

Cyclacel Pharmaceuticals, Inc.

Form 10-Q

November 07, 2008

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2008  
OR**

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

**Commission file number 0-50626  
CYCLACEL PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)**

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**91-1707622**

(IRS Employer Identification. No.)

**200 CONNELL DRIVE, SUITE 1500  
BERKELEY HEIGHTS, NJ 07922**

(Address of principal executive offices)

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

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

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

Large accelerated filer ☐

Accelerated filer ☒

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

Smaller reporting filer ☐

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

As of November 7, 2008 there were 20,433,129 shares of the issuer's common stock outstanding.

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

|                                                                                                                                                                                                                                                                                                   | December 31,<br>2007 | September 30,<br>2008<br>(Unaudited) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------------------------|
| <b>ASSETS</b>                                                                                                                                                                                                                                                                                     |                      |                                      |
| <b>Current assets:</b>                                                                                                                                                                                                                                                                            |                      |                                      |
| Cash and cash equivalents                                                                                                                                                                                                                                                                         | 30,987               | 26,723                               |
| Short-term investments                                                                                                                                                                                                                                                                            | 27,766               | 6,998                                |
| Inventory                                                                                                                                                                                                                                                                                         | 213                  | 571                                  |
| Prepaid expenses and other current assets                                                                                                                                                                                                                                                         | 4,811                | 3,017                                |
| <b>Total current assets</b>                                                                                                                                                                                                                                                                       | <b>63,777</b>        | <b>37,309</b>                        |
| Property, plant and equipment (net)                                                                                                                                                                                                                                                               | 3,016                | 2,288                                |
| Deposits and other assets                                                                                                                                                                                                                                                                         | 196                  | 196                                  |
| Intangible assets (net)                                                                                                                                                                                                                                                                           | 4,305                |                                      |
| Goodwill                                                                                                                                                                                                                                                                                          | 4,618                | 1,832                                |
| <b>Total assets</b>                                                                                                                                                                                                                                                                               | <b>75,912</b>        | <b>41,625</b>                        |
| <br><b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                                                                                                                                                                                                                                                   |                      |                                      |
| <b>Current liabilities:</b>                                                                                                                                                                                                                                                                       |                      |                                      |
| Accounts payable                                                                                                                                                                                                                                                                                  | 4,958                | 1,301                                |
| Accrued liabilities                                                                                                                                                                                                                                                                               | 4,015                | 5,710                                |
| Other current liabilities                                                                                                                                                                                                                                                                         | 1,279                | 1,291                                |
| Warrant liability                                                                                                                                                                                                                                                                                 | 3,545                | 224                                  |
| Current portion of other accrued restructuring charges                                                                                                                                                                                                                                            | 905                  | 1,349                                |
| Current portion of equipment financing                                                                                                                                                                                                                                                            | 10                   |                                      |
| <b>Total current liabilities</b>                                                                                                                                                                                                                                                                  | <b>14,712</b>        | <b>9,875</b>                         |
| Other accrued restructuring charges, net of current                                                                                                                                                                                                                                               | 2,090                | 1,361                                |
| Other long term payables                                                                                                                                                                                                                                                                          | 1,141                | 616                                  |
| <b>Total liabilities</b>                                                                                                                                                                                                                                                                          | <b>17,943</b>        | <b>11,852</b>                        |
| <br><b>Stockholders' equity:</b>                                                                                                                                                                                                                                                                  |                      |                                      |
| Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2007 and September 30, 2008; 2,046,813 shares issued and outstanding at December 31, 2007 and September 30, 2008. Aggregate preference in liquidation of \$20,673,000 at December 31, 2007 and September 30, 2008 | 2                    | 2                                    |
| Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2007 and September 30, 2008; 20,433,129 shares issued and                                                                                                                                                          | 20                   | 20                                   |

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outstanding at December 31, 2007 and September 30, 2008

|                                                   |               |               |
|---------------------------------------------------|---------------|---------------|
| Additional paid-in capital                        | 222,906       | 223,186       |
| Accumulated other comprehensive loss              | (2,630)       | 1,337         |
| Deficit accumulated during the development stage  | (162,329)     | (194,772)     |
| <b>Total stockholders' equity</b>                 | <b>57,969</b> | <b>29,773</b> |
| <b>Total liabilities and stockholders' equity</b> | <b>75,912</b> | <b>41,625</b> |

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

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

|                                                    | <b>Three Months Ended</b> |                           | <b>Nine Months Ended</b>  |                           | <b>Period from August 13, 1996 (inception) to September 30, 2008</b> |
|----------------------------------------------------|---------------------------|---------------------------|---------------------------|---------------------------|----------------------------------------------------------------------|
|                                                    | <b>September 30, 2007</b> | <b>September 30, 2008</b> | <b>September 30, 2007</b> | <b>September 30, 2008</b> |                                                                      |
| <b>Revenues:</b>                                   |                           |                           |                           |                           |                                                                      |
| Collaboration and research and development revenue |                           |                           | 10                        |                           | 3,000                                                                |
| Product revenue                                    |                           | 257                       |                           | 590                       | 590                                                                  |
| Grant revenue                                      | 33                        | 12                        | 107                       | 36                        | 3,632                                                                |
| <b>Total revenue</b>                               | <b>33</b>                 | <b>269</b>                | <b>117</b>                | <b>626</b>                | <b>7,222</b>                                                         |
| <b>Operating expenses:</b>                         |                           |                           |                           |                           |                                                                      |
| Cost of goods sold                                 |                           | 120                       |                           | 315                       | 315                                                                  |
| Research and development                           | 4,449                     | 4,030                     | 12,742                    | 15,718                    | 157,262                                                              |
| Selling, general and administrative                | 2,523                     | 3,218                     | 8,022                     | 11,337                    | 59,291                                                               |
| Goodwill and intangibles impairment                |                           | 6,344                     |                           | 6,344                     | 6,344                                                                |
| Restructuring expenses                             |                           | 489                       | 81                        | 489                       | 2,268                                                                |
| <b>Total operating expenses</b>                    | <b>6,972</b>              | <b>14,201</b>             | <b>20,845</b>             | <b>34,203</b>             | <b>225,480</b>                                                       |
| Operating loss                                     | (6,939)                   | (13,932)                  | (20,728)                  | (33,577)                  | (218,258)                                                            |
| Other income (expense):                            |                           |                           |                           |                           |                                                                      |
| Costs associated with aborted 2004 IPO             |                           |                           |                           |                           | (3,550)                                                              |
| Change in valuation of derivative                  | (19)                      |                           | (89)                      |                           | (308)                                                                |
| Change in valuation of warrants                    | 951                       | 432                       | 2,815                     | 3,321                     | 6,526                                                                |
| Foreign exchange gains/(losses)                    | 459                       | (4,776)                   | 1,139                     | (4,638)                   | (4,180)                                                              |
| Interest income                                    | 955                       | 287                       | 2,769                     | 1,184                     | 13,345                                                               |
| Interest expense                                   | (54)                      | (69)                      | (154)                     | (244)                     | (4,383)                                                              |
| <b>Total other income (expense)</b>                | <b>2,292</b>              | <b>(4,126)</b>            | <b>6,480</b>              | <b>(377)</b>              | <b>7,450</b>                                                         |
| <b>Loss before taxes</b>                           | <b>(4,647)</b>            | <b>(18,058)</b>           | <b>(14,248)</b>           | <b>(33,954)</b>           | <b>(210,808)</b>                                                     |
| Income tax benefit                                 | 433                       | 411                       | 1,549                     | 1,511                     | 16,036                                                               |
| <b>Net loss</b>                                    | <b>(4,214)</b>            | <b>(17,647)</b>           | <b>(12,699)</b>           | <b>(32,443)</b>           | <b>(194,772)</b>                                                     |
| Dividends on Preferred Ordinary shares             |                           |                           |                           |                           | (38,123)                                                             |

|                                                   |                   |    |                   |                   |                   |                   |           |    |        |
|---------------------------------------------------|-------------------|----|-------------------|-------------------|-------------------|-------------------|-----------|----|--------|
| <b>Net loss applicable to common shareholders</b> |                   |    | (4,214)           | (17,647)          | (12,699)          | (32,443)          | (232,895) |    |        |
| Net loss per share                                | Basic and diluted | \$ | (0.21)            | \$                | (0.86)            | \$                | (0.65)    | \$ | (1.59) |
| Weighted average common shares outstanding        |                   |    | <b>20,433,129</b> | <b>20,433,129</b> | <b>19,685,457</b> | <b>20,433,129</b> |           |    |        |

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

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

|                                                                                                 | <b>Nine Months Ended<br/>September 30,<br/>2007                  2008</b> |                 | <b>Period from<br/>August 13,<br/>1996<br/>(inception) to<br/>September 30,<br/>2008</b> |
|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|-----------------|------------------------------------------------------------------------------------------|
| <b>Cash flows from operating activities:</b>                                                    |                                                                           |                 |                                                                                          |
| Net loss                                                                                        | (12,699)                                                                  | (32,443)        | (194,772)                                                                                |
| Adjustments to reconcile net loss to net cash used in operating activities:                     |                                                                           |                 |                                                                                          |
| Accretion of deferred consideration payable in common stock related to the acquisition of ALIGN |                                                                           | 29              | 39                                                                                       |
| Accretion of interest on notes payable, net of amortization of debt premium                     |                                                                           | 59              | 78                                                                                       |
| Amortization of investment premiums, net                                                        | (220)                                                                     | (1,273)         | (2,146)                                                                                  |
| Change in valuation of derivative                                                               | 89                                                                        |                 | 308                                                                                      |
| Change in valuation of warrants                                                                 | (2,815)                                                                   | (3,321)         | (6,526)                                                                                  |
| Depreciation and amortization                                                                   | 707                                                                       | 1,619           | 11,832                                                                                   |
| Goodwill and intangibles impairment                                                             |                                                                           | 6,344           | 6,344                                                                                    |
| Foreign exchange (gain) loss                                                                    | (1,432)                                                                   | 5,184           | 8,104                                                                                    |
| Deferred revenue                                                                                |                                                                           |                 | (98)                                                                                     |
| Compensation for warrants issued to non employees                                               |                                                                           |                 | 1,215                                                                                    |
| Shares issued for IP rights                                                                     |                                                                           |                 | 446                                                                                      |
| Gain on disposal of property, plant and equipment                                               |                                                                           |                 | 27                                                                                       |
| Stock based compensation                                                                        | 1,335                                                                     | 1,202           | 15,089                                                                                   |
| Provision for restructuring                                                                     | 81                                                                        | 383             | 2,162                                                                                    |
| Amortization of issuance costs of Preferred Ordinary C shares                                   |                                                                           |                 | 2,517                                                                                    |
| Changes in operating assets and liabilities:                                                    |                                                                           |                 |                                                                                          |
| Prepaid expenses and other current assets                                                       | (2,088)                                                                   | 1,184           | (3,016)                                                                                  |
| Accounts payable and other current liabilities                                                  | (588)                                                                     | (2,499)         | (1,298)                                                                                  |
| <b>Net cash used in operating activities</b>                                                    | <b>(17,630)</b>                                                           | <b>(23,532)</b> | <b>(159,695)</b>                                                                         |
| <b>Investing activities:</b>                                                                    |                                                                           |                 |                                                                                          |
| Purchase of ALIGN                                                                               |                                                                           |                 | (3,763)                                                                                  |
| Purchase of property, plant and equipment                                                       | (800)                                                                     | (354)           | (8,796)                                                                                  |
| Proceeds from sale of property, plant and equipment                                             |                                                                           |                 | 26                                                                                       |
| Purchase of short-term investments                                                              | (27,429)                                                                  | (857)           | (154,454)                                                                                |
| Redemptions of short-term investments, net of maturities                                        |                                                                           | 22,899          | 153,381                                                                                  |
| <b>Net cash (used in) provided by investing activities</b>                                      | <b>(28,229)</b>                                                           | <b>21,688</b>   | <b>(13,606)</b>                                                                          |
| <b>Financing activities:</b>                                                                    |                                                                           |                 |                                                                                          |

