumulated during the development stage	(270,250)	(280,206)
Total stockholders equity	10,019	30,931
Total liabilities and stockholders equity	$ 19,354	$ 37,510

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 June 30,		Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2012	2013	2012	2013	2013
Revenues:					
Collaboration and research and development revenue	$	$	$	$	$ 3,100
Grant revenue	26	264	26	476	4,193
Total revenues	26	264	26	476	7,293
Operating expenses:					
Research and development	1,717	2,631	3,064	4,211	196,602
General and administrative	2,121	1,787	3,889	4,470	93,881
Goodwill and intangibles impairment					2,747
Other restructuring costs					2,634
Total operating expenses	3,838	4,418	6,953	8,681	295,864
Operating loss	(3,812)	(4,154)	(6,927)	(8,205)	(288,571)
Other income (expense):					
Costs associated with aborted 2004 IPO					(3,550)
Payment under guarantee					(1,652)
Non-cash consideration associated with stock purchase agreement					(423)
Change in valuation of Economic Rights	146		90	570	547
Change in valuation of liabilities measured at fair value	8		50		6,378
Foreign exchange gains (losses)	117	(101)	231	19	(3.986)
Interest income	6	3	12	4	13,751
Interest expense					(4,567)
Other income (expense), net	29	5,500	76	5,504	5,581
Total other income	306	5,402	459	6,097	12,079
(Loss) income from continuing operations before taxes	(3,506)	1,248	(6,468)	(2,108)	(276,492)
Income tax benefit, net	127	230	295	488	20,283
Net (loss) income from continuing operations	(3,379)	1,478	(6,173)	(1,620)	(256,209)
Discontinued operations:					
(Loss) income from discontinued operations	(198)	24	(359)	50	(11,759)
Income tax on discontinued operations		(10)		(20)	(357)
Net (loss) income from discontinued operations	(198)	14	(359)	30	(12,116)
Net (loss) income	(3,577)	1,492	(6,532)	(1,590)	(268,325)
Dividend on preferred ordinary shares					(38,123)

Deemed dividend on convertible exchangeable preferred shares				(8,366)	(11,881)
Dividend on convertible exchangeable preferred shares	(182)	(63)	(364)	(185)	(4,570)
Net (loss) income applicable to common shareholders	$ (3,759)	$ 1,429	$ (6,896)	$ (10,141)	$ (322,899)
Basic earnings per common share:					
Net (loss) income per share, continuing operations	$ (0.42)	$ 0.10	$ (0.80)	$ (0.86)	
Net (loss) income per share, discontinued operations	$ (0.02)	$ 0.00	$ (0.04)	$ 0.00	
Net (loss) income applicable to common shareholders	$ (0.45)	$ 0.10	$ (0.85)	$ (0.86)	
Diluted earnings per common share:					
Net (loss) income per share, continuing operations	$ (0.42)	$ 0.10	$ (0.80)	$ (0.86)	
Net (loss) income per share, discontinued operations	$ (0.02)	$ 0.00	$ (0.04)	$ 0.00	
Net (loss) income applicable to common shareholders	$ (0.45)	$ 0.10	$ (0.85)	$ (0.86)	
Weighted average shares of common stock outstanding:					
Basic	8,428,154	13,885,442	8,125,621	11,849,270	
Diluted	8,428,154	13,927,371	8,125,621	11,849,270	

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 June 30,		Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2012	2013	2012	2013	2013
Net (loss) income from continuing operations	$ (3,379)	$ 1,478	$ (6,173)	$ (1,620)	$ (256,209)
Net (loss) income from discontinued operations	(198)	14	(359)	30	(12,116)
Net (loss) income	(3,577)	1,492	(6,532)	(1,590)	(268,325)
Translation adjustment	2,398	(14)	(931)	6,638	7,353
Unrealized foreign exchange gain (loss) on intercompany loans	(2,385)	202	952	(6,691)	(7,358)
Comprehensive loss	$ (3,564)	$ 1,680	$ (6,511)	$ (1,643)	$ (268,330)

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 STATEMENT OF CASH FLOWS
(In $000s)
(Unaudited)

	Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2012	2013	2013
Operating activities:			
Net loss	$ (6,532)	$ (1,590)	$ (268,325)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accretion of interest on notes payable, net of amortization of debt premium			100
Amortization of investment premiums, net			(2,297)
Change in valuation of liabilities measured at fair value	(140)	(1,120)	(7,475)
Non-cash consideration associated with stock purchase agreement			423
Depreciation	30	36	12,651
Amortization of intangible assets			886
Fixed asset impairment			221
Unrealized foreign exchange (gains) losses			7,747
Deferred revenue			(98)
Compensation for warrants issued to non-employees			1,215
Gain on sale of patents		(5,500)	(5,500)
Shares issued for IP rights			446
Loss (gain) on disposal of property, plant and equipment	(62)		38
Goodwill and intangibles impairment			7,934
Stock-based compensation	211	146	19,549
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
Gain on termination of distribution agreements			(1,192)
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(307)	(1,124)	(1,421)
Accounts payable and other current liabilities	(709)	(1,530)	(5,075)
Net cash used in operating activities	(7,476)	(10,682)	(235,844)
Investing activities:			
Purchase of ALIGN			(3,763)
Purchase of property, plant and equipment	(10)	(92)	(8,941)
Minimum royalty payments received from termination of ALIGN license agreement		264	264
Proceeds from sale of patents		5,500	5,500
Proceeds from sale of property, plant and equipment	62		225
Purchase of short-term investments on deposit, net of maturities			(156,657)
Cash proceeds from redemption of short term securities			162,729
Net cash provided by (used in) investing activities	52	5,672	(643)

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

	Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2012	2013	2013
Financing activities:			
Payments of capital lease obligations			(3,719)
Proceeds from issuance of ordinary and preferred ordinary shares, net of issuance costs			121,678
Proceeds from issuance of common stock and warrants, net of issuance costs	2,886	22,495	118,047
Proceeds from the exercise of stock options and warrants, net of issuance costs	34		267
Payment of preferred stock dividend		(192)	(2,090)
Repayment of government loan			(455)
Government loan received			414
Loan received from Cyclacel Group plc			9,103
Proceeds of committable loan notes issued from shareholders			8,883
Loans received from shareholders			1,645
Cash and cash equivalents assumed on stock purchase of Xcyte			17,915
Costs associated with stock purchase			(1,951)
Net cash provided by financing activities	2,920	22,303	269,737
Effect of exchange rate changes on cash and cash equivalents	19	(37)	418
Net increase (decrease) in cash and cash equivalents	(4,485)	17,256	33,668
Cash and cash equivalents, beginning of period	24,449	16,412	
Cash and cash equivalents, end of period	$ 19,964	$ 33,668	$ 33,668
Supplemental cash flow information:			
Cash received during the period for:			
Interest	8	5	11,761
Taxes			18,772
Cash paid during the period for:			
Interest			(1,914)
Taxes			(166)
Schedule of non-cash transactions:			
Acquisitions of equipment purchased through capital leases			3,470
Issuance of shares of common stock 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		181	345
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 and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious diseases. Cyclacel is focused on delivering leading edge therapeutic management of cancer patients based on a clinical 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 (SPA) agreement with the US Food and Drug Administration (FDA) for the front-line treatment of acute myeloid leukemia (AML) in the elderly and in Phase 2 studies for AML, myelodysplastic syndromes (MDS), non-small cell lung cancer (NSCLC) and chronic lymphocytic leukemia. Sapacitabine is also being evaluated in a Phase 1 study in combination with seliciclib, our second clinical candidate, in patients with solid tumors. The FDA and the European Medicines Agency, or EMA, have designated sapacitabine as an orphan drug for the treatment of both AML and MDS.

The Company has evaluated seliciclib, an oral, highly selective inhibitor of CDK enzymes, in NSCLC and nasopharyngeal cancer (NPC). The Company will determine the feasibility of pursuing further development and/or partnering this asset and/or indications subject to available resources.

Our second generation CDK inhibitor, CYC065, is an oral, highly selective inhibitor of CDK enzymes. CYC065 has been shown to have increased anti-proliferative potency and improved pharmaceutical properties compared to seliciclib. Investigational new drug or IND-enabling studies with CYC065 are in progress supported by a $1.9 million grant from the UK Government s Biomedical Catalyst.

In addition to these development programs, the Company has allocated limited resources to other programs allowing the Company to maintain and build on its core competency in cell cycle biology and related drug discovery. These include CYC140, an internally-discovered, potent and selective, orally-available, small molecule inhibitor of PLK1, or polo-like kinase 1. PLKs are kinases active during cell division, that target the mitotic phase of the cancer cell cycle. In the Company s Aurora kinase inhibitor program, CYC116, an internally-discovered, orally-available, small molecule inhibitor of Aurora kinases A and B and Vascular Endothelial Growth Factor Receptor 2, or VEGFR2, has completed a multicenter Phase 1 trial. PLK and Aurora are cancer drug targets discovered by Professor David Glover, the Company s Chief Scientist.

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.

Capital Resources

The Company s existing capital resources are expected to be sufficient to complete the enrollment of the SEAMLESS Phase 3 trial but not sufficient to complete development of other indications or product candidates or to commercialize any of the Company s product candidates.

Basis of Presentation

The condensed consolidated balance sheet as of June 30, 2013, the condensed consolidated statements of operations, comprehensive loss, and cash flows for the three and six months ended June 30, 2012 and 2013 and the period from August 13, 1996 (inception) to June 30, 2013, and all related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2012 is derived from the audited consolidated financial statements included in the 2012 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 June 30, 2013, and the results of operations, comprehensive loss and cash flows for the three and six months ended June 30, 2012 and 2013, have been made. The interim results for the three months ended June 30, 2013 are not necessarily indicative of the results to be expected for the year ending December 31, 2013 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, 2012, included in the Company s Annual Report on Form 10-K filed with the SEC.

