Cyclacel Pharmaceuticals, Inc. Form 10-Q
May 15, 2012
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2012

OR

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

Commission file number 0-50626

CYCLACEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

200 Connell Drive, Suite 1500

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

Large accelerated filer o

Accelerated filer o

Non-accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting filer x

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

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

CYCLACEL PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

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

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

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

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

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

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

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

	2011	Three Mon Marc	Period from August 13, 1996 (inception) to March 31, 2012		
Cash flows from operating activities:	2011			2012	2012
Net loss	\$	(4,588)	\$	(2,955)	\$ (256,504)
Adjustments to reconcile net loss to net cash used in operating	Ψ	(1,500)	Ψ	(2,755)	(250,501)
activities: Accretion of interest on notes payable, net of amortization of debt					
premium					100
Amortization of investment premiums, net					(2,297)
Change in valuation of Economic Rights				56	56
Change in valuation of other liabilities measured at fair value		(78)		(42)	(6,413)
Warrant re-pricing					44
Depreciation and amortization		86		15	12,570
Amortization of intangible assets					886
Fixed asset impairment					221
Unrealized foreign exchange loss					7,747
Deferred revenue					(98)
Compensation for warrants issued to non-employees					1,215
Shares issued for IP rights				(47)	446
(Gain) loss on disposal of property, plant and equipment Goodwill and intangibles impairment				(47)	53 7,934
Stock based compensation		251		102	19,125
Provision for restructuring		231		102	1,779
Amortization of issuance costs of Preferred Ordinary C shares					2,517
Transaction costs on sale of economic rights				33	33
Changes in operating assets and liabilities:					
Prepaid expenses, inventory and other current assets		40		(126)	(184)
Accounts payable, accrued liabilities and other current liabilities		397		(807)	(6,120)
Net cash used in operating activities		(3,892)		(3,771)	(216,890)
Investing activities:					
Purchase of ALIGN					(3,763)
Purchase of property, plant and equipment				(9)	(8,846)
Proceeds from sale of property, plant and equipment				24	187
Purchase of short-term investments					(156,657)
Redemptions of short-term investments, net of maturities Net cash provided by (used in) investing activities				15	162,729 (6,350)
Financing activities:				13	(0,330)
Payment of capital lease obligations					(3,719)
Proceeds from issuance of ordinary and preferred ordinary shares,					(3,717)
net of issuance costs					121,678
Proceeds from issuance of common stock, warrants and economic					,,,,
rights, net of issuance costs		(80)		2,911	94,582
Net proceeds from stock options and warrants exercised		2		34	207
Payment of preferred stock dividend		(182)			(1,898)

Repayment of government loan (455)

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

(In \$000s) (Unaudited)

	1111001	Ionths Ende arch 31,	ed 2012	Period from August 13, 1996 (inception) to March 31, 2012
Government loan received				414
Loan received from Cyclacel Group Plc				9,103
Proceeds of committable loan notes issued from shareholders				8,883
Loans received from shareholders				1,645
Cash and cash equivalents assumed on stock purchase				17,915
Costs associated with stock purchase				(1,951)
Net cash (used in) provided by financing activities	(260)	2,945	246,404
Effect of exchange rate changes on cash and cash equivalents	7		2	476
Net increase (decrease) in cash and cash equivalents	(4,145)	(809)	23,640
Cash and cash equivalents at beginning of period	29,495		24,449	
Cash and cash equivalents at end of period	\$ 25,350	\$	23,640	\$ 23,640
Supplemental disclosure of cash flows information:				
Cash received during the period for:				
Interest	3		5	11,751
Taxes				18,207
Cash paid during the period for:				
Interest				(1,914)
Schedule of non-cash transactions:				2.450
Acquisitions of equipment purchased through capital leases				3,470
Issuance of common shares in connection with license agreements				592
Issuance of ordinary shares on conversion of bridging loan				1,638
Issuance of preferred ordinary C shares on conversion of secured				0.002
convertible loan notes and accrued interest				8,893
Issuance of ordinary shares in lieu of cash bonus				164
Issuance of other long term payable on ALIGN acquisition				1,122

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 at commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious diseases. Cyclacel s strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Cyclacel s clinical development priorities are focused on sapacitabine, an orally available, cell cycle modulating nucleoside analogue.

