

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2006

OR

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

For the transition period from to

Commission file number 0-50626

CYCLACEL PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction
of Incorporation or Organization)

91-1707622
(I.R.S. Employer
Identification No.)

150 JOHN F. KENNEDY PARKWAY, SHORT HILLS, NJ
(Address of principal executive offices)

07078
(Zip Code)

Registrant's telephone number, including area code: (973) 847-5955

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" as defined in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

As of August 11, 2006 there were 16,157,991 shares of the registrant's common stock outstanding.

CYCLACEL PHARMACEUTICALS, INC.

INDEX

	<u>Page</u>
PART I	FINANCIAL INFORMATION
Item 1.	Financial Statements
	Condensed Consolidated Balance Sheets as of June 30, 2006 (unaudited) and December 31, 2005
	3
	Condensed Consolidated Statements of Operations for the three months and six months ended June 30, 2006 and 2005 (unaudited) and the period from August 13, 1996 (inception) to June 30, 2006 (unaudited)
	4
	Condensed Consolidated Statements of Comprehensive Loss for the three months and six months ended June 30, 2006 and 2005 (unaudited) and the period from August 13, 1996 (inception) to June 30, 2006 (unaudited)
	5
	Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2006 and 2005 (unaudited) and the period from August 13, 1996 (inception) to June 30, 2006 (unaudited)
	6
	Notes to Condensed Consolidated Financial Statements (unaudited)
	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations
	17
Item 3.	Quantitative and Qualitative Disclosures about Market Risk
	24
Item 4.	Controls and Procedures
	24
PART II	OTHER INFORMATION

Item 1.	Legal Proceedings	25
Item 1A.	Risk Factors	25
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	39
Item 3.	Defaults Upon Senior Securities	39
Item 4.	Submission of Matters to a Vote of Security Holders	39
Item 5.	Other Information	40
Item 6.	Exhibits	41
Signature		42

[Table of Contents](#)

PART I. FINANCIAL INFORMATION

CYCLACEL PHARMACEUTICALS, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED BALANCE SHEETS

	As of June 30, 2006 (Unaudited) \$000	As of December 31, 2005 (Note 1) \$000
ASSETS		
Current assets:		
Cash and cash equivalents	63,101	3,117
Short-term investments	1,886	10,690
Prepaid expenses and other current assets	2,961	3,219
Total current assets	67,948	17,026
Property, plant and equipment (net)	1,711	2,045
Deposits and other assets	259	—
Goodwill	2,749	—
Total assets	<u>72,667</u>	<u>19,071</u>
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	1,908	2,159
Amounts due to Cyclacel Group plc	217	10,467
Accrued liabilities	1,741	1,869
Other current liabilities	164	128
Derivative liability	1,632	—
Current portion of other accrued restructuring charges	993	—
Current portion of equipment financing	218	251
Total current liabilities	6,873	14,874
Other accrued restructuring charges, net of current	1,537	—
Equipment financing, net of current	—	78
Other liabilities	11	—
Total liabilities	<u>8,421</u>	<u>14,952</u>
Stockholders' equity:		
Preferred Ordinary shares, 0.1p par value; Nil and 21,000,000 shares authorized at June 30, 2006 and December 31, 2005, respectively; Nil and 17,965,835 shares issued and outstanding at June 30, 2006 and December 31, 2005, respectively. Aggregate liquidation preference of \$Nil and \$210,954,000 (\$11.74 per share) at June 30, 2006 and December 31, 2005, respectively	—	30
Ordinary shares, 0.1p par value; Nil and 5,748,428 shares authorized at June 30, 2006 and December 31, 2005, respectively; Nil and 1,871,210 shares issued and outstanding at June 30, 2006 and December 31, 2005, respectively	—	2
Preferred stock, \$0.001 par value; 5,000,000 and Nil shares authorized at June 30, 2006 and December 31, 2005, respectively; 2,046,813 and Nil shares issued and outstanding at June 30, 2006 and December 31, 2005, respectively. Aggregate preference in liquidation of \$20,673,000 and \$Nil at June 30, 2006 and December 31, 2005, respectively.	2	—
Common stock, \$0.001 par value; 100,000,000 and Nil shares authorized at June 30, 2006 and December 31, 2005, respectively; 16,157,991 and Nil shares issued and outstanding in 2006 and 2005, respectively	16	—
Additional paid-in capital	193,995	116,063
Accumulated other comprehensive loss	(2,458)	(2,958)
Deficit accumulated during the development stage	(127,309)	(109,018)
Total stockholders' equity	<u>64,246</u>	<u>4,119</u>
Total liabilities and stockholders' equity	<u>72,667</u>	<u>19,071</u>

SEE NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

[Table of Contents](#)

CYCLACEL PHARMACEUTICALS, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

For the three months ended June 30,	For the six months ended June 30,	Period from August 13, 1996 (inception) to June 30,
---	---	--

	2006	2005	2006	2005	2006
	\$000, except per share and share amounts				
Revenues:					
Collaboration and research and development revenue	30	31	125	66	2,884
Grant revenue	6	40	62	61	3,382
	36	71	187	127	6,266
Operating expenses:(1)					
Research and development	(5,133)	(4,237)	(13,137)	(9,163)	(113,907)
General and administrative	(3,030)	(1,465)	(6,945)	(2,671)	(30,578)
Total operating expenses	(8,163)	(5,702)	(20,082)	(11,834)	(144,485)
Operating loss	(8,127)	(5,631)	(19,895)	(11,707)	(138,219)
Other income (expense):					
Costs associated with aborted 2004 IPO	—	—	—	—	(3,550)
Change in valuation of derivative	(98)	—	(98)	—	(98)
Interest income	645	169	772	408	7,051
Interest expense	(58)	(19)	(126)	(39)	(3,788)
Total other income (expense)	489	150	548	369	(385)
Loss before taxes	(7,638)	(5,481)	(19,347)	(11,338)	(138,604)
Income tax benefit	(696)	(438)	(1,056)	(905)	(11,295)
Net loss	(6,942)	(5,043)	(18,291)	(10,433)	(127,309)
Dividends on Preferred Ordinary shares	—	(2,990)	(2,827)	(5,943)	(38,122)
Net loss applicable to ordinary shareholders	(6,942)	(8,033)	(21,118)	(16,376)	(165,431)
Net loss per share – basic and diluted	\$ (0.48)	\$ (1.03)	\$ (1.90)	\$ (2.11)	
Weighted average shares	14,321,256	7,761,453	11,102,967	7,761,453	

(1) Amounts include stock-based compensation, consisting of stock-based compensation expense under SFAS 123R, the amortization of deferred stock-based compensation and the value of options issued to non-employees for services rendered, allocated as follows:

	For the three months ended June 30,		For the six months ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2006	2005	2006	2005	2006
	\$000	\$000	\$000	\$000	\$000
Research and development	1,342	313	5,888	771	7,754
General and administrative	744	73	3,169	205	3,857
	2,086	386	9,057	976	11,611

SEE NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

4

[Table of Contents](#)

CYCLACEL PHARMACEUTICALS, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	For the three months ended June 30,		For the six months ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2006	2005	2006	2005	2006
	\$000	\$000	\$000	\$000	\$000
Net loss	(6,942)	(5,043)	(18,291)	(10,433)	(127,309)
Currency translation	403	(1,076)	500	(1,690)	(2,458)
Comprehensive loss	(6,539)	(6,119)	(17,791)	(12,123)	(129,767)

SEE NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

5

[Table of Contents](#)

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

	For the six months ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2006	2005	2006
	\$000	\$000	\$000
Cash flows from operating activities:			
Net loss	(18,291)	(10,433)	(127,309)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of investment premiums, net	5	—	5
Change in valuation of derivative	98	—	98
Depreciation and amortization	603	721	8,568
Deferred revenue	—	—	(98)
Compensation for warrants issued to non employees	—	—	1,215

Shares issued for IP rights	—	—	446
Loss on disposal of property, plant and equipment	(3)	—	22
Stock based compensation	9,057	976	11,611
Amortization of issuance costs of Preferred Ordinary "C" shares	—	—	2,517
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	1,144	(222)	(1,577)
Accounts payable and other current liabilities	(3,037)	(54)	1,227
Net cash used in operating activities	(10,424)	(9,012)	(103,275)
Investing activities:			
Purchase of property, plant and equipment	(70)	(35)	(6,073)
Proceeds from sale of property, plant and equipment	18	—	18
Short-term investments on deposit, net of maturities	9,158	7,888	(1,352)
Net cash provided by (used in) investing activities	9,106	7,853	(7,407)
Financing activities:			
Payment of capital lease obligations	(128)	(176)	(3,479)
Proceeds from issuance of ordinary and preferred ordinary shares, net of issuance costs	—	—	90,858
Proceeds from issuance of common stock and warrants, net of issuance costs	42,626	—	42,626
Payment of preferred stock dividend	(307)	—	(307)
Repayment of government loan	—	—	(455)
Government loan received	—	—	414
Loan received from parent company	—	—	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	—	17,915
Short-term investments assumed on stock purchase	3,239	—	3,239
Costs associated with stock purchase	(1,951)	—	(1,951)
Net cash provided by (used in) financing activities	61,394	(176)	168,491
Effect of exchange rate changes on cash and cash equivalents	(92)	(443)	5,292
Net increase (decrease) in cash and cash equivalents	60,076	(1,335)	57,809
Cash and cash equivalents at beginning of period	3,117	7,766	—
Cash and cash equivalents at end of period	63,101	5,988	63,101

6

[Table of Contents](#)

	For the six months ended		Period from
	June 30,		August 13, 1996
	2006	2005	(inception) to
	\$000	\$000	June 30,
			\$000
Supplemental disclosure of cash flows information:			
Cash received during the period for:			
Interest	704	459	7,176
Taxes	1,906	—	10,739
Cash paid during the period for:			
Interest	(537)	(37)	(1,399)
Schedule of non-cash transactions:			
Acquisitions of equipment purchased through capital leases	—	—	3,470
Issuance of Ordinary shares in connection with license agreements	—	—	592
Issuance of Ordinary shares on conversion of bridging loan	—	—	1,638
Issuance of Preferred Ordinary "C" shares on conversion of secured convertible loan notes and accrued interest	—	—	8,893
Issuance of Ordinary shares in lieu of cash bonus	—	—	164
Deferred stock-based compensation	9,057	976	11,611

SEE NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

7

[Table of Contents](#)

CYCLACEL PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2006
(Unaudited)

1. ORGANIZATION OF THE COMPANY

Cyclacel Pharmaceuticals, Inc. ("Cyclacel", or the "Company") was incorporated in the state of Delaware in 1996 and is headquartered in Short Hills, New Jersey with research facilities located in Dundee, Scotland and Cambridge, England. Cyclacel is a development-stage biopharmaceutical company dedicated to the discovery, development and eventual commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. 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 properties, raising capital and recruiting and training personnel.