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|                                                                                            |        |       |         |
|--------------------------------------------------------------------------------------------|--------|-------|---------|
| Payment of capital lease obligations                                                       | (89)   | (10)  | (3,719) |
| Proceeds from issuance of ordinary and preferred ordinary shares,<br>net of issuance costs |        |       | 90,858  |
| Proceeds from issuance of common stock and warrants, net of<br>issuance costs              | 33,359 |       | 75,983  |
| Net proceeds from stock options and warrants exercised                                     | 163    |       | 163     |
| Payment of preferred stock dividend                                                        | (921)  | (921) | (3,065) |
| Repayment of government loan                                                               |        |       | (455)   |
| Government loan received                                                                   |        |       | 414     |

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

|                                                                                                              | <b>Nine Months Ended<br/>September 30,</b> |               | <b>Period from<br/>August 13,<br/>1996<br/>(inception) to<br/>September 30,<br/>2008</b> |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------------|------------------------------------------------------------------------------------------|
|                                                                                                              | <b>2007</b>                                | <b>2008</b>   |                                                                                          |
| Loan received from Cyclacel Group Plc                                                                        |                                            |               | 9,103                                                                                    |
| Proceeds of committable loan notes issued from shareholders                                                  |                                            |               | 8,883                                                                                    |
| Loans received from shareholders                                                                             |                                            |               | 1,645                                                                                    |
| Cash and cash equivalents assumed on stock purchase                                                          |                                            |               | 17,915                                                                                   |
| Costs associated with stock purchase                                                                         |                                            |               | (1,951)                                                                                  |
| <b>Net cash provided by (used in) financing activities</b>                                                   | <b>32,512</b>                              | <b>(931)</b>  | <b>195,774</b>                                                                           |
| Effect of exchange rate changes on cash and cash equivalents                                                 | 222                                        | (1,489)       | 4,250                                                                                    |
| Net (decrease) increase in cash and cash equivalents                                                         | (13,347)                                   | (2,775)       | 22,473                                                                                   |
| Cash and cash equivalents at beginning of period                                                             | 44,238                                     | 30,987        |                                                                                          |
| <b>Cash and cash equivalents at end of period</b>                                                            | <b>31,113</b>                              | <b>26,723</b> | <b>26,723</b>                                                                            |
| <b>Supplemental disclosure of cash flows information:</b>                                                    |                                            |               |                                                                                          |
| Cash received during the period for:                                                                         |                                            |               |                                                                                          |
| Interest                                                                                                     | 1,716                                      | 844           | 11,766                                                                                   |
| Taxes                                                                                                        |                                            | 2,113         | 14,997                                                                                   |
| Cash paid during the period for:                                                                             |                                            |               |                                                                                          |
| Interest                                                                                                     | (122)                                      | (169)         | (1,850)                                                                                  |
| 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                                                                                      |
| Issuance of other long term payable on ALIGN acquisition                                                     |                                            |               | 1,122                                                                                    |

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

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**CYCLACEL PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION**

Cyclacel Pharmaceuticals, Inc. ( Cyclacel or the Company ) is a development-stage biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Cyclacel's strategy is focused on leading edge therapeutic management of cancer patients based on a portfolio of three products marketed by its ALIGN Pharmaceuticals, LLC ( ALIGN ) subsidiary and a deep development pipeline.

As a result of the recent revised operating plan announced on September 16, 2008, the Company is focusing its clinical development priorities on:

Sapacitabine in acute myeloid leukemia or AML in the elderly;

Sapacitabine in myelodysplastic syndromes or MDS;

Sapacitabine in cutaneous T-cell lymphoma or CTCL; and

Sapacitabine in solid tumor indications

Cyclacel may continue to fund certain additional programs pending the availability of clinical data, at which time the Company will determine the feasibility of pursuing advanced development including:

Seliciclib in nasopharyngeal cancer or NPC;

Seliciclib in non small-cell lung cancer or NSCLC; and

CYC116 in patients with solid tumors

As a development stage company, 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. The Company was incorporated in the state of Delaware in 1996 and is headquartered in Berkeley Heights, New Jersey, with research facilities located in the United Kingdom.

The condensed consolidated balance sheets as of September 30, 2008, the condensed consolidated statements of operations for the three and nine months ended September 30, 2008 and 2007 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2008 and 2007, and related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2007 is derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, filed with the Securities and Exchange Commission (the SEC ). The condensed consolidated financial statements are presented on the basis of accounting principles that are generally accepted in the United States for interim financial information and in accordance with the rules and regulations of the SEC. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States for a complete set of financial statements. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the condensed consolidated balance sheet as of September 30, 2008, the results of operations for the three and nine months ended September 30, 2008 and 2007 and the consolidated statements of cash flows for the nine months ended September 30, 2008 and 2007 have been made. The interim results for the nine months ended September 30, 2008 are not necessarily indicative of the results to be expected for the year ending December 31, 2008 or for any other year. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2007, included in the Company's Annual Report on Form 10-K filed with the SEC.



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**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Consolidation***

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

***Use of Estimates***

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Cyclacel reviews its estimates on an ongoing basis. The estimates were based on historical experience and on various other assumptions that the Company believes to be reasonable under the circumstances. Actual results may differ from these estimates. Cyclacel believes the judgments and estimates required by the following accounting policies to be critical in the preparation of the Company's condensed consolidated financial statements.

***Cash and Cash Equivalents***

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

***Inventory***

Cyclacel values inventories at lower of cost or market value. The Company determines cost using the first-in, first-out method. The Company analyzes its inventory levels quarterly and writes-down inventory that becomes obsolete or that has a cost basis in excess of its expected net realizable value. Expired inventory is disposed of and the related carrying amounts are written off. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required in future periods.

***Goodwill***

Goodwill represents the difference between the purchase price and the fair value of net tangible and identifiable intangible assets acquired in a business combination. Goodwill acquired in a business combination is not amortized, but instead is tested for impairment at least annually in accordance with the provisions of Statement of Financial Accounting Standards (FAS) FAS No. 142, *Goodwill and Other Intangible Asset* (FAS 142).

To test for impairment, the Company must compare the fair value of its reporting units to their respective carrying values, including assigned goodwill. The Company has determined that it has one reportable segment with two reporting units; ALIGN and Xcyte Therapies, Inc. (Xcyte). To the extent the carrying amount of the reporting units exceeds its fair value; Cyclacel would be required to perform the second step of the impairment analysis, as this is an indication that the component of goodwill may be impaired. In this second step, Cyclacel compares the implied fair value of goodwill with its carrying amount. The implied fair value of goodwill is determined by allocating the fair value of the reporting units to all of the assets (recognized and unrecognized) and liabilities of the reporting units in a manner similar to a purchase price allocation, in accordance with FAS No. 141 *Business Combinations*. The residual fair value after this allocation represents the implied fair value of the goodwill. To the extent the implied fair value of goodwill is less than its carrying amount Cyclacel would be required to recognize an impairment loss.

The fair value of the Company's two reporting units is determined in the case of Xcyte by the fair market value of Cyclacel's outstanding common stock, preferred stock and common stock warrants and in the case of ALIGN by using the income based valuation approach with respect to projected product values.

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The Company tested goodwill for impairment for both Xcyte and ALIGN, as of September 30, 2008. The review resulted in an impairment charge of \$2.7 million for the three months ended September 30, 2008 for the Xcyte reporting unit. This was as a result of Cyclacel's market capitalization being lower than the book value of its constituent assets and liabilities as a result of Cyclacel's decreased stock price. For the three months ended September 30, 2007, there was no impairment charge required with regard to Xcyte. For the three months ended September 30, 2008 there was no impairment charge required for the ALIGN reporting unit.

### ***Intangibles***

As part of the acquisition of ALIGN, (see Note 5), the Company acquired rights to a license agreement with Sinclair Pharma PLC (Sinclair) as well as to various customer relationships. The license agreement allows Cyclacel to exclusively sell and distribute Xclair® Cream, Numoisyn Liquid and Numoisyn Lozenges in the United States. The Company amortizes the license agreement and customer relationship intangible assets over the remaining life of the contract of approximately seven years. The fair values ascribed to the license agreements and customer relationships on October 5, 2007, the acquisition date, were \$3.0 million and \$0.5 million, respectively. For the three months ended September 30, 2008, the Company amortized approximately \$0.1 million and \$17,000 for the license agreement and customer relationships, respectively. For the nine months ended September 30, 2008, the Company amortized approximately \$0.3 million and \$0.1 million for the license agreement and customer relationships, respectively. The Company expects to amortize \$0.5 million annually for these intangible assets until June 2015.

As part of the acquisition of ALIGN, the Company assumed all rights to the ALIGN trade name, as well as non-compete agreements signed between ALIGN and its senior managers and a beneficial contract pricing arrangement. The Company amortizes the fair values of these assets acquired in the ALIGN acquisition over 2 years, which represents the approximate time period that the non-compete agreements will remain in effect based on the employment contracts of the existing ALIGN management team. The fair value ascribed to the non-compete agreements, trade name and beneficial contract pricing arrangement on October 5, 2007 was \$0.4 million, \$0.1 million and \$0.5 million, respectively. During the three months ended September 30, 2008, the Company amortized approximately \$49,000 for the non-compete agreements, \$13,000 for the trade name and approximately \$59,000 for the beneficial pricing contract. During the nine months ended September 30, 2008, the Company amortized approximately \$0.1 million for the non-compete agreements, \$38,000 for the trade name and \$0.2 million for the beneficial pricing contract.

As part of the Company's annual impairment analysis during the third quarter of 2008, it was determined that the intangible assets described above, when treated as an asset group in accordance with FAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (FAS 144), were not recoverable as the sum of the undiscounted cash flows was lower than the carrying value and therefore should be impaired. Consequently the fair value of these assets was determined by using the income based valuation methodology. This resulted in the requirement to recognize an impairment charge of \$3.6 million. There will be no further amortization with respect to the intangible assets ascribed in the asset acquisition of ALIGN.

### ***Impairment of Long-lived Assets***

In accordance with the provisions of FAS 144, the Company reviews long-lived assets, including intangibles, property, plant and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Under FAS 144, impairment occurs when undiscounted estimated identifiable future cash flows expected to result from the use of the asset and its eventual dispositions are less than its carrying amount. An impairment loss, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value.

As a result of the Company announcing a restructuring plan in September 2008, the Company identified that certain research and development assets at its Cambridge, UK facility will no longer be utilized (see footnote 2 Restructuring Expenses). For the three months ended September 30, 2008, the Company recorded an asset impairment of \$0.1 million in respect to these assets and it was included as part of restructuring costs on the consolidated statement of operations in accordance with FAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (FAS 146).



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### ***Revenue Recognition***

#### ***Product sales***

The Company recognizes revenue from product sales when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the selling price is fixed and determinable; and collectability is reasonably assured.

The Company offers a general right of return on these product sales, and has considered the guidance in FAS No. 48, *Revenue Recognition When Right of Return Exists* ( FAS 48 ) and Staff Accounting Bulletin No. 104 *Revenue Recognition* ( SAB 104 ). Under these pronouncements, the Company accounts for all product sales using the sell-through method. Under the sell-through method, revenue is not recognized upon shipment of product to distributors. Instead, the Company records deferred revenue at gross invoice sales price and deferred cost of sales at the cost at which those goods were held in inventory. The Company recognizes revenue when such inventory is sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, the Company relies on third-party information, including information obtained from third-party market research data as well as from distributors with respect to their inventory levels and sell-through to customers.