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Consolidation

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

Use of Estimates

The preparation of financial statements in accordance with 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 inputs used to determine stock-based compensation expense and the fair value of financial instruments 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. Cyclacel believes the judgments and estimates required by the following accounting policies to be significant in the preparation of the Company s consolidated financial statements.

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 and categorizes such investments as held to maturity. 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. Cash and cash equivalents, composed of $1.5 million of cash and $32.2 million of cash equivalents, was $33.7 million at June 30, 2013. Cash and cash equivalents, composed of $12.3 million of cash and $4.1 million of cash equivalents, was $16.4 million at December 31, 2012. Cash equivalents include money market funds and commercial paper.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk are primarily cash and cash equivalents. The Company maintains its cash and cash equivalent balances in the form of business checking accounts, money market accounts and commercial paper, the balances of which at times may exceed federal insurance limits. Cash equivalents are invested in accordance with the Company s investment policy. The investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, accounts payable, accrued liabilities, common stock warrants, financial instruments associated with stock purchase agreements, and other arrangements. The carrying amounts of cash and cash equivalents, accounts payable, and accrued liabilities approximate their respective fair values due to the nature of the accounts, notably their short maturities. Warrants, financial instruments associated with stock purchase agreements, and certain other liabilities are measured at fair value using applicable inputs as described in *Note 3 - Fair Value*.

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Revenue Recognition

Collaboration, research and development, and grant revenue

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

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

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

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 and progress through the trial. Any initial payment made to the clinical trial site is recognized upon execution of the clinical trial agreements and expensed as research and development expenses.

Research and Development Expenditures

Research and development expenses consist primarily of costs associated with the Company s product candidates, upfront fees, milestones, compensation and other expenses for research and development personnel, supplies and development materials, costs for consultants and related contract research, facility costs 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 translation of intercompany loans that are of a long-term-investment nature, are recorded in other comprehensive income.

Fair Value Measurements

Inputs used to determine the 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, for quoted prices (unadjusted) in active markets for identical assets or liabilities, to Level 3, for unobservable inputs (see *Note 3 - Fair Value*). 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.

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Income Taxes

Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company applies the accounting guidance codified in ASC 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.

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

Tax years 2010, 2011 and 2012 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the United States and the United Kingdom, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service (IRS), the HMRC or state tax authorities if they have or will be used in a future period. The Company is currently not under examination by the IRS or any other jurisdictions for any tax years.

Income tax benefit, net from continuing operations on the consolidated statements of operations of $0.5 million for the six months ended June 30, 2013 includes $0.6 million of research and development tax credits from the HMRC and approximately $80,000 in tax expense estimated based on the application of IRS alternative minimum tax.

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, amended and restated on April 14, 2008 and further amended on May 23, 2012. Under the 2006 Plan, the Company has granted various types of awards, which are 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 date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of the Company s common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using the Black-Scholes model, which includes variables such as the expected volatility of the Company s share price, the anticipated exercise behavior of employees, interest rates, and dividend yields. These variables are projected based on historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments. Such value is recognized as an expense over the requisite service period, net of estimated forfeitures, using the

straight-line attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from 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

After considering its business activities and geographic reach, the Company has concluded that it operates in just one operating segment being the discovery, development and commercialization of novel, mechanism-targeted drugs to treat cancer and other serious disorders, with development operations in two geographic areas, namely the United States and the United Kingdom.

Net (Loss) Income Per Common Share

The Company calculates net (loss) income per common share in accordance with ASC 260 Earnings Per Share (ASC 260). Basic net loss (income) per common share was determined by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. The Company s potentially dilutive shares include outstanding common stock options, restricted stock, restricted stock units, convertible preferred stock and common stock warrants.

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The computation of basic earnings per share and diluted earnings per share for Income from continuing operations for the three and six months ended June 30, 2012 and 2013 is as follows (in $000s, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2013	2012	2013
Net (loss) income from continuing operations	$ (3,379)	$ 1,478	$ (6,173)	$ (1,620)
Deemed dividend on convertible exchangeable preferred shares				(8,366)
Dividend on convertible exchangeable preferred shares	(182)	(63)	(364)	(185)
Numerator for earnings per share for Income from continuing operations Basic and Diluted	$ (3,561)	$ 1,415	$ (6,537)	$ (10,171)
Weighted average shares of common stock outstanding Basic	8,428,154	13,885,442	8,125,621	11,849,270
Dilutive effect of stock options		41,929		
Weighted average shares of common stock outstanding Diluted	8,428,154	13,927,371	8,125,621	11,849,270
Net (loss) income from continuing operations Basic	$ (0.42)	$ 0.10	$ (0.80)	$ (0.86)
Net (loss) income from continuing operations Diluted	$ (0.42)	$ 0.10	$ (0.80)	$ (0.86)

The following potentially dilutive shares of common stock have not been included in the computation of diluted net loss per share for the three and six month periods ended June 30, 2012 and 2013 as the result would be anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2013	2012	2013
Stock options	508,766	334,996	508,766	487,719
Restricted Stock and Restricted Stock Units	44,138	123,143	44,138	123,143
Convertible preferred stock	73,747	25,573	73,747	25,573
Contingently issuable shares and common stock warrants associated with Economic Rights	440,375		440,375	
Common stock warrants	1,973,431	1,591,795	1,973,431	1,591,795
Total shares excluded from calculation	3,040,457	2,075,507	3,040,457	2,228,230

Comprehensive Income (Loss)

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

Accounting Standards Adopted in the Period

On January 1, 2013 the Company adopted guidance issued by the Financial Accounting Standards Board (FASB) on testing indefinite-lived intangible assets for impairment. This guidance states that an entity has the option first to assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. If, after assessing the totality of events and circumstances, an entity concludes that it is not more likely than not that the indefinite-lived intangible asset is impaired, then the entity is not required to take further action. However, if an entity concludes otherwise, then it is required to determine the fair value of the indefinite-lived intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying. Under the guidance, an entity also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. An entity will be able to resume performing the qualitative assessment in any subsequent period. The adoption of this guidance has not had a material impact on our consolidated financial statements.

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On January 1, 2013, the Company adopted guidance issued by the FASB on the reporting of amounts reclassified out of accumulated other comprehensive income. The guidance requires entities to present (either on the face of the statement where net income is presented or in the notes) the effects on the line items of net income of significant amounts reclassified out of accumulated other comprehensive income, but only if the item reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For other reclassification items (that are not required under GAAP) to be reclassified directly to net income in their entirety in the same reporting period, an entity should cross-reference to other disclosures currently required under GAAP. The adoption of this guidance has not had a material impact on our consolidated financial statements.

On January 1, 2013, the Company adopted guidance issued by the FASB to clarify the scope of the previously issued guidance which required companies to disclose information about offsetting and related arrangements to enable users of financial statements to understand the effect of those arrangements on its financial position. This guidance clarifies that ordinary trade receivables and receivables are not within the scope of the guidance and that the guidance only applies to derivatives, repurchase agreements and reverse purchase agreements, and securities borrowing and securities lending transactions that are either offset in accordance with specific criteria or subject to a master netting arrangement or similar agreement. The adoption of this guidance has not had a material impact on our consolidated financial statements.

Recent Accounting Pronouncements Not Yet Effective

In July 2013, the FASB issued guidance relating to the presentation of an unrecognized tax benefit when a net operating loss carryforward (NOL), a similar tax loss, or a tax credit carryforward exists. The guidance states that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a NOL, a similar tax loss, or a tax credit carryforward, except to the extent it is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. We are currently reviewing the impact of adopting this guidance.

In March 2013, the FASB issued guidance relating to certain foreign currency matters. This guidance clarifies the parent company s accounting for the cumulative translation adjustment when a reporting entity ceases to have a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business within a foreign entity or of an investment in a foreign entity. The guidance is effective prospectively for fiscal years (and interim reporting periods within those years) beginning after December 15, 2013. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In February 2013, the FASB issued guidance relating to obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date. This provides guidance for the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date, except for obligations addressed within existing guidance in GAAP. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The guidance should be applied retrospectively to all prior periods presented for those obligations resulting from joint and several liability arrangements that exist at the beginning of an entity s fiscal year of adoption. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

3. FAIR VALUE

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:

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- 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 considering counterparty credit risk in its measurement 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, 2012 (in $000s):

	Level 1	Level 2	Level 3	Total
ASSETS				
Cash equivalents	$ 5,523	$ 6,799	$	$ 12,322
Total assets	$ 5,523	$ 6,799	$	$ 12,322
LIABILITIES				
Financial instrument associated with stock purchase agreement	$	$	$	$
Economic rights			1,120	1,120
Other liabilities measured at fair value:				
Warrants liability				
Scottish Enterprise agreement			20	20
Other liabilities measured at fair value			20	20
Total liabilities	$	$	$ 1,140	$ 1,140

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 June 30, 2013 (in $000s):

	Level 1	Level 2	Level 3	Total
ASSETS				
Cash equivalents	$ 31,404	$ 800	$	$ 32,204
Total assets	$ 31,404	$ 800	$	$ 32,204
LIABILITIES				
Financial instrument associated with stock purchase agreement	$	$	$	$
Other liabilities measured at fair value:				
Warrants liability				

Scottish Enterprise agreement			20	20
Other liabilities measured at fair value			20	20
Total liabilities	$	$	$ 20	$ 20

The following table reconciles the beginning and ending balances of Level 3 inputs for the six months ended June 30, 2013 (in $000s):

	Level 3
Balance as of December 31, 2012	$ 1,140
Change in valuation of Economic Rights	(570)
Movement of valuation of Economic Rights from Level 3 to Level 2	(550)
Balance as of June 30, 2013	$ 20

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Financial Instrument Associated with Stock Purchase Agreement

On December 14, 2012, the Company entered into a common stock purchase agreement with Aspire under which Aspire purchased 158,982 shares of common stock for an aggregate purchase price of $1.0 million and committed to purchase up to an additional 1,455,787 shares from time to time as directed by the Company over the next two years at prices derived from the market prices on or near the date of each sale. However, such commitment is limited to an additional $19.0 million of share purchases. In consideration for entering into the purchase agreement, concurrent with the execution of the purchase agreement, the Company issued 74,548 shares of its common stock to Aspire in lieu of paying a commitment fee. The fair value of the 74,548 shares of common stock along with the direct costs incurred in the connection with the Aspire transaction have been allocated to the shares sold at inception of this agreement and the right to sell additional shares in the future based on the ratio of shares sold at inception to the total shares subject to this agreement. As a result, the Company recorded an expense of $0.4 million on its consolidated statements of operations for the year ended December 31, 2012.