Recent Corporate History

On March 27, 2006, Xcyte Therapies Inc. ("Xcyte") completed a Stock Purchase Agreement (the "Stock Purchase Agreement") with Cyclacel Group plc ("Group"), a public company organized under the laws of England and Wales in which Xcyte agreed to purchase from Group all of the capital stock of Cyclacel Limited ("Limited"), a private limited company organized under the laws of England and Wales and a wholly-owned subsidiary of Group (the "Stock Purchase"). Under the terms of the Stock Purchase Agreement, Xcyte issued 7,761,453 shares of common stock to Group which, after giving effect to the transaction, represented 79.7% of

the outstanding shares of Xcyte's common stock. Limited became Xcyte's wholly owned subsidiary. Xcyte changed its name to Cyclacel Pharmaceuticals, Inc. On March 27, 2006, Group effected a members' voluntary liquidation in accordance with its certificate of incorporation, memorandum and articles of association and the applicable laws of England and Wales, which has resulted in the distribution of its assets, including the Xcyte common stock it received in the Stock Purchase, to its shareholders and creditors. The transaction has been accounted for as a reverse acquisition under the purchase method of accounting for business combinations in accordance with accounting principles generally accepted in the United States and Limited is considered the acquiring company for accounting purposes. Accordingly, the purchase price has been allocated among the fair values of the assets and liabilities of Xcyte, while the historical results of Limited are reflected in the results of the Company.

Prior to the Stock purchase, on March 24, 2006 Xcyte completed an Asset Purchase Agreement (the "Asset Purchase Agreement") with Invitrogen Corporation, a Delaware corporation ("Invitrogen"), in which Invitrogen agreed to purchase Xcyte's T cell expansion technology known as the "Xcellerate Process" in exchange for \$5 million (the "Asset Sale"). The purchase price is subject to a post-closing adjustment pursuant to which Xcyte can be required to refund up to \$1 million to Invitrogen. The assets subject to the agreement included intellectual property, the clinical data generated by Xcyte in the course of six clinical trials of the lead product, Xcellerated T Cells, as well as raw materials and equipment.

On March 16, 2006, Xcyte stockholders approved a one-for-ten reverse stock split of its common stock. The reverse stock split occurred immediately prior to the completion of the Stock Purchase. All information in this report relating to the number of shares, price per share, and per share amounts of common stock are presented on a post-split basis.

On April 26, 2006, Cyclacel raised gross proceeds of \$45.3 million through a private placement of common stock and common stock purchase warrants. 6.43 million shares of its common stock were issued at a price of \$7.00 per share. In addition, 2.57 million seven year common stock purchase warrants were issued to the investors granting them the right to purchase Cyclacel's common stock at a price of \$7.00 per share.

[Table of Contents](#)

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements as of June 30, 2006 and for the three and six month periods ended June 30, 2006 and 2005 have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. The unaudited condensed interim financial statements have been prepared on the same basis as the annual financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of Cyclacel Pharmaceuticals, Inc. have been included. Operating results for the three month and six month periods ended June 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements as of December 31, 2005 and 2004 and for the years ended December 31, 2005 and 2004, the nine months ended December 31, 2003 and the period from August 13, 1996 (inception) to December 31, 2005 included in the Company's Current Report on Form 8-K filed on May 16, 2006. Financial information as of December 31, 2005 has been derived from these audited consolidated financial statements.

2. STOCK BASED COMPENSATION

On January 1, 2006, the Company adopted Financial Accounting Standards Board Statement ("FASB"), Statement No. 123R, "Share-Based Payment" ("SFAS 123R"). SFAS 123R requires the Company to measure all share-based payment awards, including those with employees, granted and cancelled after, or that were unvested as of, January 1, 2006 at fair value. Under SFAS 123R, the fair value of stock options and other equity-based compensation must be recognized as expense in the statements of operations over the requisite service period of each award.

The Company adopted SFAS 123R using the modified prospective method of transition. Accordingly, the Company has recognized stock-based compensation expense of \$9,057,000 for the six-month period ended June 30, 2006, comprising a stock-based compensation charge of \$6,971,000 for the three-month period ended March 31, 2006 in respect of outstanding share-based awards previously granted under Cyclacel Group plc's: Cyclacel Limited Share Option Plan ("1997 Plan"), the Cyclacel Limited 2000 Employees' Share Option Scheme under the Enterprise Management Incentive Scheme ("2000 Plan") and the Cyclacel Group Plc Discretionary Share Option Plan ("Discretionary Plan") and restricted stock issued to certain directors, officers and former director, and a stock-based compensation expense of \$2,086,000 for the three-month period ended June 30, 2006, in respect of outstanding share-based awards granted under Cyclacel's 2006 Stock Option and Award Plan and 2006 Stock Option and Award Plan (UK Approved SubPlan), together "2006 Plans".

Prior to January 1, 2006, the Company applied the intrinsic value-based method of accounting for share-based payment transactions with our employees, as prescribed by Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25") and related interpretations including Financial Accounting Standards Board Statement Interpretation ("FIN") No. 44, "Accounting for Certain Transactions Involving Stock Compensation-An Interpretation of APB Opinion No. 25" Under the intrinsic value method, compensation expense was recognized only if the current market price of the underlying stock exceeded the exercise price of the share-based payment award as of the measurement date (typically the date of grant). Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," ("SFAS 123") established accounting and disclosure requirements using a fair value-based method of accounting for stock-based employee compensation plans. The Company also followed the disclosure requirements of SFAS 123 and Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure".

[Table of Contents](#)

Had compensation expense been recognized for stock-based compensation plans in accordance with SFAS No. 123, the Company would have recorded the following net loss and net loss per share amounts for the three and six month periods ended June 30, 2005 (in thousands):

	June 30, 2005	June 30, 2005
Net loss:		
As reported	\$ (8,033)	\$ (16,376)
Add: Employee stock based compensation expense included in reported net loss, net of related tax effects	386	976
Deduct: total employee stock based compensation expense determined under the fair value method for all awards, net of related tax effects	(470)	(1,227)
Pro forma	<u>\$ (8,117)</u>	<u>\$ (16,627)</u>
Basic and diluted loss per common share:		
As reported	<u>\$ (1.03)</u>	<u>\$ (2.11)</u>
Pro forma	<u>\$ (1.05)</u>	<u>\$ (2.14)</u>

As a result of adopting SFAS No. 123R on January 1, 2006, the Company's net loss for the three and six month periods ended June 30, 2006 are \$2,086,000 higher and \$2,805,000 lower, respectively, than if it had continued to account for share-based compensation under APB No. 25. Basic and diluted net loss per share for the three and six-month periods ended June 30, 2006 are \$0.15 higher and \$0.25 lower, respectively, than if the Company had continued to account for share-based compensation under APB No. 25.

Stock-Based Compensation Arrangements

Prior to the Stock Purchase, Group operated a number of share option plans, which provided the opportunity to all eligible individuals, including employees of Cyclacel, to participate in the potential growth and success of Group. These were the 1997 Plan, the 2000 Plan, the SEIP, the Discretionary Plan, the Cyclacel Group Plc Savings Related Share Option Plan and the Cyclacel Group Plc Restricted Share and Co- Investment Plan collectively referred to as the "Cyclacel Plans". Options had only been issued under the 1997 Plan, the 2000 Plan, the Discretionary Plan and the SEIP.

Similarly Xcyte operated a number of share option plans, the Amended and Restated 2003 Directors' Stock Option Plan ("2003 Directors' Plan"), the Amended and Restated 1996 Stock Option Plan ("1996 Plan") and the 2003 Stock Plan ("2003 Plan"), collectively referred to as the "Xcyte Plans".

The completion of the Stock Purchase, the asset sale to Invitrogen and the members' voluntary liquidation of Group variously caused an acceleration of vesting of options according to the terms of each of the Plans as described below.

Acceleration of Options

Cyclacel Plans

The vesting of all options granted pursuant to the 1997 Plan, 2000 Plan and Discretionary Plan were accelerated on the members' voluntary liquidation of Cyclacel Group plc. As a result of this acceleration, any holder of options granted pursuant to these Plans had the right to exercise one hundred percent (100%) of the options held by such holder pursuant to such plan. However, prior to the completion of the Stock Purchase and liquidation of Cyclacel Group plc all Cyclacel employees waived their rights to exercise any options held by them. The number of options of common stock that would have become fully vested as a result of the accelerated vesting provisions of the Plans was 1,369,757. However, as the liquidation of Cyclacel Group plc was probable at the time the options were waived and the liquidation caused the acceleration of the vesting of the options, the previously unrecognized compensation cost associated with these awards has been charged as employee

[Table of Contents](#)

compensation immediately prior to the consummation of the Stock Purchase on March 27, 2006. Options granted pursuant to the Senior Executive Incentive Plan only became vested on occurrence of certain trigger events and the passage of time thereafter; moreover, there were no provisions for an acceleration of vesting on liquidation. Directors benefiting from this plan waived their rights to any options held by them and concurrently the directors were issued with restricted stock as detailed below. Accordingly, as the options had never vested and were improbable of vesting even absent the liquidation, no compensation charged associated with these awards has been charged as employee expense in this period. There were no Cyclacel common stock options outstanding on completion of the Stock Purchase or liquidation of Group.