#### ***Collaboration, research and development, and grant revenue***

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

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

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

### ***Clinical Trials Accounting***

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

**Table of Contents*****Research and Development Expenditures***

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

***Foreign Currency***

The results of operations for our one foreign subsidiary, located in the United Kingdom, are maintained in the local currency and translated using the average exchange rates during the period. Assets and liabilities are translated to U.S. dollars using the exchange rate in effect at the balance sheet date. The resulting translation adjustments are reflected on the consolidated balance sheet in stockholders' equity as a cumulative foreign currency translation adjustment, a component of accumulated other comprehensive income (loss). Gains and losses from foreign currency transactions are included in the accompanying consolidated statements of operations.

For the three months ended September 30, 2008, a foreign exchange loss of \$4.8 million was recorded on intercompany loans due to the strength of the US dollar against the British pound and is shown on the consolidated statement of operations under other income (expense). In prior years the foreign exchange gain or loss was shown as selling, general and administrative expense. The Company re-classified the foreign exchange loss due to the loan being of a financing nature rather than it being related to the operating activities of the business and also the magnitude of the charges. For the three months ended September 30, 2007, the Company recorded foreign exchange gain of \$0.5 million.

***Segments***

The Company is organized and managed as a single operating segment.

***Supplemental Financial Information:******Loss per Share***

Basic and diluted loss per share is computed by dividing loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted weighted average shares outstanding excludes shares underlying stock options; convertible preferred stock; make-whole dividend payments of common stock on convertible preferred stock and common stock warrants, since the effects would be anti-dilutive. Accordingly, basic and diluted loss per share is the same. Such excluded shares are summarized as follows:

|                                                                             | <b>September 30,<br/>2007</b> | <b>September 30,<br/>2008</b> |
|-----------------------------------------------------------------------------|-------------------------------|-------------------------------|
| Stock options                                                               | 1,968,915                     | 2,743,963                     |
| Convertible preferred stock                                                 | 870,980                       | 870,980                       |
| Make-whole dividend payments of common stock on convertible preferred stock | 190,608                       |                               |
| Common stock warrants                                                       | 3,634,703                     | 3,809,272                     |
| Total shares excluded from calculation                                      | 6,665,206                     | 7,424,215                     |

***Other Comprehensive Loss***

In accordance with FAS No. 130, *Reporting Comprehensive Income*, all components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments and changes in the fair value of available-for-sale securities, are reported, net of any related tax effect, to arrive at comprehensive income (loss).



**Table of Contents****Short-term Investments**

The following is a summary of short-term investments at December 31, 2007 and September 30, 2008:

|                                              | <b>December 31, 2007</b>                      |                                                 |                                                  |                             |
|----------------------------------------------|-----------------------------------------------|-------------------------------------------------|--------------------------------------------------|-----------------------------|
|                                              | <b>Gross<br/>amortized<br/>cost<br/>\$000</b> | <b>Gross<br/>unrealized<br/>gains<br/>\$000</b> | <b>Gross<br/>unrealized<br/>losses<br/>\$000</b> | <b>Fair value<br/>\$000</b> |
| Federal agency obligations & municipal bonds | 9,354                                         |                                                 |                                                  | 9,354                       |
| Corporate bonds & commercial paper           | 18,390                                        | 24                                              | (2)                                              | 18,412                      |
|                                              | 27,744                                        | 24                                              | (2)                                              | 27,766                      |

|                                              | <b>September 30, 2008</b>                     |                                                 |                                                  |                             |
|----------------------------------------------|-----------------------------------------------|-------------------------------------------------|--------------------------------------------------|-----------------------------|
|                                              | <b>Gross<br/>amortized<br/>cost<br/>\$000</b> | <b>Gross<br/>unrealized<br/>gains<br/>\$000</b> | <b>Gross<br/>unrealized<br/>losses<br/>\$000</b> | <b>Fair value<br/>\$000</b> |
| Federal agency obligations & municipal bonds | 500                                           |                                                 |                                                  | 500                         |
| Corporate bonds & commercial paper           | 6,499                                         | 3                                               | (4)                                              | 6,498                       |
|                                              | 6,999                                         | 3                                               | (4)                                              | 6,998                       |

For investments that are in an unrealized loss position, the Company has evaluated the nature of the investments, the duration of the impairments and concluded that the impairments are not other-than-temporary.

At September 30, 2008, all investments have contractual maturities due within one year. At December 31, 2007 investments of \$1.5 million had maturities greater than one year.

**Fair value measurements**

On January 1, 2008, the Company adopted FAS No. 157, *Fair Value Measurements* ( FAS 157 ), for its financial assets and liabilities. The Company's adoption of FAS 157 did not materially affect the Company's financial position, results of operations or liquidity. In accordance with FASB Staff Position No. 157-2, *Effective Date of FAS 157*, the Company elected to defer until January 1, 2009 the adoption of FAS 157 for all non-financial assets and non-financial liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis. As defined in FAS 157, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, FAS 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

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

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

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



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

Financial assets and liabilities carried at fair value as of September 30, 2008 are classified in the table below in one of the three categories described above:

|                                   | Level 1<br>\$000 | Level 2<br>\$000 | Level 3<br>\$000 | Total<br>\$000 |
|-----------------------------------|------------------|------------------|------------------|----------------|
| U.S. Government Agency Securities |                  | 500              |                  | 500            |
| Commercial Paper                  |                  | 2,991            |                  | 2,991          |
| Municipal Notes                   |                  |                  |                  |                |
| Corporate Bonds                   |                  | 3,507            |                  | 3,507          |
| Total assets at fair value        |                  | <b>6,998</b>     |                  | <b>6,998</b>   |
| Warrants                          |                  | (224)            |                  | (224)          |
| Total liabilities at fair value   |                  | <b>(224)</b>     |                  | <b>(224)</b>   |

**Prepaid expenses and other current assets:**

Prepaid expenses and other current assets consist of the following:

|                                                 | December<br>31,<br>2007 | September 30,<br>2008 |
|-------------------------------------------------|-------------------------|-----------------------|
|                                                 | (\$000s)                |                       |
| Research and development tax credit receivable  | 2,467                   | 1,644                 |
| Prepayments                                     | 1,741                   | 1,234                 |
| Other current assets                            | 603                     | 139                   |
| Total prepaid expenses and other current assets | 4,811                   | 3,017                 |

**Table of Contents****Accrued Liabilities and Other Current Liabilities:**

Accrued liabilities consist of the following:

|                                  | December<br>31,<br>2007 | September 30,<br>2008 |
|----------------------------------|-------------------------|-----------------------|
|                                  |                         | (\$000s)              |
| Accrued research and development | 3,681                   | 4,449                 |
| Other accrued liabilities        | 334                     | 1,261                 |
| Total accrued liabilities        | 4,015                   | 5,710                 |

Other current liabilities consist of the following:

|                                                | December<br>31,<br>2007 | September 30,<br>2008 |
|------------------------------------------------|-------------------------|-----------------------|
|                                                |                         | (\$000s)              |
| Payroll provision                              | 308                     | 114                   |
| Preferred stock dividends declared             | 307                     | 307                   |
| Deferred consideration payable in common stock | 250                     | 279                   |
| Other short term payables                      |                         | 585                   |
| Other current liabilities                      | 414                     | 6                     |
| Total other current liabilities                | 1,279                   | 1,291                 |

**Restructuring Expense**

The Company records costs and liabilities associated with exit and disposal activities, when certain criteria have been met in accordance with FAS 146, at fair value in the period the liability is incurred. The Company's restructuring and integration plan is subject to continued future refinement as additional information becomes available.

On September 16, 2008, the Company announced a revision of its operating plan and that it plans to concentrate its resources on the advancement of its lead drug, sapacitabine, while maintaining the Company's core competency in drug discovery and cell cycle biology. The plan reduced the workforce across all locations by 25 people. For the three months ended September 30, 2008, the Company recorded an accrual of approximately \$0.4 million for severance payments. As part of the plan the Company will vacate its laboratory facility in Cambridge, England, whose lease terminates in January 2011. For the three months ended September 30, 2008, the rent expense was \$32,000.

An asset impairment amounting to \$0.1 million was also charged to the consolidated statement of operations as a result of assets being identified that would no longer be utilized.

**3. STOCK BASED COMPENSATION**

At the Company's annual shareholder meeting on May 14, 2008, the stockholders approved and amended the number of shares reserved under the 2006 Equity Incentive Plan ( 2006 Plan ) to 5,200,000 shares of the Company's common stock (up from 3,000,000 shares). The shares reserved under the 2006 Plan have a maximum maturity of 10 years and generally vest over a four-year period from the date of grant.

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A summary of activity for the options under the Company's 2006 Plan for the nine months ended September 30, 2008 is as follows:

|                                              | Options   | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(years) | Aggregate<br>Intrinsic<br>Value<br>(in \$000s) |
|----------------------------------------------|-----------|------------------------------------------|--------------------------------------------------------------------|------------------------------------------------|
| Options outstanding at December 31, 2007     | 2,592,246 | \$ 6.39                                  | 9.1                                                                |                                                |
| Granted                                      | 325,000   | \$ 3.79                                  |                                                                    |                                                |
| Exercised                                    |           |                                          |                                                                    |                                                |
| Expired                                      |           |                                          |                                                                    |                                                |
| Cancelled / forfeited                        | (173,283) | \$ 6.03                                  |                                                                    |                                                |
| Options outstanding at September 30, 2008    | 2,743,963 | \$ 6.09                                  | 8.44                                                               |                                                |
| Unvested at September 30, 2008               | 1,531,254 | \$ 5.60                                  | 8.91                                                               |                                                |
| Vested and exercisable at September 30, 2008 | 1,212,709 | \$ 6.72                                  | 7.85                                                               |                                                |

The Company accounts for all share-based payment transactions under FASB, Statement No. 123R, *Share-Based Payment* (FAS 123R). FAS 123R requires the Company to measure all share-based payment awards, including those with employees, granted, modified, repurchased or cancelled after, or that were unvested as of, January 1, 2006 at fair value. Under FAS 123R, the fair value of stock options and other equity-based compensation must be recognized as compensation cost in the financial statements over the requisite service period of each award.

The Company used the Black-Scholes option-pricing model with the following assumptions for stock option grants to employees and directors for the nine months ended September 30, 2007 and 2008:

|                                             | For the Nine Months Ended<br>September 30, |       |        |       |
|---------------------------------------------|--------------------------------------------|-------|--------|-------|
|                                             | 2007                                       |       | 2008   |       |
| Expected term                               | 4.25                                       | 6 Yrs | 1      | 6 Yrs |
| Risk free interest rate                     | 4.25                                       | 5.07% | 2.15   | 3.76% |
| Expected volatility                         | 70                                         | 80%   | 45     | 75%   |
| Expected dividend yield over expected term  |                                            |       |        |       |
| Resulting weighted average grant fair value | \$4.05                                     |       | \$2.11 |       |

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

The forfeiture rates have been reviewed and updated to reflect a representative level of employee turnover given market conditions and the current business climate.

The expected volatility assumption was based on the historical volatility of the Company's common stock since the merger with Xcyte on March 27, 2006 together with an analysis of the historical volatilities of a peer group of similar biotechnology companies.

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, the Company uses 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) the Company has never declared or paid any dividends and (b) does not currently anticipate paying any cash dividends on its outstanding shares of common stock in the foreseeable future.

There were no exercises of stock options during the three and nine months ended September 30, 2008. The Company received \$0.2 million from the exercise of 25,508 stock options during the second quarter of 2007. As the Company presently has tax loss carry forwards from prior periods and expects to incur tax losses in 2008, the Company is not able to benefit from the deduction for exercised stock options in the current reporting period.

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Cash used to settle equity instruments granted under share-based payment arrangements amounted to \$0 during all periods presented.

In accordance with the terms of a retirement agreement with a former employee, the Company agreed to extend the period during which he would be entitled to exercise vested stock options to purchase Cyclacel's common stock from 30 (thirty) days following the effective date of his retirement, January 8, 2008, to 36 (thirty six) months following such effective date. The Company recorded a one time compensation expense related to the modification of the exercise period of \$0.1 million for the three months ended March 31, 2008.