During the first quarter of 2013, the Company sold 650,000 shares of its common stock to Aspire under the Common Stock Purchase Agreement in consideration for aggregate proceeds of $3.4 million.

The Company has accounted for the right to sell additional shares based on the guidance of ASC 815, Derivative Financial Instruments (ASC 815), which requires the instrument to be measured at fair value with changes in fair value reported in earnings. The instrument was deemed to have had minimal fair value at inception and such value is not expected to change throughout the term of the agreement as shares sold upon exercise are priced at an amount slightly lower than the fair value at the time of sale.

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 specified intellectual property, subject to a cap. In certain defined situations, the Company may have to issue either additional shares of common stock or warrants (collectively, the Economic Rights). The Economic Rights were accounted for as a derivative financial instrument under ASC 815 and are measured at fair value. Changes in fair value are recognized in earnings.

On April 3, 2013, the Company entered into a definitive agreement with Celgene Corporation (Celgene) to sell to Celgene four Cyclacel-owned patents related to the use of romidepsin injection, intellectual property to which the Economic Rights relates. In connection with the agreement, Celgene has made to Cyclacel a one-time payment of $5.5 million and the litigation was dismissed. As a result, the holders of the Economic Rights were paid approximately $0.6 million in April 2013 in full satisfaction of the Company s obligation under Economic Rights. The fair value of this liability was approximately $1.1 million as of December 31, 2012. The $0.6 million decrease in the fair value of the Economic Rights during the six months ended June 30, 2013 was recognized as a gain in the consolidated statements of operations.

Up to December 31, 2012, the fair value of the Economic Rights was estimated using a decision-tree analysis method. This was an income-based method that incorporates the expected benefits, costs and probabilities of contingent outcomes under varying scenarios. Each scenario within the decision-tree was discounted to the present value using the Company s credit adjusted risk-free rate and ascribed a weighted probability to determining the fair value. As of March 31, 2013, the Company had sufficient information available to estimate the fair value of the economic

rights based on the actual amount paid under the Economic Rights agreement, which was 10% of the $5.5 million one-time payment from Celgene. The Company s obligation under the Economic Rights was satisfied in April 2013.

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. As of December 31, 2012 and June 30, 2013, the fair value of the warrants was approximately zero based on the high exercise price of the warrants relative to the Company s stock price at December 31, 2012 and June 30, 2013, respectively, and the remaining term of less than 1 year. The fair value of the warrant is 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.

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The Company recognized the change in the value of warrants as a gain on the consolidated statement of operations of approximately $8,000 and $50,000 for the three and six months ended June 30, 2012. There was no change in the value of warrants for the three and six months ended June 30, 2013.

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 $6.5 million at December 31, 2012 and $6.1 million at June 30, 2013) 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 $6.1 million) and approximately £3.8 million (approximately $5.9 million) at December 31, 2012 and June 30, 2013, respectively.

This arrangement is accounted for as a liability under ASC Topic 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, 2012 and June 30, 2013, 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, 2012 and June 30, 2013, 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.

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

The following is a summary of prepaid expenses and other current assets at December 31, 2012 and June 30, 2013 (in $000s):

	December 31, 2012	June 30, 2013
Research and development tax credit receivable	$ 1,033	$ 1,517

Prepayments	358	459
Grant receivable		277
Sales tax receivable	45	219
Deposits	153	153
Other current assets	10	45
	$ 1,599	$ 2,670

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5. ACCRUED AND OTHER CURRENT LIABILITIES

Accrued and other current liabilities consisted of the following (in $000s):

	December 31, 2012	June 30, 2013
Accrued research and development	$ 3,623	$ 3,136
Accrued legal and professional fees	1,118	137
Other current liabilities	860	524
	$ 5,601	$ 3,797

6. STOCK BASED COMPENSATION

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 ¼ of the award vesting one year from the date of grant and 1/48 of the award granted vesting each month thereafter. Annual awards granted in December 2010 vest 1/48 of the award each month after the grant date. Certain awards made to executive officers vest over three to five years, depending on the terms of their employment with the Company.

The Company recognizes all share-based awards issued after the adoption of ASC 718 under the straight-line attribution method. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company evaluates its forfeiture assumptions quarterly and the expected forfeiture rate is adjusted when necessary. Ultimately, the actual expense recognized over the vesting period is based solely on those shares that vest.

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the three and six months ended June 30, 2012 and 2013 as shown in the following table (in $000s):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2013	2012	2013
General and administrative	$ 66	$ 60	$ 142	$ 117
Research and development	16	14	33	29
Discontinued operations	27		36	
Stock-based compensation costs before income taxes	$ 109	$ 74	$ 211	$ 146

2006 Plan

On March 16, 2006, the 2006 Plan was adopted, under which Cyclacel may make equity incentive grants to its officers, employees, directors and consultants. At the Company s annual shareholder meeting on May 23, 2012, the stockholders approved and amended the number of shares reserved under the 2006 Plan to 1,428,571 shares of the Company s common stock, up from 742,857 shares. Stock option awards granted under the 2006 Plan have a maximum life of 10 years and generally vest over a four-year period from the date of grant.

There were 235,000 and 32,697 options granted during the six months ended June 30, 2012 and 2013, respectively.

During the six months ended June 30, 2012, 77,062 options were exercised for proceeds of approximately $34,000. There were no stock options exercised during the six months ended June 30, 2013.

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Outstanding Options

A summary of the share option activity and related information is as follows:

Cyclacel Pharmaceuticals, Inc.	Number of options outstanding	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value ($000)
Options outstanding at December 31, 2012	463,023	$ 26.61	5.58	$ 347
Granted	32,697	$ 3.01		
Exercised		$		
Cancelled/forfeited	(8,001)	$ 17.10		
Options outstanding at June 30, 2013	487,719	$ 25.18	5.46	3
Unvested at June 30, 2013	85,606	$ 6.47	8.78	
Vested and exercisable at June 30, 2013	402,113	$ 29.20	4.76	3

The fair value of the stock options granted is calculated using the Black-Scholes option-pricing model as prescribed by ASC 718.

The expected term assumption is estimated using past history of early exercise behavior and expectations about future behaviors

Estimates of pre-vesting option forfeitures are based on the Company s experience. Currently the Company uses a forfeiture rate of 0 30% 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 Company considers many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. During the six months ended June 30, 2012, the Company recognized an expense of approximately $1,000 as a result of revised forfeiture rates. There was no change in forfeiture rates during the six months ended June 30, 2013.

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.

Restricted Stock Units

The Company issued 85,974 and 85,097 restricted stock units to employees during the six months ended June 30, 2012 and 2013, respectively. 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. The 2013 restricted stock units will vest upon the fulfillment of certain clinical and financial conditions and will terminate if they have not vested by December 31, 2014. The Company determined that the satisfaction of the vesting criteria was not probable at June 30, 2013 and, as a result, did not record any expense related to these awards for the six months ended June 30, 2013.

Summarized information for restricted stock unit activity for the six months ended June 30, 2013 is as follows:

	Restricted Stock Units		Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2012	39,377	$	5.34
Granted	85,097	$	5.71
Forfeited	(1,331)	$	3.85
Non-vested at June 30, 2013	123,143	$	5.61

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7. COMMITMENTS AND CONTINGENCIES

Distribution, Licensing and Research Agreements

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

Pursuant to the Daiichi Sankyo license under which the Company licenses certain patent rights for sapacitabine, its lead drug candidate, the Company is under an obligation to use reasonable endeavors to develop a product and obtain regulatory approval to sell a product and has agreed to pay Daiichi Sankyo an up-front fee, reimbursement for Daiichi Sankyo s enumerated expenses, milestone payments and royalties on a country-by-country basis. The up-front fee, Phase 3 entry milestone, and certain past reimbursements have been paid. 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 twelve months, if after a launch of a sapacitabine-based product, or by either party for material default.

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 certain uses of romidepsin were invalid and not infringed by Celgene s sale of ISTODAX® (romidepsin for injection). The Company subsequently counterclaimed for infringement of these four patents. On April 3, 2013, the Company entered into a definitive agreement with Celgene to sell to Celgene the four Cyclacel-owned patents related to uses of romidepsin and their foreign counterparts. In connection with the definitive agreement, Celgene has made a one-time payment of $5.5 million to Cyclacel. As a result, the litigation between Cyclacel and Celgene in the United States District Court for the District of Delaware, case number 1:10-cv-00348-GMS, was dismissed by virtue of a jointly filed stipulation requesting the Court to enter an Order dismissing the litigation and the entry of such an Order. The $5.5 million sale of patents has been recorded in other income (expense), net, in the consolidated statement of operations for the three and six months ended June 30, 2013.

