

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form 10-Q

Cyclacel Pharmaceuticals, Inc.  
Form 10-Q  
November 07, 2007

Table of Contents

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, 2007

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

91-1707622 (State or other jurisdiction of  
incorporation or organization) (IRS Employer Id. 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, or a non-accelerated filer. See definition of "accelerated filer and larger accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

As of November 6, 2007 there were 20,433,167 shares of the issuer's common stock outstanding.

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CYCLACEL PHARMACEUTICALS, INC.

INDEX

|      |   |    |  |    |         |
|------|---|----|--|----|---------|
| Page | Part I. Financial Information   | 3  | Item 1. Financial Statements (Unaudited) | 3  | Item 2. |
|      | Management's Discussion and Analysis of Financial Condition and Results of Operations | 17 | Item 3.                                  |    |         |
|      | Quantitative and Qualitative Disclosures About Market Risk                            | 28 | Item 4. Controls and Procedures          | 29 | Part    |
|      | II. Other Information   | 31 | Item 1. Legal Proceedings                | 31 | Item 2. |
|      | Unregistered Sales of Equity Securities and Use of Proceeds                           | 38 | Item 3. Defaults upon Senior Securities  | 38 |         |
|      | Item 4. Submissions of Matters to a Vote of Security Holders                          | 38 | Item 5. Other Information                | 38 | Item    |
| 6.   | Exhibits  | 38 | SIGNATURE PAGE                           |    |         |

2

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

CYCLACEL PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In \$000s, except share amounts)

December 31,

2006 September 30,

|                      |          |             |                                      |   |  |  |                            |  |
|----------------------|----------|-------------|--------------------------------------|---|--|--|----------------------------|--|
| 2007                 | (Note 1) | (Unaudited) | ASSETS                               | Current assets:   | Cash and cash equivalents                              | 44,238   |                            |  |
| 31,113               |          |             | Short-term investments               | 9,764   | 37,430   | Prepaid expenses and other current assets  | 4,163                      | 6,623  |
| Total current assets | 58,165   | 75,166      | Property, plant and equipment (net)  | 2,121   | 2,292  | Deposits and other assets  | 241                        | 233  |
|                      |          |             | Goodwill                             | 2,749   | 2,749  | Total assets   | 63,276                     | 80,440   |
|                      |          |             | LIABILITIES AND STOCKHOLDERS' EQUITY | Current liabilities:  | Accounts payable                                       | 2,175  | 2,004                      | Accrued liabilities                              |
|                      |          |             |                                      | 3,324   | 3,667  | Other current liabilities  | 290                        | 200  |
|                      |          |             |                                      | Derivative liability  | 1,135  | 302  | Warrant liability          | —  |
|                      |          |             |                                      | 3,935   | Current portion of other accrued restructuring charges | 908  | 793                        | Current portion of equipment financing           |
|                      |          |             |                                      | 89  | —  | Total current liabilities  | 7,921                      | 10,901   |
|                      |          |             |                                      | Other accrued restructuring charges, net of current   | 1,436  | 964  | Total liabilities          | 9,357  |
|                      |          |             |                                      | 11,865  | Stockholders' equity:                                  | Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2006 and September 30, 2007, respectively; 2,046,813 shares issued and outstanding at December 31, 2006 and September 30, 2007, respectively. Aggregate preference in liquidation of \$20,673,000 at December 31, 2006 and September 30, 2007. | 2                          | 2  |
|                      |          |             |                                      | Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2006 and September 30, 2007, respectively; 16,157,953 and 20,433,167 shares issued and outstanding at December 31, 2006 and September 30, 2007, respectively | 16   | 20   | Additional paid-in capital | 194,714  |
|                      |          |             |                                      | 222,815   | Accumulated other comprehensive loss                   | (2,537)  | (3,286)                    | Deficit accumulated during the development stage |
|                      |          |             |                                      | (138,276)   | (150,976)  | Total stockholders' equity   | 53,919                     | 68,575   |
|                      |          |             |                                      | 63,276  | 80,440   | Total liabilities and stockholders' equity   | 63,276                     | 80,440   |