Xcyte Plans

The vesting of all options granted pursuant to the 2003 Directors' Plan accelerated immediately upon the closing of the Stock Purchase and the asset sale to Invitrogen. As a result of this acceleration, any holder of options granted pursuant to the 2003 Directors Plan had the right to exercise one hundred percent (100%) of the options held by such holder pursuant to such plan. The number of options of common stock that became fully vested as a result of the accelerated vesting provisions of the Plan was 5,281.

The vesting of 25% of the unvested options granted pursuant to the 1996 Plan accelerated immediately upon the closing of the Stock Purchase and the asset sale to Invitrogen pursuant to the terms of the 1996 Plan. As a result of this acceleration, any holder of options granted pursuant to the 1996 Plan had the right to exercise 25% of all unvested options held by such holder under the plan. The number of options of common stock that became fully vested as a result of the accelerated vesting provisions of the Plan was 17,431.

The vesting of up to 25% of the total options granted under any award pursuant to the 2003 Plan accelerated immediately upon the closing of the Stock Purchase and the asset sale to Invitrogen pursuant to the terms of the 2003 Plan. As a result of this acceleration, any holder of options under the 2003 Stock Plan had the right to exercise the lesser of 25% of the options granted to such holder under the 2003 Stock Plan award or all remaining unvested options granted to the holder under the award pursuant to such plan. In addition, any holder of such options who is involuntarily terminated within 12 months of the closing of the transaction will have the right to exercise the lesser of an additional 25% of the options granted to such holder under the 2003 Plan award or all remaining unvested options granted to the holder under the award pursuant to such plan, for a total of 50% of the options granted to such holder under the 2003 Stock Plan award or all remaining unvested options granted to the holder under the award pursuant to such plan. The number of shares of the common stock that became fully vested as a result of the accelerated vesting provisions of the Plan was 21,779.

New Plans

On March 16, 2006, Xcyte stockholders approved the adoption of 2006 Plans, under which Cyclacel, following the acquisition in March 2006, is now able to make equity incentive grants to its officers, employees, directors and consultants. There are 1,615,795 shares of Cyclacel common stock reserved for issue under the equity incentive plan. As of the date of this report, a total of 827,619 options have been granted pursuant to the 2006 Plans of which two-thirds of the options vested immediately on grant. The remaining unvested options, which total 275,873, become fully vested 12 months following the date of grant of the options. The total fair value of

these options granted is \$3,120,000. In respect of these options, \$960,000 of compensation expense has not been recognized at June 30, 2006.

In connection with the approval of the equity incentive the holders of Xcyte common stock approved the partial termination of Xcyte's 2003 Employee Stock Purchase Plan, Amended and Restated 1996 Stock Option Plan, Amended and Restated 2003 Directors' Stock Option Plan and 2003 Stock Option Plan. As a result of such partial termination, no options will be issued under such plans. However, such partial termination will not affect the rights of holders of stock options outstanding under such stock option plans.

[Table of Contents](#)

A summary of activity for the options under our share option plans for the six months ended June 30, 2006 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in millions)
Balance as of January 1, 2006	3,188,390	\$ 1.21	8.49	5.43
Assumed on Stock Purchase	44,491	\$ 34.91	7.82	—
Granted	827,619	\$ 6.40	9.88	—
Exercised	—	—	—	—
Expired	—	—	—	—
Cancelled/forfeited	(3,208,236)	\$ 1.56	8.48	5.43
Balance as of June 30, 2006	852,264	\$ 6.69	9.84	—
Vested and unvested expected to vest at June 30, 2006	576,391	\$ 6.83	9.83	—
Vested and exercisable at June 30, 2006	576,391	\$ 6.83	9.83	—

The assumptions used in valuing stock option awards granted during 2006, along with Weighted-average grant date fair value are shown below.

	For the six months ended June 30, 2006
Expected term	3 years
Risk free Interest rate	5.06%
Volatility	90%
Dividends	0.00%
Resulting weighted average grant date fair value	\$ 3.77

The expected term assumption was estimated using the "simplified method", as described in Staff Accounting Bulletin No. 107, Share-Based Payment. This method estimates the expected term of an option based on the average of the vesting period and the contractual term of an option award.

The expected volatility assumption was based on the historical volatility of our common stock since the first day we became publicly traded (August 2000).

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, we use the weighted average of the two Federal Reserve securities closest to the expected term of the employee option.

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

In calculating the fair value of option awards granted after January 1, 2006, we, for the most part, used the same methodologies and assumptions employed prior to our adoption of SFAS 123R. For instance, our estimate of expected volatility is based exclusively on our historical volatility, since we have granted options that vest purely based on the passage of time and otherwise meet the criteria to exclusively rely on historical volatility, as set out in Staff Accounting Bulletin No. 107, "Share-based Payment".

In the first quarter of 2006 prior to the completion of the Stock Purchase, 1,750,000 shares of Cyclacel Group plc preferred stock was granted to certain directors, officers and a former director. These shares converted to 648,412 shares of restricted common stock of the Company on completion of the

[Table of Contents](#)

Stock Purchase. Because the shares granted are not subject to additional future vesting or service requirements, the stock-based compensation expense of \$5,181,000 recorded in the first quarter of 2006 constitutes the entire grant-date fair value of this award, and no future period charges will be recorded. The stock is restricted only in that it cannot be sold for a specified period of time. There are no vesting requirements. The fair value of the stock granted was \$7.99 per share based on the market price of the Company's common stock on the date of grant. There were no discounts applied for the effects of the restriction, since the value of the restriction is considered to be de minimis. Certain of the restricted stock was issued as a replacement for the previously held stock based compensation awards and the incremental fair value of the restricted stock over the original award at the date of replacement has been charged to expense during the six months ended June 30, 2006. Of the \$5,181,000 charge \$3,165,000 was reported as a component of research and development expense and \$2,016,000 was reported as a component of general and administrative expense.

There was no cash received from stock option exercises for the three months or six months ended June 30, 2006. No income tax benefits would have been recorded if there had been stock option exercises. SFAS 123R prohibits recognition of tax benefits for exercised stock option until such benefits are realized. As we presently have tax loss carry forwards from prior periods and expect to incur tax losses in 2006, we would not be able to benefit from the deduction for exercised stock option in the current reporting period.

Cash used to settle equity instruments granted under share-based payment arrangements amounted to \$Nil during all periods presented.

3. COMMITMENTS AND CONTINGENCIES

The Company has contractual obligations on leases of office and manufacturing space as follows (in thousands):

Years Ending December 31,	Operating Leases
For the remainder of 2006	\$ 947
2007	1,757
2008	1,805
2009	1,855
2010	1,710
Total	<u>\$ 8,074</u>

Rent expense, which includes lease payments related to the Company's research and development facilities and corporate headquarters and other rent related expenses, was \$137,000, \$259,000, \$291,000 and \$540,000 for the three month and six month periods ended June 30, 2005 and 2006, respectively.

In October 2000, the Company entered into a 25-year lease for its research and development facility in Dundee, Scotland. The Company also leases a second research facility at the Babraham Research Campus, Cambridge, England. The Company entered into this five-year lease in August 2005. There is an option to terminate the lease on July 31, 2007 at a cost to the Company of \$104,000.

Additionally, the Company currently leases a total of approximately 52,100 square feet of space at two former Xcyte facilities. The Company leases approximately 11,600 square feet of office space in Seattle, Washington, with monthly payments of approximately \$19,000. The lease on this space expires in September 2006, and the Company does not plan to renew the lease. The Company also leases approximately 40,500 square feet of space in Bothell, Washington, with monthly payments of approximately \$80,000. The lease term on this space expires December 2010. However, activities were discontinued at the Bothell facility during the third quarter of 2005 and the Company is exploring options for the future of this facility. Market conditions for subleasing space in Bothell are currently considered poor primarily due to an overabundance of available space. Accordingly, following the Stock Purchase on March 27, 2006, the Company recorded an accrued restructuring liability which was computed as the present value of the difference between the remaining lease payments due less the estimate of net sublease income and expenses. As of June 30, 2006 the accrued restructuring liability

[Table of Contents](#)

was \$2.5 million. This represents the Company's best estimate of the fair value of the liability as determined under SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." Subsequent changes in the liability due to accretion, or changes in estimates of sublease assumptions, etc. will be recognized as adjustments to restructuring charges in future periods.

The Company records payments of rent related to the Bothell facility as a reduction in the amount of the accrued restructuring liability. Accretion expense is recognized due to the passage of time, which is also reflected as a restructuring charge. Based on our current projections of estimated sublease income and a discount rate of 7.8%, the Company expects to record additional accretion expense of approximately \$423,000 over the remaining term of the lease.

In connection with the abandonment of the leasehold improvements in the Seattle and Bothell facilities and the sale of assets in late 2005 the Company has been subjected to a State sales tax audit by the Department of Revenue of the State of Washington. In January 2006, the Company received tax assessments from the Department of Revenue of the State of Washington with respect to its utilization of the high-technology sales and use tax deferral program. Under the high-technology sale and use tax deferral program qualified Washington companies, such as the Company, are allowed to defer sales tax on purchases of qualified assets used in research and development activities. The deferred sales taxes are then forgiven by the State, generally over a period of eight years. According to the assessments, if the deferral program requirements continue to be met, the tax assessment will be waived. The total tax liability assessed by the State of Washington equals approximately \$1 million. The Company's management believes that the majority of the assets which previously qualified for the State of Washington sales tax deferral program continue to qualify as they have been retained by the Company or have been or will be sold or transferred to a qualified entity for qualified purposes. We are in the process of discussing the potential sales tax liability with the Department of Revenue of the State of Washington and have appealed the assessment. The appeal is based on an evaluation of the extent to which the abandoned and disposed of assets have been rendered obsolete, sold or leased to eligible entities that continue to use the assets for purposes qualified under the program. The ultimate amount of the assessment that will be payable is dependent upon rulings and interpretations of the State tax laws related to this program. Based on an evaluation of the underlying asset dispositions and State tax law management believes that the potential loss from the ultimate settlement of the assessment ranges from \$270,000 to \$1 million. Based on this evaluation Xcyte accrued \$270,000 as a State tax assessment in 2005 and such amount is included in the accompanying balance sheet as a component of accrued liabilities.