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

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

Basis of Presentation

The condensed consolidated balance sheet as of March 31, 2012, the condensed consolidated statements of operations, comprehensive loss, and cash flows for the three months ended March 31, 2012 and 2011 and the period from August 13, 1996 (inception) to March 31, 2012, and all related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2011 is derived from the audited consolidated financial statements included in the 2011 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC). The condensed consolidated financial statements are presented on the basis of accounting principles that are generally accepted in the United States (GAAP) for interim financial information and in accordance with the rules and regulations of the SEC.

Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States for a complete set of financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments necessary to present fairly the condensed consolidated balance sheet as of March 31, 2012, and the results of operations, comprehensive loss and cash flows for the three months ended March 31, 2012 and 2011, have been made. The interim results for the three months ended March 31, 2012 are not necessarily indicative of the results to be expected for the year ending December 31, 2012 or for any other year. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2011, included in the Company s Annual Report on Form 10-K filed with the SEC.

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Recent Developments
Sale of Common Stock and Economic Rights
On March 22, 2012, the Company entered into a purchase agreement with certain existing institutional stockholders raising approximately \$2.9 million of proceeds, net of certain fees and expenses. The proceeds from the financing will be used to fund ongoing litigation-related expenses involving specified Cyclacel intellectual property and for general corporate purposes.
Under the terms of the purchase agreement, the investors purchased 4,688,079 shares of the Company s common stock at a price of \$0.6476, which is equal to the 10-day average closing price of the Company s common stock for the period ending on Wednesday, March 21, 2012. The shares issued at closing are subject to a lock-up period of one year from the date of issuance.
In addition to the common stock, investors received contractual rights to receive cash equal to 10% of any future litigation settlement related to the specified intellectual property, subject to a cap. In certain defined situations, the Company may have to issue either additional shares or warrants. These collective contractual rights are referred to as Economic Rights .
See Note 3, Fair Value Measurements for further details.
Preferred Stock Dividend
On March 6, 2012, the Company s Board of Directors decided not to declare a quarterly cash dividend on the Company s 6% Convertible Exchangeable Preferred Stock (Preferred Stock) with respect to the first quarter of 2012 that would have otherwise been payable on May 1, 2012.
Subsequent Developments
NASDAQ Appeal
Previously, the Company received a determination letter from NASDAQ, notifying the Company that it had not regained compliance with the minimum closing bid price requirements set forth in Listing Rule 5450(a)(1) (the Rule) during the 180 calendar days allowed to regain

compliance and that the Company s common stock was subject to delisting from the NASDAQ Global Market.

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Consolidation

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

Tab:	le o	f Co	ontents

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Critical estimates include estimated levels of product returns, and inputs used to determine stock-based compensation expense and the fair value of financial instruments, such as Economic Rights and other liabilities measured at fair value. Cyclacel reviews its estimates on an ongoing basis. The estimates are based on historical experience and on various other assumptions that the Company believes to be reasonable under the circumstances. Actual results may differ from these estimates.

Cash and Cash Equivalents

Cash equivalents are stated at cost, which is substantially the same as fair value. The Company considers all highly liquid investments with an original maturity of three months or less at the time of initial purchase to be cash equivalents. The objectives of the Company s cash management policy are to safeguard and preserve funds, to maintain liquidity sufficient to meet Cyclacel s cash flow requirements and to attain a market rate of return.

Trade Accounts Receivable and Allowance for Doubtful Accounts

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

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

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

Inventory

Cyclacel values inventories at the lower of cost or market. The Company determines cost using the first-in, first-out method. As of March 31, 2012 and December 31, 2011, all inventories were classified as finished goods. The Company analyzes its inventory levels at least quarterly to identify any items that may expire prior to sale, inventory that has a cost basis in excess of net realizable value, or inventory in excess of expected sales requirements. The determination of whether or not inventory costs will be realizable requires estimates by the Company s management. A critical input in this determination is future expected sales forecasts. The Company writes off inventory that is expected to expire before being sold. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required in future periods.