SEE NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

## Table of Contents

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

| Three Months Ended  |  |  |  |  |  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|--|--|--|--|
| September 30, Nine Months Ended   |  |  |  |  |  |  |  |  |  |  |  |
| September 30, Period from   |  |  |  |  |  |  |  |  |  |  |  |
| August 13, 1996   |  |  |  |  |  |  |  |  |  |  |  |
| (inception) to  |  |  |  |  |  |  |  |  |  |  |  |
| September 30, 2006 2007 2006 2007 2007 Revenues:  |  |  |  |  |  |  |  |  |  |  |  |
| and development revenue 27 — 152 10 3,000 Grant revenue 56 33 118 107 3,584                       |  |  |  |  |  |  |  |  |  |  |  |
| 83 33 270 117 6,584 Operating expenses: Research and development                                  |  |  |  |  |  |  |  |  |  |  |  |
| (4,059) (4,449) (17,196) (12,742) (134,717) General and administrative (2,511) (2,064)            |  |  |  |  |  |  |  |  |  |  |  |
| (9,456) (6,883) (42,836) Restructuring costs (225) — (225) (81) (306) Total operating             |  |  |  |  |  |  |  |  |  |  |  |
| expenses (6,795) (6,513) (26,877) (19,706) (177,859) Operating loss (6,712) (6,480)               |  |  |  |  |  |  |  |  |  |  |  |
| (26,607) (19,589) (171,275) Other income (expense): Costs associated with aborted                 |  |  |  |  |  |  |  |  |  |  |  |
| 2004 IPO — — — — (3,550) Change in valuation of derivative (64) (19) (162) (89) (304              |  |  |  |  |  |  |  |  |  |  |  |
| ) Change in valuation of warrants — 951 — 2,815 2,815 Interest income 793 955 1,565               |  |  |  |  |  |  |  |  |  |  |  |
| 2,769 11,376 Interest expense (52) (54) (178) (154) (4,070) Total other income (expense)          |  |  |  |  |  |  |  |  |  |  |  |
| 677 1,833 1,225 5,341 6,267 Loss before taxes (6,035) (4,647) (25,382) (14,248)                   |  |  |  |  |  |  |  |  |  |  |  |
| (165,008) Income tax benefit 603 433 1,659 1,549 14,033 Net loss (5,432) (4,214)                  |  |  |  |  |  |  |  |  |  |  |  |
| (23,723) (12,699) (150,975) Dividends on Preferred Ordinary shares — — (2,827) — (38,123)         |  |  |  |  |  |  |  |  |  |  |  |
| Net loss applicable to ordinary shareholders (5,432) (4,214) (26,550) (12,699) (189,098) Net loss |  |  |  |  |  |  |  |  |  |  |  |
| per share – Basic and diluted \$ (0.34) \$ (0.21) \$ (2.13) \$ (0.65) Weighted average shares     |  |  |  |  |  |  |  |  |  |  |  |
| 16,157,953 20,433,129 12,458,458 19,685,457   |  |  |  |  |  |  |  |  |  |  |  |