On March 24, 2006 Xcyte completed an Asset Purchase Agreement (the "Asset Purchase Agreement") with Invitrogen Corporation, a Delaware corporation ("Invitrogen"), in which Invitrogen agreed to purchase Xcyte's T cell expansion technology known as the "Xcellerate Process" in exchange for \$5 million (the "Asset Sale"). The purchase price is subject to a post-closing adjustment pursuant to which Xcyte can be required to refund up to \$1 million to Invitrogen. The assets subject to the agreement include intellectual property, the clinical data generated by Xcyte in the course of six clinical trials of the lead product, Xcellerated T Cells, as well as raw materials and equipment.

On July 28, 2005, Cyclacel Group plc signed a convertible Loan Note Instrument constituting convertible unsecured loan notes. On July, 28, 2005, it entered into a Facility Agreement with Scottish Enterprise, as lender, whereby Scottish Enterprise subscribed for £5 million (\$8.8 million) of the convertible loan notes. Upon the completion of the Stock Purchase, the convertible loan notes held by Scottish Enterprise converted into 1,231,527 preferred "D" shares in satisfaction of all amounts owed by Group under the convertible loan notes. The number of preferred "D" shares that Scottish Enterprise received was calculated by dividing the principal amount outstanding under the loan note by £4.06. Scottish Enterprise retains the ability it had under the Facility Agreement to receive a cash payment should the research operations in Scotland be significantly reduced. However, Cyclacel Limited will guarantee the amount potentially due to Scottish Enterprise which will be calculated as a maximum of £5 million less the market value of the shares held (or would have held in the event they dispose of any shares) by Scottish Enterprise at the time of any significant reduction in research facilities during the period ending on July 28, 2010.

4. MERGER

On March 27, 2006, Xcyte completed the Stock Purchase Agreement with Group for a transaction to be accounted for as a purchase under accounting principles generally accepted in the United States. The Stock Purchase was approved by Xcyte shareholders on March 16, 2006 and Group shareholders on March 27, 2006. Under the terms of the transaction, Xcyte issued 7,761,453 shares of its common stock (equivalent to 776,145 shares after adjustment for a 1 for 10 reverse stock split which occurred on March 27, 2006) for all of Limited's outstanding shares of common stock. For accounting purposes, the transaction is considered a "reverse merger" under which Limited is considered the acquirer of Xcyte. Accordingly, the purchase price was allocated among the fair values of the assets and liabilities of Xcyte, while the historical results of Limited are reflected in the results of the combined company. The 1,967,966 shares of Xcyte common stock outstanding, the 2,046,813 preferred stock outstanding and the outstanding Xcyte options, are considered as the basis for determining the consideration in the reverse merger transaction. Based on the outstanding shares of Group capital stock on March 27, 2006, each share of Group preferred stock was exchanged for approximately 0.37 shares of Xcyte common stock.

Each Limited and Group stock option and warrant that was not converted prior to the consummation of the Stock Purchase was cancelled and there were no outstanding Limited or Group options and warrants on closing.

Merger Purchase Price

The consolidated financial statements reflect the merger of Limited with Xcyte as a reverse merger wherein Limited is deemed to be the acquiring entity from an accounting perspective. Under the purchase method of accounting, Xcyte's outstanding shares of common and preferred stock were valued using the average closing price on Nasdaq of \$4.38 (as adjusted for the reverse stock split) and \$3.72 per share for common stock and preferred stock, respectively, for the two days prior to through the two days subsequent to the announcement of the transaction date of December 15, 2005. There were 1,967,967 shares of common stock and 2,046,813 shares of preferred stock outstanding as of March 27, 2006. The fair values of the Xcyte outstanding stock options were determined using the Black-Scholes option pricing model with the following assumptions: stock price of \$4.38 (as adjusted for the reverse stock split), volatility of 0.97; risk-free interest rate of 4.0%; and an expected life of three months.

The purchase price is summarized as follows (in thousands):

Fair value of Xcyte outstanding common stock	\$ 8,620
Fair value of Xcyte outstanding preferred stock	7,618
Fair value of Xcyte outstanding stock options	17
Estimated merger costs	1,951
Total purchase price	<u>\$ 18,206</u>

Merger Purchase Price Allocation

The purchase price allocation is as follows (in thousands):

Current assets	\$ 21,267
Property, plant and equipment	108
Other assets	259
Current liabilities	(4,400)
Non-current liabilities	(1,777)
Goodwill	2,749
	<u>\$ 18,206</u>

Pro Forma Results of Operations

The results of operations of Xcyte are included in Cyclacel's condensed consolidated financial statements from the date of the business combination transaction as of March 27, 2006. The following table presents pro forma results of operations and gives effect to the business combination transaction as if the business combination was consummated at the beginning of the period presented. The unaudited pro forma results of operations are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the retrospective periods or of the results that may occur in the future.

	For the six months ended June 30,	
	2006 \$000	2005 \$000
Revenues	5,187	155
Loss before taxes	(18,505)	(24,524)
Net loss applicable to ordinary shareholders	(20,276)	(29,562)
Net loss per share-basic and diluted	<u>\$ (1.83)</u>	<u>\$ (3.81)</u>
Weighted average shares	11,102,967	7,761,453

5. AMOUNTS DUE TO CYCLACEL GROUP PLC

Prior to the completion of the Stock Purchase, Cyclacel Limited was a wholly owned subsidiary of Cyclacel Group plc. The amounts outstanding of \$217,000 and \$10,467,000 as of June 30, 2006 and December 31, 2005, respectively, are a result of intercompany transactions which occurred prior to the completion of the Stock Purchase and represent amounts due to certain advisors in connection with the members' voluntary liquidation of Cyclacel Group plc. Cyclacel Pharmaceuticals, Inc. will settle the outstanding amounts and as a consequence eliminate the balance due to Cyclacel Group plc. During the three months ended June 30, 2006, Cyclacel paid certain advisors \$939,000 reducing the amounts outstanding from \$1,156,000 at March 31, 2006 to \$217,000 at June 30, 2006.

6. STOCKHOLDERS' EQUITY

Reverse Stock Split and Issue of Common Stock in Connection with the Stock Purchase Agreement

In March 2006, the Board of Directors and stockholders of the Company approved an amendment to the Company's eighth amended and restated certificate of incorporation effecting a 1-for-10 reverse stock split of common stock, (the "Reverse Stock Split"). The Reverse Stock Split occurred immediately prior to the completion of the Stock Purchase. All issued and outstanding common stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this stock split, except as specifically indicated.

Stock Purchase Agreement

In March 2006, in connection with the Stock Purchase Agreement the Company issued 7,761,453 shares of common stock (equivalent to 776,145 shares after adjustment for a 1 for 10 reverse stock split which occurred on March 27, 2006) to Cyclacel Group plc which represented 79.7% of the outstanding shares of the Company's common stock.

Stock Option Award Plan

In January 2006, the Board of Directors adopted and in March 2006, the stockholders approved the 2006 Plans. The Company had reserved a total of 986,120 shares of common stock for issuance under the 2006 Plan plus any options granted under the Company's predecessor plans that expire unexercised or are repurchased by the Company pursuant to the terms of such options. On

16

[Table of Contents](#)

July 6, 2006, the stockholders approved an amendment of the 2006 Plans to increase the number of shares of common stock issuable thereunder by an additional 629,675 shares, to an aggregate of 1,615,795 shares. As of June 30, 2006, a total of 827,619 options have been issued under the 2006 Plans.

Private Placement

On April 26 2006, the Company entered into a Stock and Purchase Agreement pursuant to which it sold to certain investors, for an aggregate purchase price of \$45.3 million, 6,428,572 shares of its common stock and warrants to purchase up to 2,571,429 additional shares of its common stock. The purchase price for the common stock and the exercise price for the warrants is \$7.00 per share. Investors in the financing paid an additional purchase price equal to \$0.125 per warrant or an additional \$0.05 for each share underlying the warrants. The warrants are not exercisable until six months after the closing and have an expiration date seven years after closing.

Amounts Receivable from Directors and Officers

In connection with the issue of Group Preferred D shares to certain directors and officers in March 2006 prior to the Stock Purchase the Company was obliged to withhold payroll taxes of \$248,000 and remit this amount to the UK tax authorities. As this is a non-cash item the taxes cannot be withheld from the payment but must be recovered from the employee. Under the UK Income and Taxes Act these payroll taxes are recoverable from the individuals by June 27, 2006 and all amounts were recovered prior to this date.

7. RECENT ACCOUNTING PRONOUNCEMENTS

In June 2006, the FASB issued FASB Interpretation No. 48 ("FIN 48"), "Accounting for Uncertainty in Income Taxes." FIN 48 clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements in accordance with SFAS No. 109, "Accounting for Income Taxes." This Interpretation defines the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 is effective for fiscal years beginning after December 15, 2006. The impact of adopting FIN 48 on the Company's financial position or results of operations, if any, has not yet been determined.

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain statements that may be deemed "forward-looking statements" within the meaning of United States securities laws. 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. Factors that could cause results to differ materially from those projected or implied in the forward looking statements are set forth in our Annual Report on Form 10-K for the year ended December 31, 2005, as updated below under the caption "Item 1A — Risk factors".

We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements.

In this report, "Cyclacel," the "Company," "we," "us," and "our" refer to Cyclacel Pharmaceuticals, Inc.