The following table summarizes the components of the Company's stock based compensation for the three and nine months ended September 30, 2007 and 2008:

|                                                    | <b>For the Three Months<br/>Ended<br/>September 30,</b> |             | <b>For the Nine Months<br/>Ended<br/>September 30,</b> |             |
|----------------------------------------------------|---------------------------------------------------------|-------------|--------------------------------------------------------|-------------|
|                                                    | <b>2007</b>                                             | <b>2008</b> | <b>2007</b>                                            | <b>2008</b> |
|                                                    | <b>(\$000s)</b>                                         |             | <b>(\$000s)</b>                                        |             |
| Research and development                           | 120                                                     | 127         | 622                                                    | 548         |
| General and administrative                         | 199                                                     | 127         | 713                                                    | 654         |
| Stock-based compensation costs before income taxes | 319                                                     | 254         | 1,335                                                  | 1,202       |

**4. COMMITMENTS AND CONTINGENCIES**

In 2005, the Company recorded an accrued restructuring liability associated with abandoning the facility in Bothell, Washington. The lease term on this space expires December 2010. The Bothell restructuring liability was computed as the present value of the difference between the remaining lease payments due less the estimate of net sublease income and expenses. The accrual balance was adjusted in 2006 to reflect a change in estimate due to continued deterioration in the local real estate market. As of September 30, 2008, the Bothell accrued restructuring liability was \$2.3 million. This represents the Company's best estimate of the fair value of the liability. 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 \$0.2 million over the remaining term of the lease.

As a result of the Company announcing a restructuring plan in September 2008 it created an additional restructuring accrual of \$0.4 million was recorded in connection with the severance payments that it made during October 2008. (see Restructuring Expense under footnote 2) The total restructuring accrual can be summarized at September 30, 2008 as follows:

|                                              | <b>\$000s</b> |
|----------------------------------------------|---------------|
| Restructuring provision at June 30, 2008     | 2,554         |
| Restructuring expense for the current period | 383           |
| Payments made in the period                  | (227)         |
| As of September 30, 2008                     | 2,710         |

|                                                  |       |
|--------------------------------------------------|-------|
| Less: amounts due within one year                | 1,349 |
| Other accrued restructuring charges    long term | 1,361 |

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In connection with the abandonment of the Bothell facility and the related 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. As a result of the potential State sales tax assessment, the Company recorded a liability of \$0.3 million during 2006. There has been no change in the Company's assessment of the liability during the three months ended September 30, 2008.

**5. ACQUISITIONS****Acquisition of ALIGN**

On October 5, 2007, the Company purchased certain net assets of ALIGN Pharmaceuticals, LLC or ALIGN. As part of the asset purchase, the Company acquired the sellers' exclusive rights to sell and distribute three products in the United States used primarily to manage the effects of radiation or chemotherapy in cancer patients: Xclair® Cream, Numoisyn Liquid and Numoisyn Lozenges. The acquired business provides Cyclacel with the foundation to build a commercial organization focused on cancer that is complementary to Cyclacel's oncology/hematology products in development and is part of Cyclacel's strategy to build a diversified biopharmaceutical business.

Under the terms of the asset purchase agreement, the Company (i) paid approximately \$3.3 million in cash to the sellers at closing, plus approximately \$0.5 million to be used to pay certain creditors of the sellers, and (ii) agreed to issue up to a maximum aggregate of 184,176 shares of the Company's common stock, or the Stock Consideration, as consideration for the asset purchase. 46,044 shares of the Stock Consideration are issuable on the first anniversary of the closing date, and the balance is issuable in two tranches upon achievement of certain operational and financial milestones (in all cases, subject to satisfaction of any outstanding indemnification obligations of the sellers). The Company has already determined that 46,044 shares of the Stock Consideration will not be issued due to the seller's failure to achieve the first of the two milestones. The Company is reviewing certain indemnity issues which may be satisfied pursuant to the terms of the asset purchase agreement. The final 92,088 shares of the Stock Consideration is issuable if the sellers meet certain financial milestones as of December 31, 2008. The Company is also committed, as part of securing long term supply arrangements, to make future payments of approximately \$0.6 million in 2009 and \$0.7 million in 2010. The present value of these commitments has been reported as other short term payables and other long term payables on the condensed consolidated balance sheets as of September 30, 2008.

The transaction was accounted for as a business combination and the consolidated results of operations of Cyclacel include the results of operations of ALIGN from October 5, 2007. The assets and certain agreed liabilities of ALIGN have been recorded, as of the closing date, at their estimated fair values.

*Acquisition Purchase Price*

The purchase price paid to acquire the Sellers' assets was calculated as follows (in thousands):

|                      |    |       |
|----------------------|----|-------|
| Cash and equity      | \$ | 3,571 |
| Acquisition costs    |    | 432   |
| Total purchase price | \$ | 4,003 |

**Table of Contents***Acquisition Purchase Price Allocation*

As part of the acquisition, the following net assets were acquired (in thousands):

|                               |    |         |
|-------------------------------|----|---------|
| Current assets                | \$ | 199     |
| Property, plant and equipment |    | 10      |
| Intangible assets             |    | 4,495   |
| Current liabilities           |    | (1,409) |
| Non-current liabilities       |    | (1,122) |
| Goodwill                      |    | 1,830   |
|                               | \$ | 4,003   |

*Pro Forma Results of Operations*

The results of operations of ALIGN are included in Cyclacel's condensed consolidated financial statements from the date of the business combination transaction as of October 5, 2007. 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 January 1, 2007. 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.

|                                              | <b>For the Three<br/>Months Ended<br/>September 30,<br/>2007<br/>(000s)</b> | <b>For the Nine<br/>Months Ended<br/>September 30,<br/>2007<br/>(000s)</b> |
|----------------------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Revenue                                      | 218                                                                         | 754                                                                        |
| Loss before taxes                            | (5,463)                                                                     | (16,620)                                                                   |
| Net loss applicable to ordinary shareholders | (5,030)                                                                     | (15,071)                                                                   |
| Net loss per share-basic and diluted         | \$ (0.25)                                                                   | \$ (0.77)                                                                  |
| Weighted average shares                      | 20,433,129                                                                  | 19,685,457                                                                 |

*Acquisition of Xcyte Therapies Inc.*

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" ). For more information please see the Company's Annual Report on Form 10-K for the year ended December 31, 2006 as filed with the SEC.

**6. STOCKHOLDERS' EQUITY***Preferred stock*

On November 3, 2004, the Company completed a public offering of 2,990,000 shares of its 6% convertible exchangeable preferred stock (the "Preferred Stock" ) at \$10.00 per share, including the shares sold to the underwriters pursuant to the over-allotment option granted in connection with the offering. Net proceeds from the offering, after deducting underwriting discounts and offering-related expenses, totaled \$27.5 million.

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Dividends on the Preferred Stock are cumulative from the date of original issue at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of February, May, August and November, commencing February 1, 2005. Any dividends must be declared by the Company's board of directors and must come from funds that are legally available for dividend payments. The Preferred Stock has a liquidation preference of \$10 per share, plus accrued and unpaid dividends. In December 2007 as well as April and July 2008 the Company's Board of Directors declared quarterly dividends in the amount of \$0.15 per share of Preferred Stock, which were paid on the first business day in February, May and August 2008, respectively. Each quarterly dividend distribution totaled \$0.3 million and was paid to holders of record as of the close of business on January 18, April 18, and July 8, 2008 respectively. On September 4, 2008 a dividend was declared and subsequently paid on October 31, 2008.

The Preferred Stock is convertible at the option of the holder at any time into the Company's common stock at a conversion rate of approximately 0.42553 shares of common stock for each share of Preferred Stock, based on a conversion price of approximately \$23.50. The Company has reserved 870,980 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding as of September 30, 2008. In each of the three month periods ended September 30, 2007 and 2008, no shares of preferred stock were converted into common stock. The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded \$35.30, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion. The Company and the holders elected not to automatically convert some or all of the Preferred Stock into common stock prior to November 3, 2007. If they had done so, the Company would have made an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through November 3, 2007, less any dividends already paid on the Preferred Stock. This additional payment would have been payable in cash or, at the Company's option, in shares of the Company's common stock, or a combination of cash and shares of common stock. As of September 30, 2008, the Company issued 81,927 shares of common stock to converting holders in satisfaction of this additional payment. During the three months ended September 30, 2008, no shares of the Company's common stock were issued.

In accordance with FASB 133, *Accounting for Derivative Instruments* ( FAS 133 ), the Company was required to separate and account for, as an embedded derivative, the dividend make-whole payment feature of the Preferred Stock. As an embedded derivative instrument, the dividend make-whole payment feature was measured at fair value and reflected as a liability. Changes in the fair value of the derivative were recognized in the condensed consolidated statement of operations as a component of other income (expense). The derivative liability was reduced to \$0 as of November 2, 2007, the last date of possible conversion. During the three and nine months ended September 30, 2007, the Company recorded a charge of \$19,000 and \$0.1 million, respectively, on the consolidated statement of operations as other expense.

The Company may elect to redeem the Preferred Stock at declining redemption prices on or after November 6, 2007. The Preferred Stock is exchangeable, in whole but not in part, at the option of the Company on any dividend payment date beginning on November 1, 2005 (the Exchange Date ) for the Company's 6% Convertible Subordinated Debentures ( Debentures ) at the rate of \$10 principal amount of Debentures for each share of Preferred Stock. The Debentures, if issued, will mature 25 years after the Exchange Date and have terms substantially similar to those of the Preferred Stock.

In order to conserve cash, the company may elect not to pay the quarterly preference dividend relating to the preference stock in future periods. The dividend would continue to be accrued within the financial statements but would result in annualized cash savings of approximately \$1.2 million. If the Company implemented this course of action then the preference stock holders would have the right to appoint two non executives to the Board after non payment of dividends in two consecutive quarters.

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



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### ***Common Stock and warrants***

#### ***February 2007 Registered Direct Offering***

On February 16, 2007, the Company raised \$36.0 million in gross proceeds, before deducting placement agent fees and offering expenses of \$2.6 million, in a registered direct offering through the sale of shares of the Company's common stock and warrants. The Company entered into subscription agreements with these investors pursuant to which it sold approximately 4.2 million units, each unit consisting of one share of common stock and a seven-year warrant to purchase 0.25 shares of common stock, at a purchase price of \$8.47125 per unit. The purchase price for the shares and the exercise price for the warrants was \$8.44 per share, the closing bid price for the Company's common stock on February 12, 2007. Investors paid \$0.125 per warrant. The Company issued 4,249,668 shares of common stock and warrants to purchase 1,062,412 shares of common stock.

The warrants issued to the investors are being accounted for as a liability in accordance with Emerging Issues Task Force (EITF) 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (EITF 00-19). At the date of the transaction, the fair value of the warrants of \$6.8 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 4.58%, expected volatility 85%, expected dividend yield 0%, and a remaining contractual life of 6.88 years. The value of the warrant shares is being marked to market each reporting period as a derivative gain or loss on the consolidated statement of operations until exercised or expiration. At September 30, 2008, the fair value of the warrants was \$0.2 million. For the three months ended September 30, 2007 and 2008, the Company recognized the change in the value of warrants of approximately \$1.0 million and \$0.4 million, respectively, as a gain on the consolidated statement of operations. For the nine months ended September 30, 2007 and 2008, the Company recognized the change in the value of warrants of approximately \$2.8 million and \$3.3 million, respectively, as a gain on the consolidated statement of operations. Since the date of the transaction, the Company recognized the change in the value of warrants of approximately \$6.5 million.