SEE NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

## Table of Contents

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

## Nine Months Ended

September 30, Period from  
 August 13, 1996  
 (inception) to

|  |            |  |            |   |                               |   |
|--|------------|--|------------|---|-------------------------------|---|
| September 30,                            | 2006       | 2007   | 2007       | Cash flows from operating activities:                                       | Net loss                      | (23,723 )   |
| (12,699 )                                | (150,975 ) |  |            | Adjustments to reconcile net loss to net cash used in operating activities: |                               |   |
| Amortization of investment premiums, net | (11 )      | (220 )   | (249 )     | Change in valuation of derivative   | 162                           |   |
| 89                                       | 304        | Change in valuation of warrants                          | — (2,815 ) | (2,815 )  | Depreciation and amortization | 869   |
| 707                                      | 9,796      | Unrealized foreign exchange (gain) loss                  | — (1,432 ) | 1,937   | Deferred revenue              | — (98 )   |
|  |            | Compensation for warrants issued to non employees        | — —        | 1,215   | Shares issued for IP rights   | — —   |
|  |            | (Loss) Gain on disposal of property, plant and equipment | (1 )       | —   | 27                            | Stock based compensation  |
| 1,335                                    | 13,489     | Provision for restructuring                              | 225        | 81  | 306                           | Amortization of issuance costs of Preferred   |
|  |            | Ordinary "C" shares—                                     | —          | —   | 2,517                         | Changes in operating assets and liabilities:  |
|  |            | other current assets                                     | (496 )     | (2,088 )  | (5,635 )                      | Accounts payable and other current liabilities  |
| (588 )                                   | (918 )     | Net cash used in operating activities                    | (16,781 )  | (17,630 )   | (130,653 )                    | Investing activities:   |
|  |            | Purchase of property, plant and equipment                | (133 )     | (800 )  | (7,469 )                      | Proceeds from sale of   |
|  |            | property, plant and equipment                            | 23         | —   | 26                            | Net redemptions (purchases) of short-term investments on deposit,                       |
|  |            | net of maturities  | 4,349      | (27,429 )   | (33,387 )                     | Net cash provided by (used in) investing activities                                     |
| (28,229 )                                | (40,830 )  | Financing activities:                                    |            |   |                               | Payment of capital lease obligations  |
| (3,709 )                                 |            |  |            |   |                               | (197 ) (89 )  |
|  |            |  |            |   |                               | Proceeds from issuance of ordinary and preferred ordinary shares, net of issuance costs |
|  |            |  |            |   |                               | — — 90,858  |
|  |            |  |            |   |                               | Proceeds from issuance of common stock and warrants, net of issuance costs              |
|  |            |  |            |   |                               | 42,626 33,359 75,985  |
|  |            |  |            |   |                               | Net proceeds from stock options and warrants exercised                                  |
|  |            |  |            |   |                               | — 163 163   |
|  |            |  |            |   |                               | Payment of preferred stock dividend   |
|  |            |  |            |   |                               | (614 ) (921 ) (1,842 )  |
|  |            |  |            |   |                               | Repayment of government loan  |
|  |            |  |            |   |                               | — — (455 )  |
|  |            |  |            |   |                               | Government loan received  |
|  |            |  |            |   |                               | — — 414   |
|  |            |  |            |   |                               | Loan received from Cyclacel Group Plc   |
|  |            |  |            |   |                               | — — 9,103   |
|  |            |  |            |   |                               | Proceeds of committable loan notes issued from  |
|  |            |  |            |   |                               | shareholders  |
|  |            |  |            |   |                               | — — 8,883   |
|  |            |  |            |   |                               | Loans received from shareholders  |
|  |            |  |            |   |                               | — — 1,645   |
|  |            |  |            |   |                               | Cash and cash equivalents   |
|  |            |  |            |   |                               | assumed on stock purchase   |
|  |            |  |            |   |                               | 17,915 — 17,915   |

5

Table of Contents

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

Nine Months Ended

September 30, Period from  
 August 13, 1996  
 (inception) to

|                    |      |      |                                      |          |      |         |   |                                    |  |         |  |       |   |       |  |        |  |        |  |       |  |   |  |        |   |        |  |                                      |          |       |       |       |       |       |   |        |
|--------------------|------|------|--------------------------------------|----------|------|---------|---|------------------------------------|--|---------|--|-------|---|-------|--|--------|--|--------|--|-------|--|---|--|--------|---|--------|--|--------------------------------------|----------|-------|-------|-------|-------|-------|---|--------|
| September 30, 2006 | 2007 | 2007 | Costs associated with stock purchase | (1,951)  | —    | (1,951) | Net cash provided by financing activities | 57,779                             | 32,512   | 197,009 | Effect of exchange rate changes on cash and cash equivalents | 1,433 | 222   | 5,587 | Net increase (decrease) in cash and cash equivalents | 45,237 | (13,347)   | 25,526 | Cash and cash equivalents at beginning of period | 3,117 | 44,238   | — | Cash and cash equivalents at end of period | 49,787 | 31,113  | 31,113 | Supplemental disclosure of cash flows information: | Cash received during the period for: | Interest | 1,625 | 1,716 | 9,770 | Taxes | 1,906 | — | 10,739 |
|                    |      |      | Cash paid during the period for:     | Interest | (78) | (122)   | (945)                                     | 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                                  |          |       |       |       |       |       |   |        |