8. STOCKHOLDERS EQUITY

Preferred Stock

As of June 30, 2013, there were 420,682 shares of the Company s 6% Convertible Exchangeable Preferred Stock (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 (the Board) 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 0.06079 shares of common stock for each share of Preferred Stock based on a price of $164.50. The Company has reserved 25,573 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at June 30, 2013.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company s common stock has exceeded $246.75, 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.

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

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, 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. No such exchanges have taken place to date.

Conversion of Convertible Preferred Stock

During the six months ended June 30, 2013, the Company converted an aggregate of 792,460 shares of Preferred Stock into an aggregate of 1,513,653 shares of the Company s common stock. There were no conversions of the Company s Preferred Stock into shares of common stock during the six months ended June 30, 2012 or during the three months ended June 30, 2013. Since the Company s transaction with Xcyte Therapies, Inc. in 2006, holders have exchanged 1,626,131 shares of Preferred Stock into common stock as a result of arms-length negotiations between the Company and the other parties. The shares of previously-converted Preferred Stock have been retired, cancelled and 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 table below provides details of the aggregate activities in 2013:

	Six months ended June 30, 2013
Preferred shares exchanged	792,460
Shares of common stock issued:	
At stated conversion terms	48,174
Incremental shares issued under the exchange transaction	1,465,479
Total shares of common stock issued	1,513,653

As the Preferred stockholders received additional shares of common stock issued to them upon conversion as compared to what they would have been entitled to receive under the stated rate of exchange, the Company recorded the excess of (1) the fair value of all securities and other consideration transferred to the holders of the Preferred Stock and (2) the fair value of securities issuable pursuant to the original conversion terms as a deemed dividend resulting in an increase in the net loss attributable to common shareholders. Specifically, the Company recorded

deemed dividends related to the additional shares issued under the exchange transactions of $8.4 million for the six months ended June 30, 2013. There were no Preferred Stock exchanges during the three months ended June 30, 2013.

On each of January 11, 2013 and April 5, 2013, the Board declared a quarterly cash dividend in the amount of $0.15 per share on the Company s Preferred Stock with respect to the fourth quarter of 2012 and first quarter of 2013, respectively. The Company paid the dividends on February 1, 2013 and May 1, 2013 to holders of record of the Preferred Stock as of the close of business on January 22, 2013 and April 19, 2013, respectively.

Common Stock

May 2013 Underwriting Agreement

On May 16, 2013, the Company entered into an underwriting agreement relating to the public offering and sale of up to 6,666,667 shares of the Company s common stock, par value $0.001, at a price to the public of $3.00 per share. On May 21, 2013, the Company closed the public offering and completed the sale of 6,833,334 shares of its common stock, which includes 166,667 shares that were subject to the underwriters over-allotment option, at a price to the public of $3.00 per share, for proceeds, net of certain fees and expenses, of approximately $19.0 million.

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Common Stock Bonus

During the six months ended June 30, 2013, the Company issued 31,643 shares of common stock with a fair value of approximately $0.2 million to employees in lieu of cash in connection with bonuses recorded for the year ended December 31, 2012. There were no such stock issuances during the six months ended June 30, 2012 or during the three months ended June 30, 2013.

December 2012 Stock Purchase Agreement

On December 14, 2012, the Company entered into a common stock purchase agreement with Aspire. Upon execution of the Purchase Agreement, Aspire purchased 158,982 shares of common stock for an aggregate purchase price of $1.0 million based the closing price of the Company s common stock December 13, 2012, the date upon which the business terms were agreed. Under the terms of the Purchase Agreement, Aspire has committed to purchase up to an additional 1,455,787 shares from time to time as directed by the Company over the next two years at prices derived from the market prices on or near the date of each sale. However, such commitment is limited to an additional $19.0 million of share purchases. In December 2012, in consideration for entering into the Purchase Agreement, the Company issued 74,548 shares of its common stock to Aspire in lieu of paying a commitment fee. During the six months ended June 30, 2013, the Company sold 650,000 shares of its common stock to Aspire under the Purchase Agreement in consideration for aggregate proceeds of $3.4 million.

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 were to be used to fund litigation-related expenses on certain intellectual property and for general corporate purposes.

Under the terms of the purchase agreement, the investors purchased 669,726 shares of the Company s common stock at a price of $4.53, which is equal to the 10-day average closing price of the Company s common stock for the period ending on March 21, 2012. In addition to the common stock, investors received contractual rights to receive cash equal to 10% of any 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 additional rights were settled in April 2013 in connection with the resolution of the Celgene matter. The shares issued at closing were subject to a lock-up period of one year from the date of issuance. See *Note 3 - Fair Value* for further details.

Common Stock Warrants

The following table summarizes information about warrants outstanding at June 30, 2013:

Issued in Connection With	Expiration Date	Common Shares Issuable		Weighted Average Exercise Price
February 2007 stock issuance	2014	151,773	$	59.08
July 2009 Series II stock issuance	2014	98,893	$	7.00
January 2010 stock issuance	2015	101,785	$	22.82
January 2010 stock issuance	2015	100,714	$	19.95
October 2010 stock issuance	2015	594,513	$	13.44
July 2011 stock issuance	2016	544,117	$	9.52
Total		1,591,795	$	17.06

There were no exercises of warrants during the three and six months ended June 30, 2012 and 2013.

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9. DISCONTINUED OPERATIONS

On August 10, 2012, the Company entered into an agreement with Sinclair to terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid.

Product revenue, cost of goods sold and selling, general and administrative costs related to the promotion and sales of the of Xclair®, Numoisyn® Liquid and Numoisyn® Lozenges have been reclassified from operating results from continuing operations to (loss) income from discontinued operations in the consolidated statement of operations for all periods presented as follows (in $000s):

	Three Months Ended June 30,		Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2012	2013	2012	2013	2013
Product revenue	$ 120	$	$ 281	$	$ 3,604
Cost of goods sold	(89)		(183)		(2,045)
Selling, general and administrative	(229)		(457)		(9,295)
Goodwill and intangible impairment					(5,187)
Interest income		24		50	82
Interest expense					(110)
Gain on termination of license agreement					1,192
(Loss) income from discontinued operations	(198)	24	(359)	50	(11,759)
Income tax expense		(10)		(20)	(357)
(Loss) income from discontinued operations, net of tax	$ (198)	$ 14	$ (359)	$ 30	$ (12,116)

The assets and liabilities associated with product promotion and sales have been classified within assets and liabilities of discontinued operations in the accompanying consolidated balance sheets (in $000s):

	December 31, 2012	June 30, 2013
Current assets of discontinued operations:		
Short term portion of minimum royalty arrangement receivable, net	$ 536	$ 492
Returns indemnification receivable	325	325
Total current assets of discontinued operations	861	817
Long-term assets of discontinued operations:		
Long-term portion of minimum royalty arrangement receivable, net	353	186
Total assets of discontinued operations	$ 1,214	$ 1,003
Current liabilities of discontinued operations:		
Accounts payable	$ 10	$
Returns provision	325	325
Total current liabilities of discontinued operations	$ 335	$ 325

The $0.7 million minimum royalty arrangement receivable outstanding as of June 30, 2013, relates to the present value of the remaining portion of the approximately $1.0 million in minimum royalty payments the Company will receive through September 30, 2015 under the terms of the termination and settlement agreement.

The Company offered a right of return on product sales made prior to the termination of the distribution agreements. The Company has estimated a provision for product returns of $0.3 million as of June 30, 2013 based on historical returns for each product, for which an offsetting asset has been recorded based on the terms of the termination and settlement agreement.

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10. SUBSEQUENT EVENTS

Preferred Dividend

On July 8, 2013, the Board declared a quarterly cash dividend in the amount of $0.15 per share of the Preferred Stock. The cash dividend was paid on August 1, 2013 to the holders of record of the Preferred Stock as of the close of business on July 22, 2013.

The Company completed an evaluation of the impact of any subsequent events through the date financial statements were issued and determined there were no other subsequent events requiring disclosure in or adjustment to these financial statements.

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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, 2012, 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

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

- Acute myeloid leukemia, or AML, in the elderly;
- Myelodysplastic syndromes, or MDS; and
- Solid tumors, including breast cancer, non-small cell lung cancer, or NSCLC, ovarian cancer and pancreatic cancer.

Sapacitabine is being evaluated in the SEAMLESS Phase 3 trial being conducted under a Special Protocol Assessment agreement, or SPA, with the US Food and Drug Administration (FDA) for the front-line treatment of AML in the elderly and in Phase 2 studies for MDS, lung cancer and chronic lymphocytic leukemia. Sapacitabine is also being evaluated in a Phase 1 study in combination with seliciclib in an orally-administered sequential treatment regimen in heavily-pretreated patients with advanced solid tumors, including those who are BRCA-mutation carriers. We have also evaluated seliciclib, a highly selective inhibitor of CDK -2, -7 and -9, in NSCLC and nasopharyngeal cancer (NPC). We will determine the feasibility of pursuing further development and/or partnering these assets and/or indications subject to available resources.

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, PLK inhibitors and Aurora kinase/Vascular Endothelial Growth Factor Receptor 2 or AK/VEGFR 2 inhibitors.

Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues and CDK inhibitor drugs, we believe that our drug candidates are differentiated in that they are orally-available and interact with unique target profiles and mechanisms. For example we believe that our sapacitabine is the only orally-available nucleoside analogue presently being tested in Phase 3 trial in AML and in Phase 2 for MDS after failure of front line agents and seliciclib is an orally-available CDK2, -7 and -9 inhibitor currently in Phase 2 trials. Our resources are primarily directed towards advancing our lead drug candidate sapacitabine through in-house development activities. We are advancing our earlier stage novel drug series through a combination of government funding and external collaborators but with limited investment by us.