#### ***December 2007 Committed Equity Financing Facility***

On December 10, 2007, Cyclacel entered into a Committed Equity Financing Facility or CEFF, with Kingsbridge Capital Limited or Kingsbridge, a private investment group, in which Kingsbridge committed to purchase the lesser of 4,084,590 shares of common stock or \$60 million of common stock from Cyclacel capital during the next three years. Under the terms of the agreement, Cyclacel will determine the exact timing and amount of any CEFF financings, subject to certain conditions. All amounts drawn down under the CEFF will be settled via the issuance of registered shares of Cyclacel's common stock. Cyclacel may access capital under the CEFF in tranches of either (a) 2% of Cyclacel's market capitalization at the time of the draw down or (b) the lesser of (i) 3% of Cyclacel's market capitalization at the time of the draw down and (ii) an alternative draw down amount based on the product of (A) the average trading volume of the 30-day trading period preceding the draw down excluding the five highest and five lowest trading days during such period, (B) the volume-weighted average trading price (VWAP) on the trading day prior to the notice of draw down, (C) the number of days during the draw down period and (D) 85%, subject to certain conditions. Each tranche will be issued and priced over an eight-day pricing period. Kingsbridge will purchase shares of common stock pursuant to the CEFF at discounts ranging from 6% to 10% depending on the average market price of the common stock during the eight-day pricing period, provided that the minimum acceptable purchase price for any shares to be issued to Kingsbridge during the eight-day period is determined by the higher of \$2.50 or 90% of Cyclacel's common stock closing price the day before the commencement of each draw down. Cyclacel currently is unable to draw down on the CEFF because the Company's common stock is trading below the \$2.50 per share floor price set forth in the CEFF.

In connection with the CEFF, Cyclacel issued a warrant to Kingsbridge to purchase up to 175,000 shares of common stock at an exercise price of \$7.17 per share which represents a 30% premium over the average of the closing bid prices of Cyclacel's common stock during the 5 trading days preceding the signing of the agreement. The warrant will become exercisable six months from the date of the agreement and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. As of September 30, 2008, the warrants issued to the investors have been classified as equity in accordance with EITF 00-19. The transaction date fair value of the warrants of \$0.6 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions:

risk free interest rate 3.605%, expected volatility 70%, expected dividend yield 0%, and a remaining contractual life of 5.5 years.

**Table of Contents***Common Stock Warrants*

The following table summarizes information about warrants outstanding at September 30, 2008:

|                                  | <b>Expiration</b> | <b>Common<br/>Shares</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> |
|----------------------------------|-------------------|--------------------------|----------------------------------------------------|
| <b>Issued in Connection With</b> | <b>Date</b>       | <b>Issuable</b>          |                                                    |
| Acquisition of Xcyte March 2006  | 2009              | 431                      | 15.29                                              |
| March 2006 stock issuance        | 2014              | 2,571,429                | 7.00                                               |
| February 2007 stock issuance     | 2014              | 1,062,412                | 8.44                                               |
| December 2007 CEFF               | 2012              | 175,000                  | 7.17                                               |
| Total                            |                   | 3,809,272                | \$ 7.41                                            |

***Exercise of Stock Options***

There were no stock option exercises during the nine months ended September 30, 2008. During the three months ended June 30, 2007, 25,508 shares of the Company's common stock were issued from the exercise of stock options resulting in proceeds of \$0.2 million.

**7. INCOME TAXES**

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

The Company applies FASB Interpretation No. 48 *Accounting for Uncertainty in Income Taxes* (FIN 48) in accounting for uncertainty in income taxes recognized in a company's financial statements. FIN 48 prescribes a minimum probability threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on de-recognition, measurement, classification, interest and penalties, accounting in interim periods as well as disclosure and transition.

Credit is taken in the accounting period for research and development tax credits, which will be claimed from H. M. Revenue & Customs, the United Kingdom's taxation and customs authority, in respect of qualifying research and development costs incurred in the same accounting period.

**8. RECENT ACCOUNTING PRONOUNCEMENTS**

In February 2007, the FASB issued FAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (FAS 159) which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. FAS 159 was effective on January 1, 2008 and the adoption of FAS 159 did not have a material impact on the Company's condensed consolidated financial statements.

In December 2007, FASB ratified the consensus reached by Emerging Issues Task Force on (EITF) Issue 07-1, *Accounting for Collaborative Arrangements* or (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable Generally Accepted Accounting Principles (GAAP) or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9,

Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products). EITF 07-1 was effective on January 1, 2008. The adoption of EITF 07-1 did not have a material impact on the Company's consolidated financial statements.



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In November 2007, the FASB issued FAS No. 141 (revised 2007), *Business Combination* ( FAS 141(R) ) and FAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* ( FAS 160 ). FAS 141(R) will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. FAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. FAS 141(R) and FAS 160 are effective for both public and private companies for fiscal years beginning on or after December 15, 2008 (January 1, 2009 for the Company). FAS 141(R) will be applied prospectively. FAS 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements of FAS 160 will be applied prospectively. Early adoption is prohibited for both standards. The Company believes that the adoption of FAS 141(R) and FAS 160 will not have a material impact on its consolidated financial statements.

In June 2007, FASB ratified the consensus reached by the EITF on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* or ( EITF 07-3 ). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 is effective for the Company beginning on January 1, 2008 and must be adopted on a prospective basis. Given a review of our current contracts and arrangements the adoption of EITF 07-3 did not have a material effect on the Company's consolidated financial statements.

On March 19, 2008, FASB issued FAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities* ( FAS 161 ). FAS 161 requires enhanced financial disclosure about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. FAS 161 achieves these improvements by requiring disclosure of the fair values of derivative instruments and their gains and losses in a tabular format. It also provides more information about an entity's liquidity by requiring disclosure of derivative features that are credit risk related. Finally, it requires cross-referencing within footnotes to enable financial statement users to locate important information about derivative instruments. FAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. The Company believes that the adoption of FAS 161 will not have a material impact on its consolidated financial statements.

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

#### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

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

*Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward looking statements due to a number of factors, including those set forth in Part I, Item 1A Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2007, as updated and supplemented by Part II, Item 1A Risk Factors of this Quarterly Report on Form 10-Q, and elsewhere in this report. These factors as well as other cautionary statements made in this Quarterly Report on Form 10-Q, should be read and understood as being applicable to all related forward-looking statements wherever they appear herein. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our judgment as of the date hereof. We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements. In this report, Cyclacel, the Company, we, us, and our refer to Cyclacel Pharmaceuticals, Inc.*

#### **Overview**

We are a development stage biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Our strategy is focused on leading edge therapeutic management of cancer patients based on a portfolio of three products marketed by ALIGN Pharmaceuticals, LLC ALIGN, our subsidiary, and a deep development pipeline.

We market directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn™ Liquid and Numoisyn™ Lozenges for xerostomia.

As a result of the recent revised operating plan announced on September 16, 2008, we are focusing its clinical development priorities on:

Sapacitabine in acute myeloid leukemia in the elderly or AML;

Sapacitabine in myelodysplastic syndromes or MDS;

Sapacitabine in cutaneous T-cell lymphoma or CTCL; and

Sapacitabine in solid tumor indications

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Cyclacel may continue to fund certain additional programs pending the availability of clinical data, at which time the Company will determine the feasibility of pursuing advanced development including:

Seliciclib in nasopharyngeal cancer or NPC;

Seliciclib in non small-cell lung cancer or NSCLC; and

CYC116 in patients with solid tumors

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 the quality of life and improving survival rates of cancer patients. We are generating several families of anticancer drugs that act on the cell cycle including nucleoside analogues, cyclin dependent kinase or CDK inhibitors and Aurora kinase/Vascular Endothelial Growth Factor Receptor 2 or AK/VEGFR2 inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitor and AK inhibitor drugs, we believe that our drug candidates are differentiated in that they are orally available and have unique target profiles or mechanisms of action. For example, we believe that our sapacitabine is the only orally available nucleoside analogue presently being tested in Phase 2 trials in AML, seliciclib is the only orally available CDK inhibitor currently in Phase 2 trials and CYC116 is the only dual Aurora A and Aurora B kinase inhibitor in clinical trials that also interacts with VEGFR2 and has anti-angiogenic activity.

Our corporate headquarters is located in Berkeley Heights, New Jersey, with research facilities located in the United Kingdom. From our inception in 1996 through September 30, 2008, we have devoted substantially all our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of September 30, 2008, our accumulated deficit during the development stage was \$194.8 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical, pre-clinical and other drugs currently in development and build our commercialization capability. Our operating expenses are primarily comprised of research and development expenses and selling, general and administrative costs.

On September 16, 2008, the Company announced a revision of its operating plan to concentrate its resources on the advancement of its lead drug, sapacitabine, while maintaining the Company's core competency in drug discovery and cell cycle biology. The plan reduced the workforce across all locations by 25 people. For the three months ended September 30, 2008, the Company recorded a restructuring charge of \$0.5 million.

As of September 30, 2008, we have not generated significant product revenue but have financed our operations and internal growth through private placements, licensing revenue, interest on investments, government grants and research and development tax credits. Our revenue has consisted of collaboration and grant revenue. Beginning in 2008, our revenue now includes product sales following the ALIGN acquisition.

***Acquisition of ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC***

On October 5, 2007, the Company purchased certain net assets of ALIGN Pharmaceuticals, LLC or ALIGN. As part of the asset purchase, the Company acquired the sellers' exclusive rights to sell and distribute three products in the United States used primarily to manage the effects of radiation or chemotherapy in cancer patients: Xclair® Cream, Numoisyn Liquid and Numoisyn Lozenges. The acquired business provides Cyclacel with the foundation to build a commercial organization focused on cancer that is complementary to Cyclacel's oncology/hematology products in development and is part of Cyclacel's strategy to build a diversified biopharmaceutical business.

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Under the terms of the asset purchase agreement, the Company (i) paid approximately \$3.3 million in cash to the sellers at closing, plus approximately \$0.5 million to be used to pay certain creditors of the sellers, and (ii) agreed to issue up to a maximum aggregate of 184,176 shares of the Company's common stock, or the Stock Consideration, as consideration for the asset purchase. 46,044 shares of the Stock Consideration are issuable on the first anniversary of the closing date, and the balance is issuable in two tranches upon achievement of certain operational and financial milestones (in all cases, subject to satisfaction of any outstanding indemnification obligations of the sellers). The Company has already determined that 46,044 shares of the Stock Consideration will not be issued due to the seller's failure to achieve the first of the two milestones. The Company is reviewing certain indemnity issues which may be satisfied pursuant to the terms of the asset purchase agreement. The final 92,088 shares of the Stock Consideration is issuable if the sellers meet certain financial milestones as of December 31, 2008. The Company is also committed, as part of securing long term supply arrangements, to make future payments of approximately \$0.6 million in 2009 and \$0.7 million in 2010. The present value of these commitments has been reported as other short term payables and other long term payables on the condensed consolidated balance sheets As of September 30, 2008.

**Results of Operations**

The results of operations and balance sheet data for the three months ended September 30, 2008 reflect the operations of the Company and its subsidiary companies, including ALIGN. However, the results of operations for the comparable periods in 2007 do not reflect the results of ALIGN and, therefore, may not be comparable to the results of the current period.

***Three Months Ended September 30, 2007 and 2008******Revenues***

The following table summarizes the components of our revenues for the three months ended September 30, 2007 and 2008:

|                 | <b>Three Months Ended September 30,</b> |                 |                   |                   |
|-----------------|-----------------------------------------|-----------------|-------------------|-------------------|
|                 | <b>2007</b>                             | <b>2008</b>     | <b>Difference</b> | <b>Difference</b> |
|                 |                                         | <b>(\$000s)</b> |                   | <b>%</b>          |
| Product revenue |                                         | 257             | 257               | 100               |
| Grant revenue   | 33                                      | 12              | (21)              | (64)              |
| Total revenue   | 33                                      | 269             | 236               | 715               |

Product revenue is derived as a result of the asset acquisition of ALIGN on October 5, 2007. During the three months ended September 30, 2008, we recorded sales of \$0.3 million.

Grant revenue is recognized as we incur and pay for qualifying costs and services under the applicable grant. Grant revenue is primarily derived from various United Kingdom government grant awards.