SEE NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

Table of Contents

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. As a development stage enterprise, substantially all efforts of the Company to date have been devoted to performing research and development, conducting clinical trials, developing and acquiring intellectual property, raising capital and recruiting and training personnel. 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 sheet as of September 30, 2007, the condensed consolidated statements of operations for the three and nine months ended September 30, 2007 and 2006 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2007 and 2006, and related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2006 is derived from the audited consolidated financial statements included in the 2006 Annual Report on Form 10-K 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, 2007, the results of operations for the three and nine months ended September 30, 2007 and 2006 and the consolidated statement of cash flows for the nine months ended September 30, 2007 and 2006 have been made. The interim results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results to be expected for the year ending December 31, 2007 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, 2006, included in the Company’s Annual Report on Form 10-K filed with the SEC.

Recent Developments

Acquisition of ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC

On October 5, 2007, Achilles Acquisition, LLC (renamed immediately following the acquisition to ALIGN Pharmaceuticals, LLC (“ALIGN”), a wholly-owned subsidiary of Cyclacel entered into a definitive asset purchase agreement (the “Agreement”) with ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC (together, the “Sellers”), to acquire substantially all of the Sellers’ assets (the “Transaction”). The closing of the Transaction occurred simultaneously with the execution of the Agreement (the “Closing Date”).

Cyclacel, through ALIGN, 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.



As consideration for the Transaction and pursuant and subject to the terms of the Agreement, Cyclacel, through ALIGN, paid \$3,331,428 in cash to the Sellers and shall pay an additional aggregate amount of \$452,464 within 130 business days from the Closing Date, in cash, shares of the Company's common stock, or a combination thereof, as further described in the Agreement. In addition, the

7

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## Table of Contents

Company may be required to issue to the Sellers a maximum number of shares of common stock, in an amount equal to \$1,116,108, issuable at a price per share of \$6.06 (the average closing price of Cyclacel's common stock on the 90 trading days immediately before the Closing Date), which issuance is contingent upon the achievement of certain operational and financial milestones and subject to satisfaction of any outstanding indemnification obligations by the Sellers. The Company will issue the shares of common stock only to the extent that the milestones are achieved. The Company, as part of securing long term supply arrangements has commitments to make future payments of approximately \$0.5 million in each of 2009 and 2010.

The transaction will be accounted for as a business combination and the results of operations of Cyclacel will include the results of operations from the Sellers' from the Closing Date. The assets and certain agreed liabilities of ALIGN will be recorded as of the Closing Date at their estimated fair values. The transaction will qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code. William C. Collins, the former chief executive officer and manager of the Sellers, was appointed as the general manager of ALIGN.

## 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 conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period, and the costs related to the merger with Xcyte Therapies, Inc. ("Xcyte") on March 27, 2006. Actual results could differ from those estimates.

### Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of 90 days or less when purchased to be cash equivalents.

Table of Contents

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:

|      | September 30,  |           |           |  |           |           |
|------|--|-----------|-----------|--|-----------|-----------|
| 2006 | September 30,  |           |           |  |           |           |
| 2007 | Stock options  | 849,153   | 1,968,915 | Convertible preferred stock            | 870,980   | 870,980   |
|      | dividend payments of common stock on convertible preferred stock | 190,608   | 190,608   | Common stock warrants                  |           |           |
|      |  | 2,572,653 | 3,634,703 | Total shares excluded from calculation | 4,483,394 | 6,665,206 |
|      | Other Comprehensive Loss   |           |           |  |           |           |

In accordance with Financial Accounting Standards Board Statement (“FASB”), Statement of Financial Accounting Standards (“SFAS”) No. 130, “Reporting Comprehensive Income, (“SFAS 130”) all components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments, are reported, net of any related tax effect, to arrive at comprehensive income (loss).