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We have worldwide rights to commercialize sapacitabine and seliciclib and our business strategy is to enter into selective partnership arrangements for 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.

From our inception in 1996 through June 30, 2013, we have devoted substantially all our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of June 30, 2013, our accumulated deficit during the development stage was $280.2 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.

Subsequent Events

Preferred Stock Dividend

On July 8, 2013, the Board declared a quarterly cash dividend in the amount of $0.15 per share of the Preferred Stock. The cash dividend was paid on August 1, 2013 to the holders of record of the Preferred Stock as of the close of business on July 22, 2013.

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Results of Operations

Three Months Ended June 30, 2012 and 2013

Results of Continuing Operations

Revenues

The following table summarizes the components of our revenues for the three months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Three months ended June 30,		Difference	
	2012	2013	$	%
Grant revenue	$ 26	$ 264	$ 238	915
Total revenue	$ 26	$ 264	$ 238	915

We recognized $26,000 and $0.3 million in grant revenue for the three months ended June 30, 2012 and 2013, respectively, from the European Union and the UK Government s Biomedical Catalyst.

The future

We expect to recognize approximately $1.4 million in grant revenue over the next two years from the UK Government s Biomedical Catalyst and approximately $37,000 in grant revenue over the next twelve months from the European Union . 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 for the three months ended June 30, 2012 and 2013.

Research and development expenses

From our inception, we have focused on drug discovery and development programs, with particular emphasis on orally-available anticancer agents and our research and development expenses have represented costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for sapacitabine, seliciclib, and sapacitabine in combination with seliciclib. We have also incurred costs in the advancement of product candidates toward clinical and pre-clinical trials and the development of in-house research to advance our biomarker

program and technology platforms. We expense all research and development costs as they are incurred. Research and development expenses primarily include:

- Clinical trial and regulatory-related costs;
- Payroll and personnel-related expenses, including consultants and contract research;
- Preclinical studies and laboratory supplies and materials;
- Technology license costs; and
- Rent and facility expenses for our laboratories.

The following table provides information with respect to our research and development expenditures for the three months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Three months ended June 30,		Difference	
	2012	2013	$	%
Sapacitabine	$ 1,827	$ 2,296	$ 469	26
Other costs related to research and development programs, management and exploratory research	(110)	335	445	405
Total research and development expenses	$ 1,717	$ 2,631	$ 914	53

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Total research and development expenses represented 45% and 60% of our operating expenses for the three months ended June 30, 2012 and 2013, respectively.

Research and development expenditures increased by $0.9 million to $2.6 million for the three months ended June 30, 2013 from $1.7 million for the three months ended June 30, 2012. The increase was primarily due to clinical trial and capsule manufacture 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, 2013 will increase compared to the year ended December 31, 2012, as we continue to enroll the randomized portion of the SEAMLESS pivotal Phase 3 trial and increase our involvement in grant-supported work.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the general and administrative expenses for the three months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Three months ended June 30,		Difference	
	2012	2013	$	%
Total general and administrative expenses	$ 2,121	$ 1,787	$ (334)	(16)

Total general and administration expenses represented 55% and 40% of our operating expenses for the three months ended June 30, 2012 and 2013, respectively.

Our general and administrative expenditure decreased by approximately $0.3 million, from $2.1 million for the three months ended June 30, 2012, to $1.8 million for the three months ended June 30, 2013. The decrease in expenses was primarily attributable to a net decrease in professional and consultancy costs of approximately $0.3 million, mostly due to legal fees related to the patent litigation with Celgene.

The future

We expect our general and administrative expenditures for the year ended December 31, 2013 to be lower than our expenditures for the year ended December 31, 2012.

Other income (expense)

The following table summarizes other income (expense) for the three months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Three months ended June 30,		Difference	
	2012	2013	$	%
Change in valuation of Economic Rights	$ 146	$	$ (146)	(100)
Change in valuation of other liabilities measured at fair value	8		(8)	(100)
Foreign exchange gains (losses)	117	(101)	(218)	(186)
Interest income	6	3	(3)	(50)
Other income (expense), net	29	5,500	5,471	18,866
Total other income	$ 306	$ 5,402	$ 5,096	1,665

Total other income increased by approximately $5.1 million, from approximately $0.3 million for the three months ended June 30, 2012, to $5.4 million for the three months ended June 30, 2013. The increase was primarily due to the $5.5 million increase in other income (expense), net as a result of the sale of four Cyclacel-owned patents to Celgene.

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Change in valuation of Economic Rights

These Economic Rights were classified as liabilities and marked to market each reporting period until their settlement in April 2013. The change in valuation of Economic Rights decreased approximately $0.1 million for the three months ended June 30, 2012. There was no change in the valuation of Economic Rights for the three months ended June 30, 2013 as the valuation of the Economic Rights as of March 31, 2013 was estimated based on the actual amount owed and paid to the holders in April 2013, which was $0.6 million.

Change in valuation of other liabilities measured at fair value

The change in valuation of other liabilities measured at fair value relates to the 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 potentially 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 and the SE Agreement are 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 or losses on the SE Agreement will be reported until the agreement expires in July 2014. For the three months ended June 30, 2012, the change in the valuation of other liabilities measured at fair value was an increase of $8,000. There was no change in the valuation of other liabilities measured at fair value for the three months ended June 30, 2013.

Foreign exchange gains (losses)

Foreign exchange gains (losses) decreased by $0.2 million, from a gain of $0.1 million for the three months ended June 30, 2012, to a loss of $0.1 million for the three months ended June 30, 2013. Foreign exchange gains (losses) are reported in the consolidated statement of operations as a separate line item within other income (expense).

Other income (expense), net

We recognized approximately $29,000 in other income (expense), net during the three months ended June 30, 2012. We recognized approximately $5.5 million in other income (expense), net during the three months ended June 30, 2013 as a result of the sale of four Cyclacel-owned patents to Celgene Corporation, or Celgene.

The future

The warrants liability and SE Agreement will continue to be re-measured at the end of each reporting period. The valuation of the warrants is not expected to change based on the exercise price relative to the market price per share of our common stock and the February 2014 expiration. 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. The litigation underlying the Economic Rights valuation was settled in April 2013.

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

Income tax benefit, net

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 the income tax benefit, net for the three months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Three months ended June 30,		Difference	
	2012	2013	$	%
Total income tax benefit, net	$ 127	$ 230	$ 103	81

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The total income tax benefit, net increased approximately $0.1 million to an income tax benefit, net of $0.2 million for the three months ended June 30, 2013 from an income tax benefit, net of $0.1 million for the three months ended June 30, 2012. Research and development tax credits recoverable increased by approximately $80,000 to $0.3 million for the three months ended June 30, 2013 from $0.2 million for the three months ended June 30, 2012. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year. In the first quarter of 2012, these credits were also restricted to the payroll taxes paid by us to the HMRC in that year. However, in July 2012, legislation was passed to eliminate this restriction for the year ended December 31, 2012 and subsequent periods.

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. The amount of tax credits we will receive is entirely dependent on the amount of eligible expenses we incur. We expect our qualifying research and development expenditure, and thus our tax credit, will remain the same or increase for the year ended December 31, 2013.

Results of Discontinued Operations

The following table summarizes our (loss) income from discontinued operations, net of tax for the three months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Three months ended June 30,		Difference	
	2012	2013	$	%
(Loss) income from discontinued operations	$ (198)	$ 24	$ 222	112
Income tax benefit (expense), net		(10)	(10)	(100)
(Loss) income from discontinued operations, net of tax	$ (198)	$ 14	$ 212	107

In August 2012, we entered into a termination and settlement agreement with Sinclair to terminate, effective September 30, 2012, our license to distribute the ALIGN products, after which we no longer generated product revenue. The operating results associated with the ALIGN products are classified within income (loss) from discontinued operations, net of tax in the consolidated statements of operations for the three months ended June 30, 2012 and 2013.

The income from discontinued operations, net of tax of approximately $14,000 in the three months to June 30, 2013 is the amortization of the discount on the minimum royalty arrangement, net of applicable taxes. The loss from discontinued operations, net of tax, for the three months ended June 30, 2012 was $0.2 million. The loss includes product revenues, cost of goods sold and selling, general and administrative expenses associate with operations that ceased in September 2012.

The future

We have ceased operations associated with the ALIGN products effective September 30, 2012 and do not expect significant activity going forward. We may earn additional income from discontinued operations over the next three years if certain sales targets are met by a successor distributor according to the termination agreement with Sinclair.

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Six Months Ended June 30, 2012 and 2013

Results of Continuing Operations

Revenues

The following table summarizes the components of our revenues for the six months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Six months ended June 30,		Difference	
	2012	2013	$	%
Grant revenue	$ 26	$ 476	$ 450	1,731
Total revenue	$ 26	$ 476	$ 450	1,731

We recognized $26,000 and $0.5 million in grant revenue for the six months ended June 30, 2012 and 2013, respectively, from the European Union and the UK Government s Biomedical Catalyst.

The future

We expect to recognize approximately $1.4 million in grant revenue over the next two years from the UK Government s Biomedical Catalyst and approximately $37,000 in grant revenue over the next twelve months from the European Union . 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 for the six months ended June 30, 2012 and 2013.

Research and development expenses

From our inception, we have focused on drug discovery and development programs, with particular emphasis on orally-available anticancer agents and our research and development expenses have represented costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for sapacitabine, seliciclib, and sapacitabine in combination with seliciclib. We have also incurred costs in the advancement of product candidates toward clinical and pre-clinical trials and the development of in-house research to advance our biomarker program and technology platforms. We expense all research and development costs as they are incurred. Research and development expenses primarily include:

- Clinical trial and regulatory-related costs;

- Payroll and personnel-related expenses, including consultants and contract research;

- Preclinical studies and laboratory supplies and materials;

- Technology license costs; and

- Rent and facility expenses for our laboratories.