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

Fair Value of Financial Instruments

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

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Revenue Recognition
Product sales
The Company recognizes revenue from product sales when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the selling price is fixed or determinable; and collectability is reasonably assured.
The Company offers a general right of return on product sales, and has considered the guidance in ASC Subtopic 605-15, <i>Revenue Recognition -Products</i> (ASC 605-15) and ASC Subtopic 605 10 <i>Revenue Recognition - Overall</i> (ASC 605-10). Under these guidelines, the Company accounts for all product sales using the sell-through method. Under the sell-through method, revenue is not recognized upon shipment of product to distributors. Instead, the Company records deferred revenue at gross invoice sales price less 5% of the current wholesale acquisition price (in accordance with our returns policy) and deferred cost of sales at the cost at which those goods were held in inventory. The Company recognizes revenue and cost of sales when such inventory is sold through to pharmacies. To estimate product sold through to pharmacies, the Company relies on third-party information, including information obtained from significant distributors with respect to their inventory levels and sell-through to pharmacies. At the time of revenue recognition, the Company also estimates a provision for returned products based on historical data and future expectations; this provision is charged against revenues.
Deferred revenue was \$0.1 million at December 31, 2011 and March 31, 2012. Deferred cost of goods sold was approximately \$20,000 and \$22,000 at December 31, 2011 and March 31, 2012, respectively.
Collaboration, research and development, and grant revenue
Certain of the Company s revenues are earned from collaborative agreements. The Company recognizes revenue when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured. Determination of whether these criteria have been met is based on management s judgments regarding the nature of the research performed, the substance of the milestones met relative to those the Company must still perform, and the collectability of any related fees. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.
Research and development revenues, which are earned under agreements with third parties for contract research and development activities, are recorded as the related services are performed. Milestone payments are non-refundable and recognized as revenue when earned, as evidenced by achievement of the specified milestones and the absence of ongoing performance obligations. Any amounts received in advance of performance are recorded as deferred revenue. None of the revenues previously recognized are refundable if the relevant research effort is not successful.
Grant revenues from government agencies and private research foundations are recognized as the related qualified research and development costs are incurred, up to the limit of the prior approval funding amounts. All grants earned and received are not refundable. The Company had deferred grant revenue of approximately \$75,000 at March 31, 2012. The Company had no such deferred revenue at December 31, 2011.

Clinical Trial Accounting

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

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Research and Development Expenditures

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

Foreign currency and currency translation

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

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

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

Fair Value Measurements

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

Income Taxes

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

amounts expected to be realized. The Company s management has established a full valuation allowance against its deferred tax assets based on the determination that it is not more likely than not that the Company will recognize the benefits of those assets.

The Company applies the guidance codified in ASC Topic 740, *Income taxes* (ASC 740) related to accounting for uncertainty in income taxes. ASC 740 specifies the accounting for uncertainty in income taxes recognized in a company s financial statements by prescribing a minimum probability threshold a tax position is required to meet before being recognized in the financial statements.

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

Stock-based Compensation

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

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

Segments

The Company has determined its reportable segments in accordance with ASC 280, Segment Reporting (ASC 280) and related disclosures about products, services, geographic areas and major customers. After considering its business activities and geographic reach, the Company has concluded that it operates in just one operating segment being the discovery, development and commercialization of novel, mechanism-targeted drugs to treat cancer and other serious disorders, with development operations in two geographic areas, namely the United States and the United Kingdom.

Net Loss per Common Share

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

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

Comprehensive Income (Loss)

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

Recent Accounting Pronouncements

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

In May 2011, the FASB issued ASU 2011-04, which amends the guidance on fair value measurement in ASC 820 to converge the fair value measurement and disclosure requirements under GAAP and International Financial Reporting Standards (IFRS) fair value measurement and disclosure requirements. The amendments change the wording used to describe the requirements for measuring fair value, changes certain fair

value measurement principles and enhances disclosure requirements. This guidance is effective for annual periods beginning after December 15, 2011, applied prospectively. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

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3. FAIR VALUE MEASUREMENTS

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

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2: Inputs other than quoted prices within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3: Unobservable inputs that are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

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

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

	Level 1	Level 2	Level 3	Total
	\$000	\$000	\$000	\$000
Cash equivalents	19,894			•