|   | For the three months ended September 30, |          | For the nine months ended September 30, |           |                      |    |        |
|---|--|----------|---|-----------|----------------------|----|--------|
|   | 2006                                     | 2007     | 2006                                    | 2007      | (\$000s)             |    |        |
| Net loss  | (5,432 )                                 | (4,214 ) | (23,723 )                               |           |                      |    |        |
| (12,699 ) Unrealized gain (loss) on marketable securities | —  | 50       | —                                       | 16        | Currency translation | 91 | (409 ) |
| 591 (765 ) Comprehensive loss                             | (5,341 )                                 | (4,573 ) | (23,132 )                               | (13,448 ) |                      |    |        |
| Other Accrued Liabilities                                 |  |          |   |           |                      |    |        |

Other accrued liabilities consist of the following:

|      | December 31,                              |       |       |                           |       |       |
|------|---|-------|-------|---------------------------|-------|-------|
| 2006 | September 30,                             |       |       |                           |       |       |
| 2007 | (\$000s) Accrued research and development | 1,406 | 2,622 | Other accrued liabilities | 1,918 | 1,045 |
|      | Total accrued liabilities                 | 3,324 | 3,667 |                           |       |       |

3. STOCK BASED COMPENSATION

On January 1, 2006, the Company adopted FASB, Statement No. 123R, “Share-Based Payment” (“SFAS 123R”). SFAS 123R requires the Company to measure all share-based payment awards, including those with employees, granted, modified, repurchased or cancelled after, or that were

9

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Table of Contents

unvested as of, January 1, 2006 at fair value. Under SFAS 123R, the fair value of stock options and other equity-based compensation must be recognized as compensation cost in the financial statements over the requisite service period of each award.

At the Company's annual shareholder meeting on May 21, 2007, the stockholders approved and amended the number of shares reserved under the 2006 Equity Incentive Plan ("2006 Plan") to 3,000,000 shares of the Company's common stock (up from 1,615,795 shares). The shares reserved under the 2006 Plan have a maximum maturity of 10 years and generally exercisable over a four-year period from the date of grant. For the three and nine months ended September 30, 2007, the Company granted 307,296 and 661,046 stock options, respectively, to its employees and directors under the 2006 Plan which vest ratably over four years. For the three and nine months ended September 30, 2006, the Company granted 16,667 and 844,286 stock options, respectively, to its employees and directors. Based on the Black-Scholes option-pricing model, the total fair value of all options granted under the 2006 Plan is \$8.2 million, of which \$4.3 million of share based compensation will be recognized as compensation over the remaining vesting periods. A summary of activity for the options under the Company's 2006 Plan for the nine months ended September 30, 2007 is as follows:

|                    |                                |   |           |         |        |                           |             |  |  |
|--------------------|--------------------------------|---|-----------|---------|--------|---------------------------|-------------|--|--|
| Options            | Weighted                       |   |           |         |        |                           |             |  |  |
| Average            |                                |   |           |         |        |                           |             |  |  |
| Exercise Price     | Weighted Average               |   |           |         |        |                           |             |  |  |
| Remaining          |                                |   |           |         |        |                           |             |  |  |
| Contractual        |                                |   |           |         |        |                           |             |  |  |
| Term (years)       | Aggregate                      |   |           |         |        |                           |             |  |  |
| Intrinsic          |                                |   |           |         |        |                           |             |  |  |
| Value              | (in \$000s)                    | Options outstanding at December 31, 2006  | 1,335,841 | \$ 6.42 | 9.44   | —                         | Granted     |  |  |
| 661,046            | \$ 5.53                        | Exercised (25,508 )                       | \$ 6.40   | Expired | —      | —                         | Cancelled / |  |  |
| forfeited (2,464 ) | \$ 6.40                        | Options outstanding at September 30, 2007 | 1,968,915 | \$ 6.68 | 9.48   |                           |             |  |  |
| 71,064             | Unvested at September 30, 2007 | 1,160,259                                 | \$ 6.69   | 8.65    | 66,156 | Vested and exercisable at |             |  |  |
| September 30, 2007 | 808,656                        | \$ 6.66                                   | 9.14      | 4,908   |        |                           |             |  |  |