Overview

We are a development-stage biopharmaceutical company dedicated to the discovery, development and eventual commercialization of novel, mechanism-targeted drugs to treat human cancers and other

17

[Table of Contents](#)

serious disorders. We describe drugs, compounds or molecules as mechanism-targeted if they are designed to affect identified biological processes through known mechanisms and novel if they have been recently discovered using advanced technologies. Our core area of expertise is in cell cycle biology, or the processes by which cells

divide and multiply. We focus primarily on the discovery and 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 quality of life and improving survival rates of cancer patients. We have been focused on the cell cycle since our inception. We were founded in 1996 by Professor Sir David Lane, a recognized leader in the field of tumor suppressor biology who discovered the p53 protein, which operates as one of the body's own anticancer "drugs" by inhibiting cell cycle targets. In 1999, we were joined by Professor David Glover, a recognized leader in the mechanism of mitosis, or cell division, who discovered, among other cell cycle targets, the mitotic kinases, Polo and Aurora, enzymes that act in the mitosis phase of the cell cycle. Our expertise in cell cycle biology is at the center of our business strategy.

We are generating several families of anticancer drugs that act on the cell cycle including Cyclin Dependent kinase (CDK) and Aurora kinase (AK) inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop CDK inhibitor drugs, we believe that our lead drug candidate, seliciclib, is the only orally available CDK inhibitor drug candidate currently in Phase II trials.

We are advancing three of our anticancer drug candidates, seliciclib, sapacitabine and CYC116 through in-house research and development activities. On June 29, 2006 we announced that we were beginning a Phase IIb, multi-center, randomized, double-blinded trial to evaluate the efficacy and safety of seliciclib as a third line treatment in patients with non-small cell lung cancer (NSCLC). The trial is being initiated following Food and Drug Administration and central Institutional Review Board approval of the trial protocol. The "APPRAISE" study builds on the observation of prolonged stable disease experienced by heavily-pretreated NSCLC patients enrolled in a Phase I study of single agent seliciclib. Sapacitabine has completed two Phase I studies evaluating 87 patients in refractory solid tumors. We are currently conducting a Phase Ib dose escalation clinical trial with sapacitabine for the treatment of patients with advanced malignancies with approximately 30 patients enrolled to date. On June 15, 2006, we initiated a Phase I clinical trial of sapacitabine, an orally available nucleoside analogue, in patients with advanced leukemias or myelodysplastic syndromes (MDS). We are also developing CYC116, an Aurora kinase inhibitor, for the treatment of cancer, and we expect to file an investigational new drug application in the fourth quarter of 2006. We have worldwide rights to commercialize seliciclib, sapacitabine and CYC116 and our business strategy is to enter into selective partnership arrangements with these programs.

We have a further seven novel drug series: five for cancer, one for HIV/AIDS and one for Type 2 Diabetes. In addition, we have partnered with Genzyme Corporation on certain preclinical stage CDK inhibitors for nephrology or inflammatory kidney disease applications. 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.

Our corporate headquarters is located in Short Hills, New Jersey, with our main research facility located in Dundee, Scotland, and a second research facility located in Cambridge, England.

We have incurred net losses since inception, as we have devoted substantially all of our resources to research and development, including clinical trials. As of June 30, 2006, our accumulated deficit was \$127.3 million.

Results of Operations

Collaboration and Research and Development Revenue

We have not generated any revenue from sales of commercial products and do not expect to generate any product revenue for the foreseeable future. To date, our revenue has consisted of collaboration and grant revenue.

18

[Table of Contents](#)

Grant Revenue Credits

Grant revenue is recognized as we pay for services under the applicable grant.

Research and Development Expense

Since we became operational, we have been focused on drug discovery and development programs, with particular emphasis on orally available anticancer agents. Research and development expense represents costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for seliciclib and sapacitabine, to advance product candidates toward clinical trials, to develop in-house research and preclinical study capabilities and to advance our biomarker program and technology platforms. We expense all research and development costs as they are incurred.

The following table provides information with respect to our research and development expenditures:

	Three months ended		Six months ended		Period
	June 30,		June 30,		from
	2006	2005	2006	2005	August 13,
	(unaudited)	(unaudited)	(unaudited)	(unaudited)	1996
	(in thousands)				(inception)
					to June 30,
					2006
					(unaudited)
Seliciclib	\$ 712	\$ 1,031	\$ 962	\$ 2,491	\$ 31,145
Sapacitabine	491	607	920	1,318	5,777
CYC116	1,719	928	3,550	2,184	12,591
Other Costs Related to Research and Development Programs, Management and Exploratory Research	869	1,358	1,817	2,399	56,640
	3,791	3,924	7,249	8,392	106,153
Stock Based Compensation	1,342	313	5,888	771	7,754
Total Research and Development Expenses	\$ 5,133	\$ 4,237	\$ 13,137	\$ 9,163	\$ 113,907

Three Months Ended June 30, 2006 and 2005

Research and Development Expenses

Research and development expenses increased \$0.9 million from \$4.2 million for the three-month period ended June 30, 2005 to \$5.1 million for the three-month period ended June 30, 2006. The major component of the increase in expenses is our stock-based compensation expense which increased from \$0.3 million in the three-month period ended June 30, 2005 to \$1.3 million in the three-month period ended June 30, 2006. The increase in the stock-based compensation charge is primarily due to the options granted in June 2006 under the 2006 Plan.

Our research and development expenditure, excluding stock-based compensation costs, decreased \$0.1 million from \$3.9 million in the three-month period ended June 30, 2005 to \$3.8 million in the three-month period ended June 30, 2006 primarily as a reflection of reduced costs on seliciclib ahead of the commencement of the Phase IIB clinical trials partially offset by the increased expenditure on CYC116 now in IND-directed studies.

General and Administrative Expenses

General and administrative expenses increased \$1.5 million, from \$1.5 million for the three-month period ended June 30, 2005 to \$3.0 million for the three-month period ended June 30, 2006. This increase was primarily due to the stock-based compensation charge. Our stock-based compensation expense increased \$0.6 million from an expense of \$0.1 million in the three-month period ended June 30, 2005 to an expense of \$0.7 million in the three-month period ended June 30, 2006. The

[Table of Contents](#)

increase in the stock-based compensation charge is primarily due to the options granted in June 2006 under the 2006 Plan. Our general and administrative expenditure, excluding stock-based compensation costs, increased \$0.9 million from \$1.4 million in the three-month period ended June 30, 2005 to \$2.3 million in the three-month period ended June 30, 2006 primarily due to \$0.5 million related to the Seattle and Bothell facilities and \$0.3 million related to increased level of advisors costs and insurances as we now operate as a public company.

Interest and Other Income and Expense

Interest and other income and expense increased \$0.3 million, from \$0.2 million for the three-month period ended June 30, 2005 to \$0.5 million for the three-month period ended June 30, 2006. This increase was primarily attributable to higher average balances of cash, cash equivalents and investments in 2006 following receipt of \$42.6 million from the private placement.

Research and Development Tax Credits

Research and development tax credits increased \$0.3 million, from \$0.4 million for the three-month period ended June 30, 2005 to \$0.7 million for the three-month period ended June 30, 2006. This increase was a reflection of the higher research and development expenditure in the three-month period ended June 30, 2006.

Six Months Ended June 30, 2006 and 2005

Research and Development Expenses

Research and development expenses increased \$3.9 million from \$9.2 million for the six-month period ended June 30, 2005 to \$13.1 million for the six-month period June 30, 2006. The major component of the increase in expenses is our stock-based compensation expense which increased from \$1.0 million in the six-month period ended June 30, 2005 to \$5.9 million in the six month period ended June 30, 2006. The \$5.1 million increase in the stock-based compensation charge is comprised (i) \$3.2 million related to restricted stock granted to certain employees (ii) \$0.9 million due to the acceleration of vesting of options due to the Stock Purchase and (iii) \$1.0 million related to the options granted in June 2006 under the 2006 Plan. Our research and development expenditure, excluding stock-based compensation costs, decreased \$1.2 million from \$8.4 million in the six-month period ended June 30, 2005 to \$7.2 million in the six-month period ended June 30, 2006 primarily as a reflection of reduced costs on seliciclib in 2006 ahead of the commencement of the Phase IIB clinical trials against the 2005 costs on the seliciclib Phase IIa clinical trials offset by the increased expenditure on CYC116 as activities focus on IND-directed studies in this program.

General and Administrative Expenses

General and administrative expenses increased \$4.3 million, from \$2.7 million for the six-month period ended June 30, 2005 to \$7.0 million for the six-month period ended June 30, 2006. This increase was primarily due to the stock-based compensation charge. Our stock-based compensation expense increased \$3.0 million from an expense of \$0.2 million in the six month period ended June 30, 2005 to an expense of \$3.2 million in the six-month period ended June 30, 2006. The increase in the stock-based compensation charge comprises, (i) \$2.1 million due to the grant of restricted stock, (ii) \$0.3 million due to the acceleration of vesting of options due to the Stock Purchase and (iii) \$0.6 million due to the options granted in June 2006 under the 2006 Plan. Our general and administrative expenditure, excluding stock-based compensation costs, increased \$1.3 million from \$2.5 million in the six-month period ended June 30, 2005 to \$3.8 million in the six-month period ended June 30, 2006 primarily due to \$0.5 million related to the Seattle and Bothell facilities and \$0.3 million related to increased level of advisors costs and insurances as we operate as a public company.

The future

As a public company, we operate in an increasingly demanding regulatory environment that requires us to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the

[Table of Contents](#)

Securities and Exchange Commission, or SEC, and the Nasdaq National Market, including those related to expanded disclosures, accelerated reporting requirements and more complex accounting rules. We expect that our general and administrative expenses will continue to increase in subsequent periods due to these requirements and to increasing personnel and infrastructure expenses as we advance our product candidates.

Interest and Other Income and Expense

Interest and other income and expense increased \$0.2 million, from \$0.3 million for the six-month period ended June 30, 2005 to \$0.5 million for the six-month period ended June 30, 2006. This increase was primarily attributable to higher average balances of cash, cash equivalents and investments in 2006 following receipt of \$42.6 million from the private placement.

Research and Development Tax Credits

Research and development tax credits increased \$0.3 million, from \$0.4 million for the three-month period ended June 30, 2005 to \$0.7 million for the three month period ended June 30, 2006. This increase was a reflection of the higher research and development expenditure in the three month period ended June 30, 2006.