The following table provides information with respect to our research and development expenditures for the six months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Six months ended June 30,		Difference	
	2012	2013	$	%
Sapacitabine	$ 3,064	$ 3,304	$ 240	8
Other costs related to research and development programs, management and exploratory research		907	907	100
Total research and development expenses	$ 3,064	$ 4,211	$ 1,147	37

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Total research and development expenses represented 44% and 49% of our operating expenses for the six months ended June 30, 2012 and 2013, respectively.

Research and development expenditures increased by $1.1 million to $4.2 million for the six months ended June 30, 2013 from $3.1 million for the six months ended June 30, 2012. The increase was primarily due to clinical trial and capsule manufacture 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, 2013 will increase compared to the year ended December 31, 2012, as we continue to enroll the randomized portion of the SEAMLESS pivotal Phase 3 trial and increase our involvement in grant supported work.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the general and administrative expenses for the six months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Six months ended June 30,		Difference	
	2012	2013	$	%
Total general and administrative expenses	$ 3,889	$ 4,470	$ 581	15

Total general and administration expenses represented 56% and 51% of our operating expenses for the six months ended June 30, 2012 and 2013, respectively.

Our general and administrative expenditure increased by approximately $0.6 million from $3.9 million for the six months ended June 30, 2012, to $4.5 million for the six months ended June 30, 2013. The increase in expenses was primarily attributable to a net increase in professional and consultancy costs of approximately $0.5 million, mostly due to legal fees related to the patent litigation with Celgene.

The future

We expect our general and administrative expenditures for the year ended December 31, 2013 to be lower than our expenditures for the year ended December 31, 2012.

Other income (expense)

The following table summarizes other income (expense) for the six months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Six months ended June 30,		Difference	
	2012	2013	$	%
Change in valuation of Economic Rights	$ 90	$ 570	$ 480	533
Change in valuation of other liabilities measured at fair value	50		(50)	(100)
Foreign exchange gains	231	19	(212)	(92)
Interest income	12	4	(8)	(67)
Other income (expense), net	76	5,504	5,428	7,142
Total other income	$ 459	$ 6,097	$ 5,638	1,228

Total other income increased by approximately $5.6 million, from income of approximately $0.5 million for the six months ended June 30, 2012, to income of $6.1 million for the six months ended June 30, 2013. The increase was primarily due to the $5.5 million increase in other income (expense), net as a result of the Celgene settlement.

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Change in valuation of Economic Rights

The change in valuation of Economic Rights is related to the Economic Rights sold in connection with the purchase agreement completed in March 2012. These collective rights were classified as liabilities and marked to market each reporting period until their settlement in April 2013. The change in valuation of Economic Rights increased approximately $0.5 million from an approximately $0.1 million gain for the six months ended June 30, 2012 to a $0.6 million gain for the six months ended June 30, 2013. The valuation of the Economic Rights during the six months ended June 30, 2013 was estimated based on the actual amount owed and paid to the holders in April 2013, which was $0.6 million.

Change in valuation of other liabilities measured at fair value

The change in valuation of other liabilities measured at fair value relates to the 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 potentially 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 and the SE Agreement are 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 or losses on the SE Agreement will be reported until the agreement expires in July 2014. For the six months ended June 30, 2012, the change in the valuation of other liabilities measured at fair value was an increase of $0.1 million. There was no change in the valuation of other liabilities measured at fair value for the six months ended June 30, 2013.

Foreign exchange gains

Foreign exchange gains decreased by $0.2 million, from a gain of $0.2 million for the six months ended June 30, 2012, to a gain of $19,000 for the six months ended June 30, 2013. Foreign exchange gains (losses) are reported in the consolidated statement of operations as a separate line item within other income (expense).

Other income (expense), net

We recognized approximately $0.1 million in other income (expense), net during the six months ended June 30, 2012. We recognized approximately $5.5 million in other income (expense), net during the six months ended June 30, 2013 as a result of four Cyclacel-owned patents to Celgene.

The future

The warrants liability, and SE Agreement will continue to be re-measured at the end of each reporting period. The valuation of the warrants is not expected to change based on the exercise price relative to the market price per share of our common stock and the February 2014 expiration. 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. The litigation underlying the Economic Rights valuation was settled in April 2013.

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

Income tax benefit, net

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 the income tax benefit, net for the six months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Six months ended June 30,		Difference	
	2012	2013	$	%
Total income tax benefit, net	$ 295	$ 488	$ 193	65

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The total income tax benefit, net increased approximately $0.2 million to $0.5 million for the six months ended June 30, 2013 from $0.3 million for the six months ended June 30, 2012. Research and development tax credits recoverable increased by approximately $0.2 million to $0.5 million for the six months ended June 30, 2013 from $0.3 million for the six months ended June 30, 2012. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year. In the first quarter of 2012, these credits were also restricted to the payroll taxes paid by us to the HMRC in that year. However, in July 2012, legislation was passed to eliminate this restriction for the year ended December 31, 2012 and subsequent periods.

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. The amount of tax credits we will receive is entirely dependent on the amount of eligible expenses we incur. We expect our qualifying research and development expenditure, and thus our tax credit, will remain the same or increase for the year ended December 31, 2013.

Results of Discontinued Operations

The following table summarizes our (loss) income from discontinued operations, net of tax for the six months ended June 30, 2012 and 2013 (all numbers in table are in thousands except percentages):

	Six months ended June 30,		Difference	
	2012	2013	$	%
(Loss) income from discontinued operations	$ (359)	$ 50	$ 409	114
Income tax (expense), net		(20)	(20)	(100)
(Loss) income from discontinued operations, net of tax	$ (359)	$ 30	$ 389	108

In August 2012, we entered into a termination and settlement agreement with Sinclair to terminate, effective September 30, 2012, our license to distribute the ALIGN products, after which we no longer generated product revenue. The operating results associated with the ALIGN products are classified within income (loss) from discontinued operations, net of tax in the consolidated statements of operations for the six months ended June 30, 2012 and 2013.

The income from discontinued operations, net of tax of approximately $30,000 in the six months to June 30, 2013 is the amortization of the discount on the minimum royalty arrangement, net of applicable taxes. (Loss) income from discontinued operations, net of tax, for the six months ended June 30, 2012 was a loss of $0.4 million. The loss includes product revenues, cost of goods sold and selling, general and administrative expenses associate with operations that ceased in September 2012.

The future

We have ceased operations associated with the ALIGN products effective September 30, 2012 and do not expect significant activity going forward. We may earn additional income from discontinued operations over the next three years if certain sales targets are met by a successor distributor according to the termination agreement with Sinclair.

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Liquidity and Capital Resources

The following is a summary of our key liquidity measures at December 31, 2012 and June 30, 2013 (all numbers in table are in thousands except percentages):

	December 31, 2012	June 30, 2013	$ Difference	% Difference
Cash and cash equivalents	$ 16,412	$ 33,668	$ 17,256	105%
Working capital:				
Current assets	$ 18,872	$ 37,155	$ 18,283	97%
Current liabilities	(9,335)	(6,579)	(2,756)	(30)%
Working capital	$ 9,537	$ 30,576	$ 21,039	221%

At June 30, 2013, we had cash and cash equivalents of $33.7 million as compared to $16.4 million at December 31, 2012. The increase in balance was primarily due to $19.0 million in proceeds from the issuance of common stock under an underwriting agreement closed in May 2013.

Since our inception, we have generated a limited amount of product revenues from ALIGN product sales, which are presented within loss from discontinued operations, net of tax. The ALIGN product revenues ceased on September 30, 2012. We have relied primarily on the proceeds from sales of common and preferred equity securities, as well as the exercise of warrants, to finance our operations and internal growth. Additional funding has come through interest on investments, licensing revenue, government grants, the sale of product rights, and research and development tax credits. We have incurred significant losses since our inception. As of June 30, 2013, we had a deficit accumulated during the development stage of $280.2 million.

We believe that existing funds together with cash generated from operations and recent financing activities are sufficient to satisfy our planned working capital, capital expenditures and other financial commitments for at least the next twelve months. However, we do not currently have sufficient funds to complete development and commercialization of any of our drug candidates. Current business and capital market risks could have a detrimental effect on the availability of sources of funding and our ability to access them in the future which may delay or impede our progress of advancing our drugs currently in the clinical pipeline to approval by the FDA for commercialization.

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

Cash provided by (used in) operating, investing and financing activities for the six months ended June 30, 2012 and 2013, is summarized as follows (all numbers in table are in thousands):

	Six months ended June 30,	
	2012	2013

Net cash used in operating activities	$	(7,476)	$	(10,682)
Net cash provided by investing activities	$	52	$	5,672
Net cash provided by financing activities	$	2,920	$	22,303

Cash flows generated from discontinued operations have been combined with the cash flows from continuing operations within each of the Operating, Investing and Financing activities sections.

Operating activities

Net cash used in operating activities increased by $3.2 million, from $7.5 million for the six months ended June 30, 2012 to $10.7 million for the six months ended June 30, 2013. Net cash used in operating activities during the six months ended June 30, 2013 of $10.7 million resulted primarily from our net loss of $1.6 million, adjusted for the $5.5 million sale of patents, $0.9 million of material non-cash activities comprising of change in valuation of liabilities measured at fair value, depreciation and stock based compensation expense and a net increase of $2.7 million due to an increase in prepaid expenses and other current assets combined with a net decrease in accounts payable and other current liabilities.