Summarized Black-Scholes-Merton option pricing model assumptions for stock option grants to employees and directors for the nine months ended September 30, 2006 and 2007:

|                      |  |              |   |              |                     |       |           |           |              |
|----------------------|--|--------------|---|--------------|---------------------|-------|-----------|-----------|--------------|
| For the three months |  |              |   |              |                     |       |           |           |              |
| ended September 30,  | For the nine months ended                  |              |   |              |                     |       |           |           |              |
| September 30,        | 2006                                       | 2007         | 2006  | 2007         | Expected term       | 5 Yrs | 5 – 6 Yrs | 3 – 5 Yrs | 4.25 – 6 Yrs |
| interest rate        | 4.56 – 4.68%                               | 4.25 – 4.92% | 4.56 – 5.06%                                | 4.25 – 5.07% | Expected volatility | 90%   | 70 – 80%  | 90%       | 70 –         |
| 80%                  | Expected dividend yield over expected term | —————        | Resulting weighted average grant fair value | \$3.41       | \$3.49              |       |           |           |              |
| \$3.86               | \$4.05                                     |              |   |              |                     |       |           |           |              |

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

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.

Table of Contents

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 our outstanding shares of common stock in the foreseeable future.

The Company received approximately \$0.2 million from the exercise of 25,508 stock options during the second quarter of 2007. There were no exercises of stock options during the three months ended September 30, 2007. No income tax benefits have been recorded associated with these stock option exercises. SFAS 123R prohibits recognition of tax benefits for exercised stock options until such benefits are realized. As the Company presently has tax loss carry forwards from prior periods and expects to incur tax losses in 2007, the Company is not able to benefit from the deduction for exercised stock options in the current reporting period.

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

The following table summarizes the components of the Company's stock based compensation for the three and nine months ended September 30, 2006 and 2007:

| For the three months<br>ended September 30, |      |      | For the nine months<br>ended September 30, |       |  |                          |     |       |
|---|------|------|--|-------|--|--------------------------|-----|-------|
|   | 2006 | 2007 | 2006                                       | 2007  | (\$000s)   | Research and development | 164 | 120   |
| 622 General and administrative              | 93   | 199  | 3,262                                      | 713   | Stock-based compensation costs before income taxes |                          |     | 6,052 |
|   | 257  | 319  | 9,314                                      | 1,335 |  |                          |     |       |

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 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, 2007 the accrued restructuring liability was \$1.8 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.

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.

5. MERGER

On March 27, 2006, Xcyte completed the Stock Purchase Agreement with Cyclacel Group plc whereby Xcyte acquired all of the outstanding shares of common stock of Cyclacel Limited or Limited, from Cyclacel Group plc. Xcyte changed its name to Cyclacel Pharmaceuticals, Inc., or Cyclacel, and Cyclacel was listed on the Nasdaq Global Market under the ticker symbol CYCC. The transaction was considered a “reverse merger” and was accounted for as a purchase by Cyclacel under accounting principles generally accepted in the United States. Accordingly, the purchase price was

11

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Table of Contents

allocated among the fair values of the assets and liabilities of Xcyte, while the historical results of Limited are reflected in the results of the combined company. The 1,967,967 shares of Xcyte common stock outstanding, the 2,046,813 preferred stock outstanding and the outstanding Xcyte options, were considered as the basis for determining the consideration in the reverse merger transaction.

Merger Purchase Price

The consolidated financial statements reflect the merger of Limited with Xcyte as a reverse acquisition wherein Limited is deemed to be the acquiring entity from an accounting perspective. Under the purchase method of accounting, Xcyte's outstanding shares of common and preferred stock were valued using the average closing price on Nasdaq for the two days prior to through the two days subsequent to the announcement of the transaction date, December 15, 2005, which were \$4.38 (as adjusted for a reverse stock split) and \$3.72 per share for common stock and preferred stock, respectively. There were 1,967,967 shares of common stock and 2,046,813 shares of preferred stock outstanding as of March 27, 2006. The fair values of the Xcyte outstanding stock options were determined using the Black-Scholes-Merton option pricing model with the following assumptions: stock price of \$4.38 (as adjusted for the reverse stock split), volatility – 97%; risk-free interest rate – 4.0%; and an expected life – three months.