***Cost of goods sold***

|                    | <b>Three Months Ended September 30,</b> |                 |                   |                   |
|--------------------|-----------------------------------------|-----------------|-------------------|-------------------|
|                    | <b>2007</b>                             | <b>2008</b>     | <b>Difference</b> | <b>Difference</b> |
|                    |                                         | <b>(\$000s)</b> |                   | <b>%</b>          |
| Cost of goods sold |                                         | 120             | 120               | 100               |

Total cost of sales represented 47% of product revenue for the three months ended September 30, 2008.

During the three months ended September 30, 2008, we recorded cost of goods sold of \$0.1 million related to the sale of the ALIGN products.

**Table of Contents*****Research and development expenses***

To date, we have 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 sapacitabine, seliciclib and CYC116, to advance product candidates through 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. Research and development expenses primarily include:

payroll and related-expense, including consultants and contract research;

clinical trial and regulator-related costs;

pre-clinical studies;

screening and identification of drug candidates;

laboratory supplies and materials;

technology license costs;

rent and facility expenses for our laboratories; and

scientific consulting fees.

The following table provides information with respect to our research and development expenditure for the three months ended September 30, 2007 and 2008:

|                                         | <b>Three Months Ended September 30,</b> |                 |                   |                   |
|-----------------------------------------|-----------------------------------------|-----------------|-------------------|-------------------|
|                                         | <b>2007</b>                             | <b>2008</b>     | <b>Difference</b> | <b>Difference</b> |
|                                         |                                         | <b>(\$000s)</b> |                   | <b>%</b>          |
| Sapacitabine                            | 477                                     | 1,299           | 822               | 172               |
| Seliciclib                              | 758                                     | 797             | 39                | 5                 |
| CYC116                                  | 672                                     | 183             | (489)             | (73)              |
| Other research and development costs    | 2,542                                   | 1,751           | (791)             | (31)              |
| Total research and development expenses | 4,449                                   | 4,030           | (419)             | (9)               |

Total research and development expenses represented 64% and 28% of our operating expenses for the three months ended September 30, 2007 and 2008, respectively.

Research and development expenditure decreased \$0.4 million from \$4.4 million for the three month period ended September 30, 2007 to \$4.0 million for the three month period ended September 30, 2008. Sapacitabine costs increased by \$0.8 million primarily due to the commencement of a Phase 2 trial in elderly AML in December 2007 and costs related to pre-clinical and product scale-up costs. This was further offset by a reduction of \$0.5 million in the CYC116 program due to re-formulation of the drug as well as a reduction in other programs in order to conserve cash.

***The future***

We plan to invest in our research and development programs to further enhance our clinical and regulatory capabilities to allow us to advance the development of our drug candidates. In August 2008, we announced the results of the Phase 2 trial of seliciclib in the APPRAISE study. We do not expect to incur additional expenses after the last enrolled patient completes follow-up according to the study protocol other than the normal costs associated with preparing the final study reports. In September 2008, we announced a revision of our operating plan and we plan to concentrate on

the advancement of our lead drug sapacitabine and in doing so reduce our research and development costs and conserve our cash.

**Table of Contents*****Selling, general and administrative expenses***

Selling, general and administrative expenses include costs for sales and marketing and administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the selling, general and administrative expenses for the three months ended September 30, 2007 and 2008:

|                                                    | <b>Three Months Ended September 30,</b> |                 |                   |                   |
|----------------------------------------------------|-----------------------------------------|-----------------|-------------------|-------------------|
|                                                    | <b>2007</b>                             | <b>2008</b>     | <b>Difference</b> | <b>Difference</b> |
|                                                    |                                         | <b>(\$000s)</b> |                   | <b>%</b>          |
| Total selling, general and administrative expenses | 2,523                                   | 3,218           | 695               | 28                |

Total selling, general and administration expenses represented 36% and 23% of our operating expenses for the three months ended September 30, 2007 and 2008, respectively.

Our selling, general and administrative expenditure increased by \$0.7 million to \$3.2 million for the three months ended September 30, 2008 from \$2.5 million for the three months ended September 30, 2007. The increase of \$0.7 million in expenses was primarily attributable to \$0.7 million of ALIGN related costs maintaining our sales force and marketing efforts as well as a \$0.2 million charge on the amortization of intangibles.

***The future***

Following the acquisition of ALIGN, we expect to incur additional costs in support of developing ALIGN's commercial operations. Additionally, we expect that our selling, general and administrative expenses will continue to increase in subsequent periods due to supporting these sales and marketing requirements and the added costs of ensuring the ALIGN business complies with the requirements of the Sarbanes-Oxley Act of 2002.

***Goodwill and intangible asset impairment***

In accordance with FAS 142, we recorded an impairment charge related to the goodwill acquired in the Xcyte transaction of approximately \$2.7 million during the three months ended September 30, 2008 as a result of our market capitalization being lower than the book value of its constituent assets and liabilities as a result of our reduced common stock price. In accordance with FAS No. 144, we recorded an impairment charge related to the intangible assets ascribed in the ALIGN transaction of approximately \$3.6 million during the three months ended September 30, 2008 as a result of the sum of the undiscounted cash flows are less than the carrying amount of the intangible assets on September 30, 2008.

***Restructuring expense***

As of September 30, 2008, the restructuring liability associated with exiting the Bothell facility was \$2.3 million accounting for the estimated fair value of the remaining lease payments, net of estimated sub-lease income. The restructuring liability is subject to a variety of assumptions and estimates. We review these assumptions and estimates on a quarterly basis and will adjust the accrual if necessary. There was no change in the estimate for the three months ended September 30, 2008.

For the three months ended September 30, 2007 and 2008, we recorded accretion expense associated with the Bothell restructuring lease of \$0.1 million on the consolidated statement of operations as interest expense. A further \$0.2 million of accretion expense will be recognized over the remaining life of the lease to December 2010.

In September 2008, we announced a revision of our operating plan that concentrates our resources on the advancement of our lead drug, sapacitabine, while maintaining our core competency in drug discovery and cell cycle biology. The plan reduced the workforce across all locations by 25 people. We recorded an estimated \$0.4 million charge for severance payments and \$0.1 million accelerated depreciation charge for assets that will no longer be used during the three months ended September 30, 2008.

**Table of Contents*****Other income (expense)***

Other income (expense) is comprised of the change in valuation of the derivative, change in value of liability classified warrants, foreign exchange gains and losses, interest income and interest expense. The following table summarizes the other income (expense) for the three months ended September 30, 2007 and 2008:

|                                   | <b>Three Months Ended September 30,</b> |                 |                   |                   |
|-----------------------------------|-----------------------------------------|-----------------|-------------------|-------------------|
|                                   | <b>2007</b>                             | <b>2008</b>     | <b>Difference</b> | <b>Difference</b> |
|                                   |                                         | <b>(\$000s)</b> |                   | <b>%</b>          |
| Change in valuation of derivative | (19)                                    |                 | 19                | 100               |
| Change in valuation of warrants   | 951                                     | 432             | (519)             | (55)              |
| Foreign exchange gains/(losses)   | 459                                     | (4,776)         | (5,235)           | (1,141)           |
| Interest income                   | 955                                     | 287             | (668)             | (70)              |
| Interest expense                  | (54)                                    | (69)            | (15)              | (28)              |
| Total other income (expense)      | 2,292                                   | (4,126)         | (6,418)           | (280)             |

On November 3, 2007, the embedded derivative associated with the dividend make-whole payment expired reducing the liability to \$0 and thus no further marked to market adjustments will be made with regard to this embedded derivative. For the three months ended September 30, 2007, the derivative valuation expense was \$19,000.

The change in valuation of warrants relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007. The warrants issued to the investors meet the requirements of and are being accounted for as a liability in accordance with EITF 00-19. The value of the warrants is being marked to market each reporting period as a derivative gain or loss until exercised or expiration. For the three months ended September 30, 2007 and 2008, we recognized the change in the value of warrants of approximately \$1.0 million and \$0.4 million, respectively, as other income in the consolidated statement of operations.

For the three months ended September 30, 2008, we recorded a foreign exchange loss of \$4.8 million on our intercompany loans due to the strength of the US dollar against the British pound. This is shown on the consolidated statement of operations as a separate line item called foreign exchange gains/ (losses) within other income (expense) and re-classified from selling, general and administrative as the underlying loan activity is of a financing nature rather than related to the operating activities of the business and also owing to its magnitude. The comparative figures have also been re-classified and for the three months to September 30, 2007 there was a foreign exchange gain of \$0.5 million.

Interest income decreased by \$0.7 million from \$1.0 million for three months ended September 30, 2007 to \$0.3 million for the three months ended September 30, 2008. The decrease is primarily attributable to lower average balances of cash and cash equivalents and short-term investments in 2008 as compared to 2007.

Interest expense increased by \$15,000 to \$0.1 million for the three months ended September 30, 2008 from \$54,000 for the three months ended September 30, 2007. During the three months ended September 30, 2007 and 2008 interest expenses included accretion expenses associated with the Bothell lease restructuring provision. During the three months ended September 30, 2008, there was also interest associated with the deferred consideration and notes payable in relation to the acquisition of ALIGN on October 5, 2007.

***The future***

The valuation of the liability-classified warrants will continue to be re-measured at the end of each reporting period. The valuation of the warrants are dependent upon many factors including estimated market volatility and stock price, and may fluctuate significantly and could have a significant impact on our consolidated statement of operations. We will also continue to be subject to foreign currency movements as a result of our research activities within the United Kingdom.



**Table of Contents*****Income tax benefit***

Credit is taken for research and development tax credits, which are claimed from the United Kingdom's revenue and customs authority, or HMRC, in respect of qualifying research and development costs incurred.

The following table summarizes research and development tax credits for the three months ended September 30, 2007 and 2008:

|                          | <b>2007</b> | <b>Three Months Ended September 30,<br/>2008<br/>(\$000s)</b> | <b>Difference</b> | <b>Difference<br/>%</b> |
|--------------------------|-------------|---------------------------------------------------------------|-------------------|-------------------------|
| Total income tax benefit | 433         | 411                                                           | (22)              | (5)                     |

Research and development tax credits recoverable decreased by \$22,000 from \$0.43 million for three months ended September 30, 2007 to \$0.41 million for the three months ended September 30, 2008. This decrease was a reflection of decreased income taxes available for recovery as a consequence of lower eligible research and development payroll expenses in 2008.

***The future***

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so.

***Nine Months Ended September 30, 2007 and 2008******Revenues***

The following table summarizes the components of our revenues for the nine months ended September 30, 2007 and 2008:

|                                                    | <b>2007</b> | <b>Nine Months Ended September 30,<br/>2008<br/>(\$000s)</b> | <b>Difference</b> | <b>Difference<br/>%</b> |
|----------------------------------------------------|-------------|--------------------------------------------------------------|-------------------|-------------------------|
| Collaboration and research and development revenue | 10          |                                                              | (10)              | (100)                   |
| Product revenue                                    |             | 590                                                          | 590               | 100                     |
| Grant revenue                                      | 107         | 36                                                           | (71)              | (66)                    |
| Total revenue                                      | 117         | 626                                                          | 509               | 435                     |

Collaboration and research and development revenue was derived from several agreements under which the Company provides compounds for evaluation for an agreed consideration.

Grant revenue is recognized as we incur and pay for qualifying costs and services under the applicable grant. Grant revenue is primarily derived from various United Kingdom government grant awards.

Product revenue is derived as a result of the asset acquisition of ALIGN on October 5, 2007. During the nine months ended September 30, 2008, we recorded sales of \$0.6 million.

***Cost of goods sold***

|                    | <b>2007</b> | <b>Nine Months Ended September 30,<br/>2008<br/>(\$000s)</b> | <b>Difference</b> | <b>Difference<br/>%</b> |
|--------------------|-------------|--------------------------------------------------------------|-------------------|-------------------------|
| Cost of goods sold |             | 315                                                          | 315               | 100                     |

Total cost of sales represented 53% of product revenue for the nine months ended September 30, 2008.