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Investing activities

Net cash (used in) provided by investing activities increased from approximately $52,000 for the six months ended June 30, 2012 to approximately $5.7 million for the six months ended June 30, 2013, primarily as a result of the receipt of $5.5 million from the sale of patents and the receipt of approximately $0.3 million in payments under a minimum royalty arrangement associated with discontinued operations, offset by approximately $0.1 million in purchases of laboratory equipment.

Financing activities

Net cash provided by financing activities was $22.3 million for the six months ended June 30, 2013, primarily as a result of approximately $19 million in proceeds from the issuance of common stock under an underwriting agreement closed in May 2013.

Net cash provided by financing activities was $2.9 million for the six months ended June 30, 2012. During the six months ended June 30, 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

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 June 30, 2013, totaling $7.3 million, of which $3.1 million is derived from fees under collaborative agreements and $4.2 million of grant revenue from various United Kingdom government grant awards. We have also recorded $3.6 million from product sales within income (loss) from discontinued operations, although these sales ceased effective September 30, 2012. We have also recognized $20.0 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.

We expect to continue to incur substantial operating losses in the future and cannot guarantee that we will generate any significant product revenues until a product candidate has been approved by the FDA or similar regulatory agencies in other countries and successfully commercialized. We have generated a limited amount of product revenues from ALIGN product sales but these product revenues ceased on September 30, 2012. However, we will receive a total of approximately $0.9 million in quarterly installments through September 2015 as part of a minimum royalty arrangement included in our termination agreement with Sinclair, which will be reported as cash flows provided by (used in) investing activities in our condensed consolidated statements of cash flows.

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.

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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.

Clinical Trial Accounting

Data management and monitoring of our clinical trials are performed with the assistance of contract research organizations (CROs) or clinical research associates (CRAs) in accordance with our standard operating procedures. Typically, CROs and some CRAs bill monthly for services performed, and others bill based upon milestones achieved. For outstanding amounts, we accrue 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 and progress through the trial. Any initial payment made to the clinical trial site is recognized upon execution of the clinical trial agreements and expensed as research and development expenses.

Research and Development Expenditures

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

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 and May 23, 2012. 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.

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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 $42,000 for the six months ended June 30, 2012 to reflect the change in fair value. We did not record any change in fair value for the six months ended June 30, 2013. 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. We do not expect changes in any of these variables to result in material adjustments to the expense recognized for changes in the valuation of the warrants liability. We do not expect the valuation of the warrants to change based on the exercise price relative to the market price per share of our common stock and the February 2014 expiration.

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 $6.5 million and $6.1 million at December 31, 2012 and June 30, 2013, respectively) 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 December 31, 2012 and June 30, 2013. 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 December 31, 2012 and June 30, 2013, 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 the six months ended June 30, 2012 and 2013.

Recent Accounting Pronouncements Not Yet Effective

In July 2013, the Financial Accounting Standards Board (FASB) issued guidance relating to presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The guidance should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In March 2013, FASB issued guidance relating to certain foreign currency matters. This guidance clarifies the parent company s accounting for the cumulative translation adjustment when a reporting entity ceases to have a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business within a foreign entity or of an investment in a foreign entity. The guidance is effective prospectively for fiscal years (and interim reporting periods within those years) beginning after December 15, 2013. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In February 2013, the FASB issued guidance relating to obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date. This provides guidance for the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date, except for obligations addressed within existing guidance in U.S. GAAP. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The guidance should be applied retrospectively to all prior periods presented for those obligations resulting from joint and several liability arrangements that exist at the beginning of an entity s fiscal year of adoption. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide information in response to this item.

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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 June 30, 2013, 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 June 30, 2013, 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 June 30, 2013 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.

PART II. Other Information

Item 1. Legal proceedings

On April 27, 2010, we were served with a complaint filed by Celgene Corporation in the United States District Court for the District of Delaware seeking a declaratory judgment that four of our own patents, claiming certain uses of romidepsin were invalid and not infringed by Celgene s sale of ISTODAX® (romidepsin for injection). We subsequently counterclaimed for infringement of these four patents. On April 3, 2013, we entered into a definitive agreement with Celgene to sell to Celgene the four owned patents related to uses of romidepsin and their foreign counterparts. In connection with the definitive agreement, Celgene has made a one-time payment of $5.5 million to us. As a result, the litigation between us and Celgene in the United States District Court for the District of Delaware, case number 1:10-cv-00348-GMS, was dismissed by virtue of a jointly filed stipulation requesting the Court to enter an Order dismissing the litigation and the entry of such an Order.

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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, 2012. 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.

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:

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- 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 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 pharmacodynamics behaviors;

- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;

- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;

- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;

- inability or unwillingness of medical investigators to follow our clinical protocols; and

- unavailability of clinical trial supplies.

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

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

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

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

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

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

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

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

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

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

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 a 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;

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- 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. 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.

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 and technical personnel. Competition for these types of personnel is intense. The loss of the services of any member of our senior management, clinical development, scientific or technical

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. 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. This strategy will require us to recruit additional executive management and clinical development, scientific, technical and sales and marketing personnel. There is currently intense competition for skilled executives and employees with relevant clinical development, scientific, technical and sales and marketing 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 a New Drug Application, or 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.

Following regulatory approval of any of our drug candidates, we will be 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 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 drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

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

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

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

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

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. 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 depends upon their market acceptance among physicians, patients, healthcare providers and payors and the medical community.

If our drug candidates are approved, or approved together 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. The degree of market acceptance of any of our approved drugs will depend on a variety of factors, including:

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

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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 for our drug candidate seliciclib 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. If we fail to satisfy any of our obligations under these licenses, they would be terminated, which could harm our business.

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

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

We may also be exposed to additional risks of product liability claims. These risks exist even with respect to drugs 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.

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

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

If a 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 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.

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

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 currently have no 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 ourselves or through a strategic alliance, product revenues may suffer, we may incur significant additional losses and our share price would be negatively affected.

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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.

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 instability 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 uncertainty characterized by unprecedented intervention by the United States federal government and the European Union. We believe the current economic conditions and financial market instability 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.

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

We are at an early stage of development as a company and have a limited operating history on which to evaluate our business and prospects. While we earned modest product revenues from the ALIGN business prior to terminating operations effective September 30, 2012, 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.

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 AML, MDS, NSCLC and CLL. A combination of sapacitabine and seliciclib is currently in a Phase 1 clinical trial. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

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

We have incurred operating losses in each year since beginning operations in 1996 due to costs incurred in connection with our research and development activities and selling, general and administrative costs associated with our operations, and we may never achieve profitability. As of December 31, 2012 and June 30, 2013, our accumulated deficit was $270.3 million and $280.2 million, respectively. Our net loss was $3.6 million for the three months ended June 30, 2012 and net income was $1.5 million for the three months ended June 30, 2013. Our net loss was $6.5 million and $1.6 million for the six months ended June 30, 2012 and 2013, respectively. Our net loss applicable to common stockholders from inception through June 30, 2013 was $322.9 million. Our drug candidates are in the mid-stages of clinical testing and we must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of our drugs. We expect to incur continued losses for several years, as we continue our research and development of our drug candidates, seek regulatory approvals and commercialize any approved drugs. 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, and employees and fewer business development opportunities.

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

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

- fund research and development and clinical trials connected with our research;

- fund clinical trials and seek regulatory approvals;

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- build or access manufacturing and commercialization capabilities;

- implement additional internal control systems and infrastructure;

- commercialize and secure coverage, payment and reimbursement of our drug candidates, if any such candidates receive regulatory approval;

- maintain, defend and expand the scope of our intellectual property; and

- hire additional management, sales and scientific personnel.

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;

- the costs and timing of seeking and obtaining regulatory approvals;

- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the costs associated with establishing sales and marketing capabilities;

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

- the effect of competing technological and market developments; and

- the payment, other terms and timing of any strategic alliance, licensing or other arrangements that we may establish.

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

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

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

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

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

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

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

Risks Related to our Intellectual Property

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

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

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

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

Specifically, an amorphous form of sapacitabine is covered in granted, composition of matter patents that expire in 2014 in the United States and expired in 2012 outside the United States. Sapacitabine is further protected by additional granted, composition of matter patents claiming certain, stable crystalline forms of sapacitabine and their pharmaceutical compositions and therapeutic uses that expire in 2022 (and may be eligible for a Hatch-Waxman term restoration of up to five years, which could extend the expiration date to 2027); patent applications claiming the combination of sapacitabine with other agents, for example, hypomethylating agents, including decitabine, which is being tested as one of the arms of the SEAMLESS Phase 3 trial, and a United States granted patent claiming a specified method of administration of sapacitabine with patent exclusivity until July 2030. In early development, amorphous sapacitabine was used. We have used one of the stable, crystalline forms of sapacitabine in nearly all our Phase 1 and in all of our Phase 2 and Phase 3 clinical studies. We have also chosen this form for commercialization. Additional patents and applications claim certain medical uses, formulations and dosing regimens of sapacitabine which have emerged in our clinical trials, as well as a process for the preparation of sapacitabine.

Seliciclib is protected by granted, composition of matter patents that expire in 2016. Additional patents and applications claim certain medical uses of seliciclib, including combination use with sapacitabine, which have emerged in our preclinical research and clinical trials. The latest to expire of the granted patents expires in 2026. Failure to obtain, maintain or extend the patents could adversely affect our business. We will only be able to protect our drug candidates and our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

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

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Even if patents are issued regarding our drug candidates or methods of using them, those patents can be challenged by our competitors who may argue such patents are invalid and/or unenforceable. Patents also will not protect our drug candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The U.S. Federal Food, Drug and Cosmetic Act and FDA regulations and policies and equivalents in other jurisdictions provide incentives to manufacturers to challenge patent validity or create modified, non-infringing versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage manufacturers to submit NDAs that rely on literature and clinical data not prepared for or by the drug sponsor.