Liquidity and Capital Resources

At June 30, 2006, we had cash and cash equivalents and short-term investments of \$65.0 million. Since our inception, we have not generated any significant product revenue and have relied primarily on the proceeds from sales of equity and preferred securities to finance our operations and internal growth. Additional funding has come through interest on investments, licensing revenue, government grants and research and development tax credits. We have incurred significant losses since our inception. As of June 30, 2006, Cyclacel had an accumulated deficit of \$127.3 million.

At June 30, 2005, we had cash and cash equivalents and short-term investments of \$12.6 million, as compared to \$65.0 million at June 30, 2006. This higher balance at June 30, 2006 was primarily due to the receipt of proceeds of cash and cash equivalents and short-term investments of \$42.6 million from the private placement, \$21.6 million assumed on completion of the Stock Purchase and \$9.1 million received from our former parent company, described below. Short-term investments decreased from \$6.6 million at June 30, 2005 to \$1.9 million at June 30, 2006.

Net cash used in operating activities increased \$1.4 million, from \$9.0 million in the six months ended June 30, 2005 to \$10.4 million in the six months ended June 30, 2006. This increase was due primarily to working capital movements.

Net cash provided by investing activities increased \$1.2 million, from \$7.9 million in the six months ended June 30, 2005 to \$9.1 million in the six months ended June 30, 2006.

Net cash provided by financing activities increased \$61.6 million, from \$(0.2) million in the six months ended June 30, 2005 to \$61.4 million in the six months ended June 30, 2006. The increase was primarily due to the cash, cash equivalents and short term investments received from the private placement of \$42.6 million and the \$21.6 million assumed on the Stock Purchase.

On July 28, 2005, Cyclacel Group plc signed a convertible Loan Note Instrument constituting convertible unsecured loan notes. On July, 28, 2005, it entered into a Facility Agreement with Scottish Enterprise, as lender, whereby Scottish Enterprise subscribed for £5 million (\$8.8 million) of the convertible loan notes. Upon the completion of the Stock Purchase, the convertible loan notes held by Scottish Enterprise converted into 1,231,527 preferred "D" shares in satisfaction of all amounts owed by Group under the convertible loan notes. The number of preferred "D" shares that Scottish Enterprise received was calculated by dividing the principal amount outstanding under the loan note by £4.06. Scottish Enterprise retains the ability it had under the Facility Agreement to receive a cash payment should the research operations in Scotland be significantly reduced. However, Cyclacel has guaranteed the amount potentially due to Scottish Enterprise which would be calculated as a

[Table of Contents](#)

maximum of £5 million less the market value of the shares held (or would have held in the event they dispose of any shares) by Scottish Enterprise at the time of any significant reduction in research facilities during the period ending on July 28, 2010.

Cyclacel was also a party to a long-term debt instrument, a government loan of \$441,000 that accrued interest at 5% per annum, which loan was wholly repaid in November 2005. As of June 30, 2006, we had contractual obligations, relating to our facilities and equipment leases, as follows:

	Total	Payments Due by Period			
		Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Contractual obligations					
Capital lease obligations	\$ 218	\$ 218	\$ —	\$ —	\$ —
Operating lease obligations	8,608	1,017	3,803	3,350	438
Purchase obligations	1,440	1,440	—	—	—
	<u>\$ 10,266</u>	<u>\$ 2,675</u>	<u>\$ 3,803</u>	<u>\$ 3,350</u>	<u>\$ 438</u>

We also currently have a number of contractual arrangements with our partners under which milestone payments totaling \$23.4 million would be payable subject to achievement of all the specific contractual milestones and our decision to continue with these projects. Under these contractual arrangements, we make annual payments that do not and will not exceed \$0.1 million.

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur substantial operating losses in the future. We will not receive any product revenue until a product candidate has been approved by the U.S. Federal Drug Agency ("FDA") or similar regulatory agencies in other countries and successfully commercialized. We currently anticipate that our cash, cash equivalents, marketable securities and proceeds from the private placement will be sufficient to fund our operations at least through to the second quarter of 2008. However, we will need to raise substantial additional funds to continue our operations. We cannot be certain that any of our programs will be successful or that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in development, should they succeed. Additionally, we plan to continue to evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

Our future funding requirements will depend on many factors, including but not limited to:

- the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;
- the costs associated with establishing manufacturing and commercialization capabilities;
- the costs of acquiring or investing in businesses, product candidates and technologies;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the effect of competing technological and market developments; and
- the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. 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. 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 our company.

[Table of Contents](#)

Critical Accounting Policies

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

Stock-based Compensation

On January 1, 2006, we adopted SFAS 123R. Under SFAS 123R, the fair value of stock options and other equity-based compensation must be recognized as expense in the statements of operations over the requisite service period of each award. Prior to January 1, 2006, we accounted for stock-based employee compensation arrangements in accordance with the provisions of APB No. 25, SFAS No. 123 and comply with the disclosure requirements of SFAS No. 148. Under APB No. 25, compensation expense is based on the difference, if any, on the date of grant, between the estimated fair value of its ordinary shares and the exercise price. SFAS 123R defines a "fair value" based method of accounting for an employee stock option or similar equity investment.

Derivative Instruments

The terms of our November 2004 convertible preferred stock offering include a dividend make-whole payment feature. If we elect to automatically convert, or the holder elects to voluntarily convert, some or all of the convertible preferred stock into shares of our common stock prior to November 3, 2007, we will make an additional payment on the convertible preferred stock equal to the aggregate amount of dividends that would have been payable on the convertible preferred stock through and including November 3, 2007, less any dividends already paid on the convertible preferred stock. This additional payment is payable in cash or, at our option, in shares of our common stock, or a combination of cash and shares of common stock. This dividend make-whole payment feature is considered to be an embedded derivative and has been recorded on the balance sheet at fair value as a current liability. We will be required to recognize other income (expense) in our statements of operations as the fair value of this derivative fluctuates from period to period.

The accounting for derivatives is complex, and requires significant judgments and estimates in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The fair value of the dividend make-whole payment feature is based on various assumptions, including the estimated market volatility and discount rates used in determination of fair value. The use of different assumptions may have a material effect on the estimated fair value amount and our results of operations.

Goodwill

Goodwill represents the difference between the purchase price and the fair value of net tangible and identifiable intangible assets acquired in the business combination.

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations," and SFAS No. 142, "Goodwill and Other Intangible Assets". Under SFAS No. 141, all business combinations initiated after June 30, 2001 must be accounted for using the purchase method. Under SFAS No. 142, goodwill and intangible assets with indefinite lives are no longer amortized but are reviewed annually (or more frequently if there are indicators such assets may be impaired) for impairment. Separable intangible assets that are not deemed to have indefinite lives will continue to be amortized over their estimated useful lives. There were no triggering events calling into question the recoverability of goodwill, during the six month period ended June 30, 2006.

[Table of Contents](#)

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our short-term investments as of June 30, 2006 consisted of \$0.7 million in corporate bonds and \$1.1 million in federal agency obligations with contractual maturities of one year or less. Due to the short-term nature of our investments, we believe that our exposure to market interest rate fluctuations is minimal. The corporate bonds in which we invest are rated "A" or better by both Moody's and Standard and Poor's. Our cash and cash equivalents are held primarily in highly liquid money market accounts. A hypothetical 10% change in short-term interest rates from those in effect at June 30, 2006 would not have a significant impact on our financial position or our expected results of operations. We do not currently hold any derivative financial instruments with interest rate risk.

Foreign Currency Risk

We do not engage in foreign currency hedging; however, we have entered into certain contracts denominated in foreign currencies and therefore, we are subject to currency exchange risks. However, we will not have a significant impact on our financial position or our expected results of operations with respect to currency exchange risks going forward.

Derivatives Valuation Risk

The Company's November 2004 convertible preferred stock remained in place following completion of the Stock Purchase. The terms of the convertible preferred stock include a dividend make-whole payment feature. This feature is considered to be an embedded derivative and was valued on the balance sheet at \$1.6 million at June 30, 2006. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

Item 4. Controls and Procedures

Spiro Rombotis, our President and Chief Executive Officer, and Paul McBarron, our Chief Operating Officer and Executive Vice President, Finance, after evaluating the effectiveness of our “disclosure controls and procedures” (as defined in Securities Exchange Act Rule 13a-15(e)), have concluded that as of June 30, 2006 our disclosure controls and procedures are effective.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as such term is defined in SEC Rule 13a-15(e), that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Executive Vice-President of Finance, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Executive Vice-President of Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Executive Vice-President of Finance concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

24

[Table of Contents](#)

PART II. OTHER INFORMATION

Item 1. Legal proceedings

None

Item 1A. Risk Factors

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in this quarterly report on Form 10-Q. 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.

As a result of the closing of the transactions whereby Cyclacel became a publicly traded company in March 2006, the risk factors below represent material changes from those presented with the Form 10-K, filed with the SEC on March 23, 2006, which represented only risk factors associated with Xcyte’s business.

We are subject to the following significant risks, among others:

Our stockholders may not realize a benefit from the Stock Purchase commensurate with the ownership dilution they will experience in connection with the Stock Purchase.

If the combined company is unable to realize the strategic and financial benefits anticipated from the Stock Purchase, our stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit.

We are at an early stage of development as a company and we do not have, and may never have, any products that generate 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. Since beginning operations in 1997, we have not generated any product revenues. We currently have no products for sale and we cannot guarantee that we will ever have any marketable products. We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the Food and Drug Administration, or 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 its 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. Seliciclib and sapacitabine, our most advanced drug candidates for the treatment of cancer, are currently our only drug candidates in clinical trials and 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, if any, will be derived from sales of drugs that we do not expect to become marketable for several years, if at all.

We have a history of operating losses and we may never become profitable.