During the nine months ended September 30, 2008, we recorded cost of goods sold of \$0.3 million related to the sale of ALIGN products.



**Table of Contents*****Research and development expenses***

The following table provides information with respect to our research and development expenditure for the nine months ended September 30, 2007 and 2008:

|                                         | 2007   | Nine Months Ended September 30,<br>2008<br>(\$000s) | Difference | Difference<br>% |
|-----------------------------------------|--------|-----------------------------------------------------|------------|-----------------|
| Sapacitabine                            | 1,862  | 4,940                                               | 3,078      | 165             |
| Seliciclib                              | 2,405  | 2,408                                               | 3          |                 |
| CYC116                                  | 1,564  | 1,578                                               | 14         |                 |
| Other research and development costs    | 6,911  | 6,792                                               | (119)      | (2)             |
| Total research and development expenses | 12,742 | 15,718                                              | 2,976      | 23              |

Total research and development expenses represented 61% and 46% of our operating expenses for the nine months ended September 30, 2007 and 2008, respectively.

Research and development expenditures increased by \$3.0 million to \$15.7 million for the nine months ended September 30, 2008 from \$12.7 million for the nine months ended September 30, 2007. The cost increase of \$3.1 million, related to sapacitabine, is due to increased clinical trial activity in particular the commencement of the Phase 2 trial in elderly AML in December 2007 as well as additional pre-clinical and product scale-up.

***Selling, general and administrative expenses***

Selling, general and administrative expenses include costs for sales and marketing and administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the selling, general and administrative expenses for the nine months ended September 30, 2007 and 2008:

|                                                    | 2007  | Nine Months Ended September 30,<br>2008<br>(\$000s) | Difference | Difference<br>% |
|----------------------------------------------------|-------|-----------------------------------------------------|------------|-----------------|
| Total selling, general and administrative expenses | 8,022 | 11,337                                              | 3,315      | 41              |

Total selling, general and administration expenses represented 38% and 33% of our operating expenses for each of the nine months ended September 30, 2007 and 2008, respectively.

Our selling, general and administrative expenditure increased by \$3.3 million to \$11.3 million for the nine months ended September 30, 2008 from \$8.0 million for the nine months ended September 30, 2007. The increase of \$3.3 million in expenses was primarily attributable to our ALIGN subsidiary with \$2.2 million related to the costs of our sales force and marketing efforts and \$0.8 million in intangible assets amortization charges. The remaining increase of \$0.3 million relates to increased professional fees and personnel related expenses.

***Goodwill and intangible asset impairment***

In accordance with FAS 142, we recorded an impairment charge related to the goodwill acquired in the Xcyte transaction of approximately \$2.7 million during the three months ended September 30, 2008 as a result of our market capitalization being lower than the book value of its constituent assets and liabilities as a result of our reduced common stock price. In accordance with FAS No. 144, we recorded an impairment charge related to the intangible assets ascribed in the ALIGN transaction of approximately \$3.6 million during the three months ended September 30, 2008 as a result of the sum of the undiscounted cash flows are less than the carrying amount of the intangible assets on September 30, 2008.

**Table of Contents*****Restructuring expense***

As of September 30, 2008, the restructuring liability associated with exiting the Bothell facility was \$2.3 million accounting for the estimated fair value of the remaining lease payments, net of estimated sub-lease income. The restructuring liability is subject to a variety of assumptions and estimates. We review these assumptions and estimates on a quarterly basis and will adjust the accrual if necessary. There was no change in the estimate for the nine months ended September 30, 2008.

For the nine months ended September 30, 2007 and 2008, we recorded accretion expense associated with the Bothell restructuring lease of \$0.2 million on the consolidated statement of operations as interest expense. A further \$0.2 million of accretion expense will be recognized over the remaining life of the lease to December 2010.

In September 2008, we announced a revision of our operating plan that concentrates our resources on the advancement of our lead drug, sapacitabine, while maintaining a core competency in drug discovery and cell cycle biology. The plan reduced the workforce across all locations by 25 people. We recognized \$0.4 million expense for severance payments and \$0.1 million of accelerated depreciation for assets that will no longer be utilized for the three months September 30, 2008.

***Other income (expense)***

Other income (expense) is comprised of the change in valuation of the derivative, change in value of liability classified warrants, foreign exchange gains and losses, interest income and interest expense. The following table summarizes the other income (expense) for the nine months ended September 30, 2007 and 2008:

|                                   | <b>Nine Months Ended September 30,</b> |                 |                   |                   |
|-----------------------------------|----------------------------------------|-----------------|-------------------|-------------------|
|                                   | <b>2007</b>                            | <b>2008</b>     | <b>Difference</b> | <b>Difference</b> |
|                                   |                                        | <b>(\$000s)</b> |                   | <b>%</b>          |
| Change in valuation of derivative | (89)                                   |                 | 89                | 100               |
| Change in valuation of warrants   | 2,815                                  | 3,321           | 506               | 18                |
| Foreign exchange gain/(losses)    | 1,139                                  | (4,638)         | (5,777)           | (507)             |
| Interest income                   | 2,769                                  | 1,184           | (1,585)           | (57)              |
| Interest expense                  | (154)                                  | (244)           | (90)              | (58)              |
| Total other income (expense)      | 6,480                                  | (377)           | (6,857)           | (106)             |

On November 3, 2007, the embedded derivative associated with the dividend make-whole payment expired reducing the liability to \$0 and thus no further marked to market adjustments will be made with regard to this embedded derivative. For the nine months ended September 30, 2007, the derivative valuation credit was \$0.1 million.

The change in valuation of warrants relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007. The warrants issued to the investors meet the requirements of and are being accounted for as a liability in accordance with EITF 00-19. The value of the warrants is being marked to market each reporting period as a derivative gain or loss until exercised or expiration. For the nine months ended September 30, 2007 and 2008, we recognized the change in the value of warrants of approximately \$2.8 million and \$3.3 million, respectively, as other income in the consolidated statement of operations.

For the nine months ended September 30, 2008 there were unfavorable foreign exchange movements of \$4.6 million on intercompany loans due to the decrease in the strength of the British pound against the US dollar. This is shown on the consolidated statement of operations as a separate line item called foreign exchange gains/(losses) within other income (expense) and re-classified from selling, general and administrative as the underlying loan activity is of a finance nature rather than related to the operating activities of the business and also owing to its magnitude. The comparative figures have also been re-classified and for the nine months to September 30, 2007 there was a foreign exchange gain of \$1.1 million.

Interest income decreased by \$1.6 million from \$2.8 million for the nine months ended September 30, 2007 to \$1.2 million for the nine months ended September 30, 2008. The decrease is primarily attributable to lower average balances of cash and cash equivalents and short-term investments in 2008 as compared to 2007.



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Interest expense increased by \$0.1 million to \$0.2 million for the nine months ended September 30, 2008 from \$0.1 million for the nine months ended September 30, 2007. During the nine months ended September 30, 2007 and 2008 interest expenses included accretion expenses associated with the Bothell lease restructuring provision. During the nine months ended September 30, 2008, there was also interest associated with the deferred consideration and notes payable in relation to the acquisition of ALIGN on October 5, 2007.

***Income tax benefit***

Credit is taken for research and development tax credits, which are claimed from HMRC, in respect of qualifying research and development costs incurred.

The following table summarizes research and development tax credits for the nine months ended September 30, 2007 and 2008:

|                          | <b>Nine Months Ended September 30,</b> |                 |                   |                   |
|--------------------------|----------------------------------------|-----------------|-------------------|-------------------|
|                          | <b>2007</b>                            | <b>2008</b>     | <b>Difference</b> | <b>Difference</b> |
|                          |                                        | <b>(\$000s)</b> |                   | <b>%</b>          |
| Total income tax benefit | 1,549                                  | 1,511           | (38)              | (2)               |

Research and development tax credits recoverable decreased by \$15,000. The decrease was a reflection of decreased income taxes available for recovery as a consequence of the lower eligible research and development payroll expenses in 2008.

***Liquidity and Capital Resources***

The following is a summary of our key liquidity measures at December 31, 2007 and September 30, 2008:

|                                            | <b>December</b> | <b>September 30,</b> |
|--------------------------------------------|-----------------|----------------------|
|                                            | <b>31,</b>      | <b>2008</b>          |
|                                            | <b>2007</b>     | <b>2008</b>          |
|                                            | <b>(\$000s)</b> |                      |
| Cash and cash equivalents                  | 30,987          | 26,723               |
| Short-term investments, available for sale | 27,766          | 6,998                |
| Current assets                             | 63,777          | 37,309               |
| Current liabilities                        | 14,712          | 9,875                |
| Working capital                            | 49,065          | 27,434               |

At September 30, 2008, we had cash and cash equivalents and short-term investments of \$33.7 million as compared to \$58.8 million at December 31, 2007. The lower balance at September 30, 2008 was primarily due to the ongoing research and development of our product candidates. Since our inception, we have not generated any significant revenue and have relied primarily on the proceeds from sales of equity and preferred securities to finance our operations and internal growth. Additional funding has come through interest on investments, licensing revenue, government grants and research and development tax credits. We have incurred significant losses since our inception. As of September 30, 2008, we had an accumulated deficit of \$194.8 million. We believe that existing funds together with cash generated from operations are sufficient to satisfy our planned working capital, capital expenditures, debt service and other financial commitments for the next twelve months but business and environmental risks could have a detrimental affect on our availability of cash.

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Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2007 and 2008, is summarized as follows:

|                                                     | <b>Nine Months Ended September 30,</b> |             |
|-----------------------------------------------------|----------------------------------------|-------------|
|                                                     | <b>2007</b>                            | <b>2008</b> |
|                                                     | <b>(\$000s)</b>                        |             |
| Net cash used in operating activities               | (17,630)                               | (23,532)    |
| Net cash (used in) provided by investing activities | (28,229)                               | 21,688      |
| Net cash provided by (used in) financing activities | 32,512                                 | (931)       |

In our Annual Report on Form 10-K for the year ended December 31, 2007 under the heading *Liquidity and Capital Resources*, we outlined our contractual obligations and other commitments. For the nine months ended September 30, 2008, there have been no material changes in our contractual obligations and other commitments. As disclosed in our current report on Form 8-K filed with the SEC on March 24, 2008, we entered into a three-year employment agreement with our Chief Executive Officer and President; which contain severance and change-in-control provisions. As disclosed in our current report on Form 8-K filed with the SEC on April 2, 2008, we entered into a three-year employment agreement with our Executive Vice President, Finance and Chief Operating Officer which contain severance and change-in-control provisions.

*Operating Capital and Capital Expenditure Requirements*

We expect to continue to incur substantial operating losses in the future. Although we expect to receive a modest amount of product revenues from the ALIGN business acquired on October 5, 2007, we will not receive any product revenue on our drug candidates currently in development until they have been approved by the U.S. Food and Drug Administration ( FDA ) or similar regulatory agencies in other countries and successfully commercialized.

We currently anticipate that our cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next twelve months. However, we will need to raise substantial additional funds to continue our operations. We cannot be certain that any of our research and development 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 or if we can successfully increase product revenues in the ALIGN business. 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, including the cost of establishing and growing a sales force;

- 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;

- the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter; and

the costs associated with establishing the ALIGN business and the level of market penetration and market share that is established.

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Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or curtail commercialization activities. 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 future economic value of those programs to us.

### *Operating activities*

Net cash used in operating activities increased \$5.9 million to \$23.5 million for the nine months ended September 30, 2008 from \$17.6 million for the nine months ended September 30, 2007. The increase of \$5.9 million in cash used in operations was mainly due to our ongoing efforts in research and development and to a lesser extent costs associated with ALIGN.