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

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

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

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

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;

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- be required to pay substantial royalties or grant a cross license to our patents to another patent holder; decide to locate some of our research, development or manufacturing operations outside of Europe or the United States;

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

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

Risks Related to Securities Regulations and Investment in Our Securities

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

If we fail to maintain our internal controls or fail to implement required new or improved controls, as such control standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting. Effective internal controls are necessary for us to produce reliable financial reports and are important in the prevention of financial fraud. If we cannot produce reliable financial reports or prevent fraud, our business and operating results could be harmed. We have concluded that our internal control over financial reporting was effective as of December 31, 2012.

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

As a public company, we face and will continue to face increased legal, accounting, administrative and other costs and expenses as a public company that we would not incur as a private company. Compliance with the Sarbanes Oxley Act of 2002, as well as other rules of the SEC, the Public Company Accounting Oversight Board and the NASDAQ Global Market resulted in a significant initial cost to us as well as an ongoing compliance cost. As a public company, we are subject to Section 404 of the Sarbanes Oxley Act relating to internal control over financial reporting. We have completed a formal process to evaluate our internal controls for purposes of Section 404, and we concluded that as of December 31, 2012, our internal control over financial reporting was effective. As our business grows and changes, there can be no assurances that we can maintain the effectiveness of our internal controls over financial reporting. In addition, our independent certified public accounting firm has not provided an opinion on the effectiveness of our internal controls over financial reporting for the year ended December 31, 2012 because we are a smaller reporting company. In the event our independent auditor is required to provide an opinion on such controls in the future, there is a risk that the auditor would conclude that such controls are ineffective.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating

results could be harmed. We have completed a formal process to evaluate our internal control over financial reporting. However, guidance from regulatory authorities in the area of internal controls continues to evolve and substantial uncertainty exists regarding our on-going ability to comply by applicable deadlines. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our common stock may have a volatile public trading price.

An active public market for our common stock has not developed. Our stock can trade in small volumes which may make the price of our stock highly volatile. The last reported price of our stock may not represent the price at which you would be able to buy or sell the stock. The market prices for securities of companies comparable to us have been highly volatile. Often, these stocks have experienced significant price and volume fluctuations for reasons that are both related and unrelated to the operating performance of the individual companies. In addition, the stock market as a whole and biotechnology and other life science stocks in particular have experienced significant recent volatility. Like our common stock, these stocks have experienced significant price and volume fluctuations for reasons unrelated to the operating performance of the individual companies. Factors giving rise to this volatility may include:

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- disclosure of actual or potential clinical results with respect to product candidates we are developing;

- regulatory developments in both the United States and abroad;

- developments concerning proprietary rights, including patents and litigation matters;

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

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

- public announcements by our competitors or others; and

- general market conditions and comments by securities analysts and investors.

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

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

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

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us. If analysts do not publish research reports or one or more of these analysts who were publishing research cease coverage of us or fail to regularly

publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock or if our operating results do not meet their expectations, our stock price could decline.

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

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

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

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

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

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

In March 2008 (as subsequently amended, most recently as of January 1, 2011), we entered into employment agreements with our President and Chief Executive Officer and our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, which contain severance arrangements in the event that such executive s employment is terminated without cause or as a result of a change of control (as each such term is defined in each agreement). The financial obligations triggered by these provisions may prevent a business combination or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our stock.

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

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

In addition, in the event a third party seeks to acquire our company or acquire control of our company by way of a merger, but the terms of such offer do not provide for our preferred stock to remain outstanding or be converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our preferred stock, the terms of the Certificate of Designation of our preferred stock provide for an adjustment to the conversion ratio of our preferred stock such that, depending on the terms of any such transaction, preferred stockholders may be entitled, by their terms, to receive up to $10.00 per share in common stock, causing our common stockholders not to receive as favorable a price as the price at which such shares may be trading at the time of any such transaction. As of June 30, 2013, there were 420,682 shares of our preferred stock issued and outstanding. If the transaction were one in which proceeds were received by the Company for distribution to stockholders, and the terms of the Certificate of Designation governing the preferred stock were strictly complied with, approximately $5.0 million would be paid to the preferred holders before any distribution to the common stockholders, although the form of transaction could affect how the holders of preferred stock are treated. In such an event, although such a transaction would be subject to the approval of our holders of common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time. Thus, the terms of our preferred stock might hamper a third party s acquisition of our company.

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

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

- authorize the issuance of preferred stock that can be created and issued by the Board of Directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of our common stock;

- provide for the Board of Directors to be divided into three classes; and

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent.

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

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

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

Delaware law may limit our ability to pay cash dividends on our preferred stock. Under Delaware law, cash dividends on our preferred stock may only be paid from surplus or, if there is no surplus, from the corporation s net profits for the current or preceding fiscal year. Delaware law defines surplus as the amount by which the total assets of a corporation, after subtracting its total liabilities, exceed the corporation s capital, as determined by its board of directors.

Since we are not profitable, our ability to pay cash dividends will require the availability of adequate surplus. Even if adequate surplus is available to pay cash dividends on our preferred stock, we may not have sufficient cash to pay dividends on the preferred stock or we may choose not to declare the dividends. On January 11, 2013, the Board of Directors declared a quarterly dividend and, on February 1, 2013, paid such dividend to the holders of record of the Preferred Stock as of the close business on January 22, 2013. On April 5, 2013, the Board of Directors declared a quarterly dividend and, on May 1, 2013, paid such dividend to the holders of record of the Preferred Stock as of the close business on April 19, 2013. On July 8, 2013, the Board declared a quarterly dividend and, on August 1, 2013, paid such dividend to the holders of record of the Preferred Stock as of the close business on July 22, 2013.

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

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

- additions to or departures of our key personnel;
- announcements of technological innovations or new products or services by us or our competitors; announcements concerning our competitors or the biotechnology industry in general;
- new regulatory pronouncements and changes in regulatory guidelines;
- general and industry-specific economic conditions;

- changes in financial estimates or recommendations by securities analysts;

- variations in our quarterly results; and

- announcements about our collaborators or licensors; and changes in accounting principles.

The market prices of the securities of biotechnology companies, particularly companies like us without product revenues and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the performance of particular companies. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Moreover, market prices for stocks of biotechnology-related and technology companies frequently reach levels that bear no relationship to the performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management s attention and resources and harm our financial condition and results of operations.

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

If our common or preferred stockholders sell substantial amounts of our stock in the public market, or the market perceives that such sales may occur, the market price of our common and preferred stock could fall. If additional holders of preferred stock elect to convert their shares to shares of common stock at renegotiated prices, such conversion as well as the sale of substantial amounts of our common stock, could cause dilution to existing holders of our common stock, thereby also negatively affecting the price of our common stock. For example, during the first quarter of 2013, we issued an aggregate of 1,513,653 shares of our common stock in exchange for an aggregate of 792,460 shares of our preferred stock in arms-length negotiations between us and the other parties who had approached us to propose the exchanges.

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

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

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

We may automatically convert the convertible preferred stock into common stock if the closing price of our common stock exceeds $246.75. There is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred and the automatic conversion date.

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

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

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

stock.

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

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

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

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

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

Our management team will have broad discretion over the use of the net proceeds from the sale of our common stock to Aspire Capital Fund, LLC.

On December 14, 2012, we entered into a Stock Purchase Agreement with Aspire Capital Fund, LLC, pursuant to which we may require Aspire Capital to purchase up to an additional 1,455,787 shares from time to time through December 2014 at prices derived from the market prices on or near the date of each sale. However, such commitment is limited to $19.0 million of share purchases. During the first quarter of 2013, we sold 650,000 shares of our common stock under this arrangement in consideration of aggregated proceeds of $3.4 million. Our management will use its discretion to direct the net proceeds from the sale of those shares. We intend to use all of the net proceeds, together with cash on hand, for general corporate purposes. General corporate purposes may include working capital, capital expenditures, development costs, strategic investments or possible acquisitions. Our management s judgments may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

We have registered for sale the shares that we have already issued to Aspire Capital and an additional 1,455,787 shares that we may sell to Aspire Capital under the Stock Purchase Agreement. During the first quarter of 2013, the Company issued 650,000 shares of common stock in exchange for $3.4 million. It is anticipated that shares registered will be sold by Aspire Capital over a period of up to approximately 24 months from January 2013. Under the Stock Purchase Agreement, we have the right, but not the obligation, to sell more than the 1,689,317 shares of common stock, if we obtain shareholder approval or an exception pursuant to the rules of the NASDAQ Global Market is obtained to issue more than 19.99%, to be in compliance with the applicable listing maintenance rules of the NASDAQ Global Market. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Global Market. In addition, we must register under the Securities Act the sale by Aspire Capital of any additional shares we may elect to sell to Aspire Capital before we can put such additional shares to Aspire Capital under the Stock Purchase Agreement. Further, the number of shares ultimately offered for sale by Aspire Capital is dependent upon the number of shares we elect to sell to Aspire Capital under the Stock Purchase Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Stock Purchase Agreement may cause the trading price of our common stock to decline.

In addition to the shares sold to Aspire to date, we may ultimately sell all, some or none of the remaining 805,787 shares of common stock we are entitled to sell to Aspire. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to

effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

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

None.

Item 3. Defaults upon Senior Securities

None.

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Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	The following materials from Cyclacel Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the three months ended June 30, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Income, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

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

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SIGNATURES

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

CYCLACEL PHARMACEUTICALS, INC.

Date: August 14, 2013

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