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 general and administrative costs associated with our operations, and we may never achieve profitability. As of June 30, 2006, our accumulated deficit was \$127.3 million. Our net loss for the six months ended June 30, 2006 and 2005 was \$18.3 million, and \$10.4 million respectively. Our net loss attributable to ordinary shareholders from inception through June 30, 2006 was \$165.4 million. Our initial drug candidates are in the early

25

[Table of Contents](#)

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 its drugs. We expect to incur continued losses for several years, as we continue our research and development of our initial drug candidates, seek regulatory approvals and commercialize any approved drugs. If our initial 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, you could lose all or part of your investment.

We will need to raise substantial additional capital to fund our operations and if we fail to obtain additional funding, we may be unable to complete the development and commercialization of our drug candidates or continue our research and development programs.

We have funded all of our operations and capital expenditures with proceeds from private placements of our securities, interest on investments, government grants and research and development tax credits. 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. To meet these 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 shareholders 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. If we are unable to obtain additional funds, we may be forced to delay or terminate our clinical trials and the development and marketing of our drug candidates.

Clinical trials are expensive, time consuming and subject to delay.

Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We estimate that clinical trials of our most advanced drug candidates will continue for several years, but may take significantly longer to complete. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future drug candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for its clinical trials;
- delays in obtaining institutional review board, or IRB, and other regulatory approvals to commence a clinical trial;
- slower than anticipated patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues; and
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols.

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 revenues and our development costs could increase significantly.

[Table of Contents](#)

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

We have programs to develop small molecule inhibitors of Cyclin Dependent kinases (CDK) and Aurora kinases. Our lead drug candidate, seliciclib, is a CDK inhibitor, and CYC116 is an Aurora kinase inhibitor, based on our understanding of CDK and Aurora Kinase inhibitors. Although a number of pharmaceutical and biotechnology companies are attempting to develop CDK or Aurora inhibitor drugs for the treatment of cancer, no CDK or Aurora kinase inhibitor has yet reached the market. Our seliciclib program relies on our understanding of the interaction of CDKs with other cellular mechanisms that regulate key stages of cell growth. If our understanding of the role played by CDKs or Aurora kinase inhibitors in regulating the cell cycle is incorrect, our lead drug and CYC116 may fail to produce therapeutically relevant results, hindering our ability to pursue our clinical and regulatory strategy.

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 its drug development or research programs. If we elect to fund drug development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

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

We are making extensive use of biomarkers in an effort to facilitate our drug development and to optimize our clinical trials. Biomarkers are proteins or other substances whose presence in the blood can serve as an indicator of specific cell processes. We believe that these biological markers serve a useful purpose in helping us to evaluate whether our drug candidates are having their intended effects through their assumed mechanisms, and thus enable it to identify more promising drug candidates at an early stage and to direct its 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 yet 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.

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

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

27

[Table of Contents](#)

- fund research and development and clinical trials connected with its research;
- seek regulatory approvals;
- build or access manufacturing and commercialization capabilities;
- commercialize and secure coverage, payment and reimbursement of our drug candidates, if any such candidates receive regulatory approval; and
- hire additional management 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, 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.

Due to our reliance on contract research organizations or other third parties to conduct clinical trials, we are 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, 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 II stage of clinical testing. These arrangements may place the development of our drug candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

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

- we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;

28

[Table of Contents](#)

- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

We have no manufacturing capacity and will rely on third party manufacturers for the late stage development and commercialization of any drugs we may develop.

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 to expand our operations to include manufacturing capacities. Any performance failure on the part of

future manufacturers could delay late stage clinical development or regulatory approval of our drug candidates or commercialization of our drugs, producing additional losses and depriving us of potential product revenues.

If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities. 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 third party manufacturers or on our own, for any of our drug candidates in a timely or economic manner, or at all. For example, the manufacture of our drug candidate sapacitabine and CYC116 require several steps and it is not yet known if scale up to commercial production is feasible. 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, the drug development, regulatory approval or commercial launch of any related drugs may be delayed 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.

We currently have no marketing or sales staff. If we are unable to conclude strategic alliances with marketing partners or if we are unable to develop our own sales and marketing capabilities, we may not be successful in commercializing any drugs we may develop.

Our strategy is to develop compounds through the Phase II stage of clinical testing and market or co-promote certain of our drugs on our own. We 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 will suffer, we will incur significant additional losses and our share price will be negatively affected.

[Table of Contents](#)

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

If we advance our drug candidates through clinical trials, we will need to expand our development and regulatory capabilities and develop 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 where 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 could impair our drug development and commercialization efforts.

We are highly dependent on our senior management and key scientific and technical personnel. The loss of the services of any member of our senior management, 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 research and development 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 scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. The inability to attract and retain sufficient scientific, technical and managerial personnel could limit or delay our product development efforts, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

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

The clinical development, manufacturing, selling and marketing of 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 Investigational New Drug application, or IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, an NDA may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In addition, failure to comply with FDA and other applicable foreign and U.S. regulatory requirements may subject it to administrative or judicially imposed sanctions. These include warning

[Table of Contents](#)

letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve either pending NDAs, or supplements to approved NDAs.

Despite the substantial time and expense invested in preparation and submission of an NDA or equivalents in other jurisdictions, regulatory approval is never guaranteed. The FDA and other regulatory authorities in the United States, the European Union and elsewhere exercise substantial discretion in the drug approval process. The number, size and design of preclinical studies and clinical trials that will be required for FDA or other

regulatory approval will vary depending on the drug candidate, the disease or condition for which the drug candidate is intended to be used and the regulations and guidance documents applicable to any particular drug candidate. The FDA or other regulators can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to:

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

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 yet been demonstrated in clinical trials for any of our drug candidates. Toxicity and "severe adverse effects" as defined in trial protocols have been noted in preclinical and clinical trials involving certain of our drug candidates. For example, elevation of liver enzymes and decrease in potassium levels have been observed in some patients receiving our lead drug candidate, seliciclib. In addition, we may pursue clinical trials for 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. We are conducting Phase IIa clinical trials to test the safety and efficacy of seliciclib, in the treatment of non small cell lung cancer and hematological cancers. Independent investigators are conducting a Phase I clinical trial to test the safety of seliciclib in nasopharyngeal cancer and Phase I clinical trials to test the safety of sapacitabine in patients with advanced cancers. We expect to report final results of these trials in 2006. We believe but cannot be certain that the independent investigators will publish their results in the near future. If these trials or any future trials are unsuccessful, our business and reputation could be harmed and our share price could be negatively affected.

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 the Company 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.

[Table of Contents](#)

Following regulatory approval of any drug candidate, we would be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit its ability to commercialize its potential drugs.

If one of our drug candidates is approved by the FDA or by another regulatory authority, we would be 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 its drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

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

We currently license some of the compounds and drug candidates used in its research programs from third parties. These include sapacitabine, licensed from Sankyo Co., Ltd and CYC381 and related intellectual property, licensed from Lorus Therapeutics, Inc. Our present research involving these compounds relies upon previous research conducted by third parties over which we had no control and before we in-licensed the drug candidates. In order to receive regulatory approval of a drug candidate, we must present all relevant data and information obtained during our research and development, including research conducted prior to our licensure of the drug candidate. Although we are not currently aware of any such problems, any problems that emerge with preclinical research and testing conducted prior to our in-licensing may affect future results or our ability to document prior research and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our drug candidates.

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

We are engaged in a rapidly changing and highly competitive field. We are seeking to develop and market products that will compete with other products and drugs that currently exist or are being developed. We compete with companies that are developing small molecule drugs, as well as companies that have developed drugs or are developing alternative drug candidates for cancer or other serious disorders where there is abnormal cell proliferation. We believe that other companies are currently developing drugs targeting cancer that may compete with our drug candidates, including Astex, AstraZeneca, Eisai, Kyowa Hakko, Onconova, Pfizer, Schering AG, and Sunesis. Although Aventis, a predecessor of Sanofi-Aventis, had previously announced that it has ceased Phase II development of avlocidib or flavopiridol, a CDK inhibitor, we believe that the National Cancer Institute's Cancer Therapy Evaluation Program is continuing to enroll patients in a Phase II trial and that Sanofi-Aventis has reinitiated development of avlocidib in Phase III clinical trials in patients with chronic leukemia. Several pharmaceutical and biotechnology companies have nucleoside analogs on the market or in clinical trials for oncology indications, including Chiron, Eli Lilly and GlaxoSmithKline. A number of companies are pursuing discovery and research activities in each of the other areas that are the subject of our research and drug development programs. We believe that AstraZeneca, Merck, jointly with Vertex, Millennium and Nerviano

Medical Sciences have commenced Phase I and Phase II clinical trials of Aurora kinase inhibitors in patients with advanced cancers. Several companies have reported selection of Aurora kinase inhibitor candidates for development, including Astex, Rigel and Sunesis, and may have started or are expected to start

[Table of Contents](#)

clinical trials within the next twelve months. We believe that Chiron, Eli Lilly, GlaxoSmithKline, Novartis and Novo Nordisk have reported selection of GSK-3 inhibitor candidates for development in type 2 diabetes, Alzheimer's and stroke indications and Boehringer Ingelheim and Onconova of Plk inhibitors candidates for 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 drug 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 by the FDA or by another regulatory authority, the resulting drugs, if any, may not gain market acceptance among physicians, healthcare providers and payors, patients and the medical community. The degree of market acceptance of any of our approved drugs will depend on a variety of factors, including:

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

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

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

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

[Table of Contents](#)

In some countries, pricing of prescription drugs is subject to government control. In such countries, pricing negotiations with governmental authorities can take three to 12 months or longer following application to the competent authorities. To obtain reimbursement or pricing approval in such countries may require conducting an additional clinical trial comparing the cost-effectiveness of the drug to other alternatives. In the United States, the Medicare Part D drug benefit to be implemented in 2006 will limit drug coverage through formularies and other cost and utilization management programs, while Medicare Part B limits drug payments to a certain percentage of average price or through restrictive payment policies of "least costly alternatives" and "inherent reasonableness." Our business could be materially harmed if coverage, reimbursement or pricing is unavailable or set at unsatisfactory levels.

We may be exposed to product liability claims that may damage its reputation and 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 its 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.