Net cash used in operating activities during the nine months ended September 30, 2008 of \$23.5 million resulted from our net operating loss of \$32.4 million, adjusted for material non-cash activities comprising amortization of investment premiums (discounts), change in valuation of liability-classified warrants, depreciation and amortization, goodwill and intangibles impairment, unrealized foreign exchange losses, non-cash stock based compensation expense and provision for restructuring costs, amounting to \$6.6 million and net decrease in working capital of \$1.3 million due to a decrease in prepaid expenses and other current assets combined with a net increase in accounts payable and other current liabilities.

Net cash used in operating activities during the nine months ended September 30, 2007 of \$17.6 million resulted from our net operating loss of \$12.7 million, adjusted for material non-cash activities comprising depreciation and amortization, and non-cash stock based compensation expense amounting to \$2.2 million, and net increase in working capital of \$2.7 million, primarily due to a net increase in prepaid expenses and other current assets.

### *Investing activities*

Net cash used in investing activities for the nine months ended September 30, 2007 amounted to \$28.2 million. During the nine months ended September 30, 2008, cash provided by investing activities amounted to \$21.7 million. For the nine months ended September 30, 2008, we redeemed \$22.9 million of short-term investments which was partially offset by purchases of short-term investments of \$0.9 million while in the comparable period last year \$27.4 million of short term investments were purchased

Capital spending is important to our research and development initiatives and to maintain our operational capabilities. Capital expenditures for property, plant and equipment for the nine months ended September 30, 2007 and 2008 totaled approximately \$0.8 million and \$0.4 million, respectively, for normal replacements and improvements.

To reduce our risk profile, we have invested proceeds from maturing short-term investments in cash or cash equivalents in order to make funds available for operational requirements.

### *Financing activities*

Net cash provided by financing activities decreased by \$33.4 million, from a source of \$32.5 million for the nine months ended September 30, 2007 to a use of \$0.9 million for the nine months ended September 30, 2008.

For the nine months ended September 30, 2008, the net cash outflow by financing activities related to the payment of our preferred stock dividend of \$0.9 million. For the nine months ended September 30, 2007, the net cash provided by financing activities related primarily to our registered direct financing in February 2007, offset by the payment of our preferred stock dividends of \$0.6 million and by payment of capital lease obligations of \$0.1 million.

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In February 2007, we raised \$36.0 million in gross proceeds, before deducting placement agent fees and offering expenses of \$2.6 million, in a registered direct offering through the sale of shares of our common stock and warrants. We sold approximately 4.2 million units, each unit consisting of one share of our common stock and a seven-year warrant to purchase 0.25 shares of our common stock, at a purchase price of \$8.47125 per unit. The purchase price for the shares and the exercise price for the warrants was \$8.44 per share, the closing bid price for our common stock on February 12, 2007. Investors paid \$0.125 per warrant. The Company issued 4,249,668 shares of common stock and warrants to purchase 1,062,412 shares of common stock.

In December 2007, we entered into a Committed Equity Financing Facility or CEFF, with Kingsbridge Capital Limited or Kingsbridge, in which Kingsbridge committed to purchase the lesser of 4,084,590 shares of common stock or \$60 million of common stock from Cyclacel capital during the next three years. Under the terms of the agreement, we will determine the exact timing and amount of any CEFF financings, subject to certain conditions. All amounts drawn down under the CEFF will be settled via the issuance of our common stock. We may access capital under the CEFF in tranches of either (a) 2% of our market capitalization at the time of the draw down or (b) the lesser of (i) 3% of our market capitalization at the time of the draw down and (ii) an alternative draw down amount based on the product of (A) the average trading volume of the 30-day trading period preceding the draw down excluding the five highest and five lowest trading days during such period, (B) the volume-weighted average trading price or VWAP on the trading day prior to the notice of draw down, (C) the number of days during the draw down period and (D) 85%, subject to certain conditions. Each tranche will be issued and priced over an eight-day pricing period. Kingsbridge will purchase shares of common stock pursuant to the CEFF at discounts ranging from 6% to 10% depending on the average market price of the common stock during the eight-day pricing period, provided that the minimum acceptable purchase price for any shares to be issued to Kingsbridge during the eight-day period is determined by the higher of \$2.50 or 90% of our common stock closing price the day before the commencement of each draw down. As of September 30, 2008, our share price is below the floor price of \$2.50 per share and therefore we are unable to utilize the facility at this time.

In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 175,000 shares of common stock at an exercise price of \$7.17 per share which represents a 30% premium over the average of the closing bid prices of our common stock during the 5 trading days preceding the signing of the agreement. The warrant will become exercisable six months from the date of the agreement and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. As of September 30, 2008, the warrants issued to the investors are classified as equity in accordance with EITF 00-19.

### **Critical Accounting Policies**

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

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### ***Revenue Recognition***

#### ***Product sales***

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

We offer a general right of return on these product sales, and have considered the guidance in FAS No. 48, *Revenue Recognition When Right of Return Exists* ( FAS 48 ) and Staff Accounting Bulletin No. 104 *Revenue Recognition* ( SAB 104 ). Under these pronouncements, we account for all product sales using the sell-through method. Under the sell-through method, revenue is not recognized upon shipment of product to distributors. Instead, upon the shipment of product to distributors, the Company records deferred revenue at gross invoice sales price and deferred cost of sales at the cost at which those goods were held in inventory. The Company recognizes revenue when such inventory is sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, the Company relies on third-party information, including information obtained from certain distributors with respect to their inventory levels and sell-through to customers, and third-party market research data.

#### ***Stock-based Compensation***

On January 1, 2006, we adopted FAS 123R. Under FAS 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 determination of grant-date fair value is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, the anticipated exercise behavior of our employees, interest rates, forfeiture rates and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments.

#### ***Warrants liability***

EITF 00-19 requires freestanding contracts that are settled in our own stock, including common stock warrants to be designated as an equity instrument, asset or liability. Under the provisions of EITF 00-19, a contract designated as an asset or a liability must be carried at fair value until exercised or expired, with any changes in fair value recorded in the results of operations. A contract designated as an equity instrument must be included within equity, and no subsequent fair value adjustments are required. We review the classification of the contracts at each balance sheet date. Pursuant to EITF 00-19, since we are unable to control all the events or actions necessary to settle the warrants in registered shares the warrants have been recorded as a current liability at fair value. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the consolidated statements of operations. The change in fair value recognized in the financial statements during the three months ended September 30, 2007 and 2008 was \$1.0 million and \$0.4 million, respectively, with regards to the February 2007 financing. Fair value is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrants liability.

#### ***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. We recorded goodwill in March 2006 with respect to the merger with Xcyte and in October 2007 with respect to the acquisition of ALIGN. Under FAS No. 142, *Goodwill and Other Intangible Assets*, 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.

The Company tested goodwill for impairment on September 30, 2008, with respect to Xcyte and ALIGN at a component level as part of a single reportable segment. As a result of the recent decrease in our stock price over the past quarter, our market capitalization being below our carrying book value of goodwill, we recorded a charge of \$2.7 million in relation to the Xcyte business.



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**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

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

**Interest Rate Risk**

Our short-term investments as of September 30, 2008 consisted of \$6.5 million in corporate bonds and commercial paper and \$0.5 million in federal agency and municipal 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 September 30, 2008 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 are exposed to foreign currency rate fluctuations related to the operation of our subsidiary in the United Kingdom. At the end of each reporting period, income and expenses of the subsidiary are remeasured into U.S. dollars using the average currency rate in effect for the period and assets and liabilities are remeasured into U.S. dollars using either historical rates or the exchange rate in effect at the end of the relevant period. We currently 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. For the period ended September 30, 2008 differences on foreign currency translation of \$3.9 million are shown as a component of other comprehensive loss. In the nine months ended September 30, 2008 foreign currency losses of \$4.8 million were charged to the consolidated condensed statement of operations.

**Common Stock Price Risk**

In February 2007, we issued common stock and warrants. Pursuant to EITF 00-19, we recorded the fair value of the warrants as a current liability. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the condensed consolidated statements of operations. The change in fair value recognized in the financial statements during the three months ended September 30, 2007 and 2008 was \$1.0 million and \$0.4 million, respectively. The change in fair value recognized in the financial statements during the nine months ended September 30, 2007 and 2008 was \$2.8 million and \$3.3 million, respectively. Fair value of the warrants will be affected by estimates of various factors that may affect the respective instrument, including our stock price, the risk free rate of return and expected volatility in the fair value of our stock price. As the fair value of these warrants may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

In December 2007, we entered into a CEFF with Kingsbridge, in which Kingsbridge committed to provide us up to \$60 million of capital during the next three years. Under the terms of the agreement, we will determine the exact timing and amount of any common stock issues, subject to certain conditions.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*

Spiro Rombotis, our President and Chief Executive Officer, and Paul McBarron, our Executive Vice President, Finance, and Chief Operating Officer, 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, 2008 our disclosure controls and procedures are effective.

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**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, 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, 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, Finance, concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

***Changes in Internal Control Over Financial Reporting***

During the most recently completed fiscal quarter, there has not been any change in our internal control over financial reporting in connection with the evaluation required by Rule 13a-15(d) under the Securities Exchange Act of 1934 that has materially affected or is reasonably likely to materially affect, our internal control over financial reporting.

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**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 Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2007 and on our quarterly report on Form 10-Q for the quarters ended March 31 and June 30, 2008. 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.*

***If we do not realize the expected benefits from the restructuring that we announced in September 2008, our operating results and financial conditions could be negatively impacted.***

In September 2008, we announced a strategic restructuring designed to focus our resources on our lead drug, sapacitabine, while maintaining the company's core competency in drug discovery and cell cycle biology. We cannot guarantee that we will not have to undertake additional restructuring activities, that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our restructuring. If we are unable to realize the expected operational efficiencies from our restructuring, our operating results and financial condition could be adversely affected.

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

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

***If regulatory agencies do not accept our proposed registration pathways based on Phase 2 data, then we will likely need to conduct large, controlled pivotal studies, which are time-consuming and expensive.***

Regulatory agencies including but not limited to the U.S. Food and Drug Administration, or FDA, have in certain instances accepted Phase 2 data from uncontrolled studies, as sufficient for approval in indications where an unmet medical need exists or in exceptional circumstances. If regulatory agencies including but not limited to FDA, determine that the results of our Phase 2 studies are not sufficient for approval of our investigational drugs, we will likely need to undertake large, controlled pivotal studies, which are time-consuming and expensive. Because we have limited resources, and research and development is an expensive process, any such requirements may adversely impact our operating results and financial condition and delay our ability to commercialize our drug candidates.

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If the results of our studies do not meet the minimal level of statistical significance or other requirements of the U.S. Food and Drug Administration, or the FDA, or other regulatory agencies, we will likely need to undertake placebo-controlled Phase 3 studies, which are time-consuming and expensive. Because we have limited resources, and research and development is an expensive process, any such requirements by the FDA may adversely impact our operating results and financial condition and delay our ability to commercialize our lead drug candidate.

Even if we believe the data collected from clinical trials of our drug candidates are promising with respect to safety and efficacy, such data may not be deemed sufficient by regulatory authorities to warrant product approval. Clinical data can be interpreted in different ways. Regulatory officials could interpret such data in different ways than we do which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our drug candidates, or in receiving regulatory approval for the commercialization of our drug candidates, may severely harm our business and reputation.

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

None.

### **Item 3. Defaults upon Senior Securities.**

None.

### **Item 4. Submissions of Matters to a Vote of Security Holders.**

None.

### **Item 5. Other Information.**

None.

### **Item 6. Exhibits.**

- |      |                                                                                                                                                                      |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 31.1 | Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1 | Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002                                                               |
| 32.2 | Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002                                                               |

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**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 Berkeley Heights, New Jersey, on November 7, 2008.

**CYCLACEL PHARMACEUTICALS, INC.**

Dated: November 7, 2008

By: /s/ Paul McBarron

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

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**EXHIBIT INDEX**

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                   |
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