Once we have commercially available drugs based on our drug candidates, we will be exposed to the risk of product liability claims. This risk exists even with respect to those 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 intend to secure limited product liability insurance coverage, but may not be able to obtain 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 create 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 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 its business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Defending against claims relating to improper handling, storage or disposal of hazardous chemical, radioactive or biological materials could be time consuming and expensive.

Our research and development involves the controlled use of hazardous materials, including chemicals, radioactive and biological materials such as chemical solvents, phosphorus and bacteria. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

[Table of Contents](#)

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. We will only be able to protect our drug candidates and its 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.

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

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

If we infringe intellectual property rights of third parties, we may increase our costs or be prevented 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 our research explores. 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. 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. In addition, the production, manufacture, commercialization or use of our product candidates may infringe existing patents of which we are not aware.

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

[Table of Contents](#)

substantial damages or take other actions that are adverse to our business. As a result of intellectual property infringement claims, or to avoid potential claims, we might:

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder; or
- be required to redesign the formulation of a drug candidate so it does not infringe, which may not be possible or could require substantial funds and time.

The development programs for our two lead drug candidates are based in part on intellectual property rights we licensed from others, and any termination of those licenses could seriously harm our business.

We have in-licensed certain patent rights in connection with the development programs for each of our two lead drug candidates. With respect to seliciclib, we hold a license from Centre National de Recherche Scientifique, or CNRS, and Institut Curie. With respect to sapacitabine, we hold a license from Sankyo Co., Ltd. of Japan. Both of these license agreements impose payment and other material obligations on us. Under the CNRS/Institut Curie license, we are obligated to pay license fees, milestone payments and royalties. We are also obligated to use reasonable efforts to develop and commercialize products based on the licensed patents. Under the Sankyo license we are obligated to pay license fees, milestone payments and royalties. We are also obligated to use commercially reasonable efforts to commercialize products based on the licensed rights and to use reasonable efforts to obtain regulatory approval to sell the products in at least one country by September 2011. Although we are currently in compliance with all of our material obligations under these licenses, if we were to breach any such obligations our counterparties would be permitted to terminate the licenses. This would restrict or delay or eliminate our ability to develop and commercialize these drug candidates, which could seriously harm our business.

Intellectual property rights of third parties could adversely affect our ability to commercialize our drug candidates.

If patents issued to third parties contain valid claims that cover our compounds or their manufacture or use, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We are aware of several published patent applications, and understand that others may exist, that could support claims that, if granted, could cover various aspects of our developmental programs, including in some cases our lead drug candidate, seliciclib, particular uses of that compound, sapacitabine or other therapeutic candidates, or gene sequences and techniques that we use in the course of our research and development. Based on our review of the published applications, we believe that it is unlikely that a valid claim would be issued that covered seliciclib. In addition, we understand that other applications exist relating to potential uses of seliciclib and sapacitabine that are not part of our current clinical programs for these compounds. 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. If a patent is issued that covers our compounds or their manufacture or use then we may not be in a position to commercialize the related drug candidate unless we successfully pursue litigation to have that patent invalidated or enter into a licensing arrangement with the patent holder. Any such litigation would be time consuming and costly, and its outcome would not be guaranteed, and we cannot be certain that we would be able to enter into a licensing arrangement with the patent holder on commercially reasonable terms. In either case, our business prospects could be materially adversely affected.

[Table of Contents](#)

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 certificate of incorporation and bylaws contain provisions that could delay or prevent a change in our board of directors and management teams. Some of these provisions:

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

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

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

We may have limited ability to pay cash dividends on the convertible preferred stock.

Delaware law may limit our ability to pay cash dividends on the convertible preferred stock. Under Delaware law, cash dividends on our capital stock may only be paid from “surplus” or, if there is no “surplus,” from the corporation’s net profits for the current or preceding fiscal year. Delaware law defines “surplus” as the amount by which the total assets of a corporation, after subtracting its total liabilities, exceed the corporation’s capital, as determined by its board of directors. Since we are not profitable, our ability to pay cash dividends will require the availability of adequate surplus. Even if adequate surplus is available to pay cash dividends on the convertible preferred stock, we may not have sufficient cash to pay dividends on the convertible preferred stock. If that was to happen, holders of preferred stock would be granted certain additional rights until such dividends were repaid.

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

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

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

- changes in financial estimates or recommendations by securities analysts;
- variations in our quarterly results;
- announcements about our collaborators or licensors; and
- changes in accounting principles.

[Table of Contents](#)

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.

The future sale of our common and convertible preferred stock, and future issuances of our common stock upon conversion of our convertible preferred stock and upon the payment of make-whole dividends, if any, could negatively affect our stock price.

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

In addition, if we exercise our rights to pay make-whole dividends in common stock rather than in cash upon conversion of our convertible preferred stock to common stock, then the sale of such shares of common stock or the perception that such sales may occur could cause the market price of our stock to fall. Additionally, after our convertible preferred stock offering, the holders of our convertible preferred stock had the right to convert each share of convertible preferred stock into approximately 0.42553 shares of our common stock. Such conversion rate is subject to certain antidilution adjustments that, upon the occurrence of certain events, will increase the number of shares of common stock that each holder of convertible preferred stock will receive upon conversion into common stock. Such antidilution price adjustments may apply in the case of any strategic alternative that we pursue which may result in further dilution to the holders of outstanding common stock. The conversion of our convertible preferred stock into common stock and the payment of any make-whole dividends in shares of common stock in lieu of cash, may result in substantial dilution to the interests of our holders of common stock.

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

An exchange of convertible preferred stock for debentures, as well as any dividend make-whole or interest make-whole payments paid in our common stock, will be taxable events for U.S. federal income tax purposes, which may result in tax liability for the holder of convertible preferred stock without any corresponding receipt of cash by the holder. In addition, the debentures may be treated as having original issue discount, a portion of which would generally be required to be included in the holder's gross income even though the cash to which such income is attributable would not be received until maturity or redemption of the debenture. We will not distribute any cash to you 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 elect to automatically convert the convertible preferred stock on or prior to maturity if our common stock price has exceeded 150% of the conversion price for at least 20 trading days during a 30-day trading period ending within five trading days prior to the notice of automatic conversion. You should be aware that 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 its 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

[Table of Contents](#)

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.

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

Unregistered sales of securities

On April 26 2006, the Company entered into a Stock Purchase Agreement pursuant to which it sold to certain investors, for an aggregate purchase price of \$45.3 million, 6,428,572 shares of its common stock and warrants to purchase up to 2,571,429 additional shares of its common stock. The purchase price for the common stock and the exercise price for the warrants is \$7.00 per share. Investors in the financing paid an additional purchase price equal to \$0.125 per warrant or an additional \$0.05 for each share underlying the warrants. The warrants are not exercisable until six months after the closing and have an expiration date seven years after closing. All securities were sold in a private placement exempt from registration under the Securities Act of 1933 by virtue of Section 4(2) and/or Regulation D promulgated thereunder as transactions not involving any public offering. The Company received net proceeds of \$42.6 million.

We claimed exemption from registration under the Securities Act for the sale and issuance of securities in the Stock Purchase by virtue of Section 4(2) and/or Regulation D promulgated thereunder as transactions not involving any public offering. All of the purchasers of unregistered securities for which we relied on Section 4(2) and/or Regulation D represented that they were accredited investors as defined under the Securities Act. We claimed such exemption on the basis that each investor represented that (a) it is an accredited investor (as defined under the Securities Act of 1933, as amended), (b) it is acquiring the securities for investment only and not with a view to the distribution thereof, and (c) it either received adequate information about the Company

or had access to such information. Appropriate legends were affixed to the warrants and the certificates representing the shares of common stock. The shares sold in the Stock Purchase have subsequently been registered on a registration statement on Form S-3 (Reg. No. 333-134945) which was declared effective by the SEC on July 14, 2006.

No payments for such expenses related to these offerings were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities, or (iii) any of our affiliates.

The net proceeds from these offerings have been invested into short-term investment grade securities and money market accounts. We have begun, and intend to continue to use, our net proceeds to fund clinical and preclinical development of our product candidates, to discover additional product candidates and for general corporate purposes, including capital expenditures and working capital. We may use a portion of our net proceeds to in-license product candidates or to invest in businesses or technologies that we believe are complementary to our own.

Item 3. Defaults Upon Senior Securities

None.

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

On July 6, 2006, the Annual General Meeting of Stockholders was held and the shares present voted on the following matters:

1. A proposal to approve the election of two Class 3 directors to hold office until the 2009 Annual Meeting and until their successors are duly elected and qualified was approved with for Paul McBarron 8,795,475 votes FOR, and for Dr Christopher Henney, 8,795,475 votes FOR.
2. A proposal to approve the amendment of the 2006 Equity Incentive Plan to increase the number of shares of common stock issuable thereunder by an additional 629,675 shares, to an aggregate of 1,615,795 shares was approved with 8,070,203 votes FOR, 10,455 votes AGAINST, and 876 ABSTAINING.

39

[Table of Contents](#)

3. A proposal to ratify the selection of Ernst & Young LLP as our independent registered public accounting firm for the year ending December 31, 2006 was approved with 8,815,368 votes FOR, 421 votes AGAINST, and 65 ABSTAINING.

Item 5. Other Information

None.

40

[Table of Contents](#)

Item 6. Exhibits

- 31.1 Certification of Chief 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 Chief 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 Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

41

[Table of Contents](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in Short Hills, New Jersey, on August 14, 2006.

CYCLACEL PHARMACEUTICALS, INC.

Dated: August 14, 2006

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

42

**Certification of President and Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Spiro Rombotis, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cyclacel Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2006

/s/ Spiro Rombotis _____
Spiro Rombotis
President and Chief Executive Officer

**Certification of Executive Vice President, Finance
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Paul McBarron, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cyclacel Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2006

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

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

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2006 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: August 14, 2006

/s/ Spiro Rombotis _____
Spiro Rombotis
President and Chief Executive Officer

**Certification of Executive Vice President Finance
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2006 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: August 14, 2006

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