The purchase price is summarized as follows (\$000s):

|                                  |       |   |       |                                       |  |
|----------------------------------|-------|---|-------|---------------------------------------|--|
|                                  |       |   |       |                                       | Fair value of Xcyte outstanding common |
| stock                            | 8,620 | Fair value of Xcyte outstanding preferred stock | 7,618 | Fair value of Xcyte outstanding stock |  |
| options                          | 17    | Merger costs                                    | 1,951 | Total purchase price                  | 18,206                                 |
| Merger Purchase Price Allocation |       |   |       |                                       |  |

The purchase price allocation is as follows (\$000s):

|                                 |       |              |        |                     |                |                         |                     |
|---------------------------------|-------|--------------|--------|---------------------|----------------|-------------------------|---------------------|
|                                 |       |              |        |                     | Current assets | 21,267                  | Property, plant and |
| equipment                       | 108   | Other assets | 259    | Current liabilities | (4,400)        | Non-current liabilities | (1,777)             |
|                                 | 2,749 |              | 18,206 |                     |                |                         | Goodwill            |
| Pro Forma Results of Operations |       |              |        |                     |                |                         |                     |

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

## Table of Contents

For the nine

months ended

|                    |                |       |                   |          |  |          |                                      |           |                         |            |
|--------------------|----------------|-------|-------------------|----------|--|----------|--------------------------------------|-----------|-------------------------|------------|
| September 30, 2006 | (000s) Revenue | 5,270 | Loss before taxes | (24,540) | Net loss applicable to ordinary shareholders | (25,708) | Net loss per share-basic and diluted | \$ (2.01) | Weighted average shares | 12,806,491 |
|--------------------|----------------|-------|-------------------|----------|--|----------|--------------------------------------|-----------|-------------------------|------------|

## 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.

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 January, April, July and October 2006, 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, August and November 2006, respectively. Each quarterly dividend distribution totaled \$0.3 million and was paid to holders of record as of the close of business on January 20, 2006, April 29, 2006, July 24, 2006 and October 23, 2006, respectively. In January, April, July and September 2007, 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 2007, respectively. Each quarterly dividend distribution totaled \$0.3 million and was paid to holders of record as of the close of business on January 22, April 20, and July 20, 2007, respectively. Additionally, a dividend was declared in September, 2007 and was paid on November 1, 2007 to holders of record on October 19, 2007.

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 4.2553 shares of common stock for each share of Preferred Stock, based on an initial conversion price of \$2.35. The initial conversion price is subject to adjustment in certain events, including the one for ten reverse stock split of Xcyte's common stock pursuant to which the conversion price of the convertible Preferred Stock now equals approximately \$23.50. Such adjusted conversion price is equivalent to a conversion rate of approximately 0.42553 shares of common stock for each share of convertible Preferred Stock. 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, 2007 (after giving effect to the one for ten reverse stock split of Xcyte's common stock). In the year ended December 31, 2004, holders converted 910,187 shares of Preferred Stock into 3,873,124 shares of common stock. In the year ended December 31, 2005, holders converted 33,000 shares of preferred stock into 140,425 shares of common stock. During 2006 and for the nine months ended September 30, 2007 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.



## Table of Contents

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, 2007 the Company issued 81,927 shares of common stock (as adjusted for the reverse stock split) to converting holders in satisfaction of this additional payment.

In accordance with SFAS 133, "Accounting for Derivative Instruments" ("SFAS 133"), the Company is 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 must be measured at fair value and reflected as a liability. Changes in the fair value of the derivative are recognized in the condensed consolidated statement of operations as a component of other income (expense). As of December 31, 2006 and September 30, 2007, the fair value of the dividend make-whole payment feature was \$1.2 million and \$0.3 million, respectively. The carrying value of this derivative was reduced by \$0.9 million during the nine months ended September 30, 2007 based on cash dividends paid during the period. As a result, the Company has charged \$19,000 and \$89,000, as other expense for the three and nine months ended September 30, 2007, respectively.

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.

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

## Common Stock and warrants

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.

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") requires freestanding contracts that are settled in a Company's own stock, including common stock warrants to be classified as an equity instrument, asset or liability. As of September 30, 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. 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 until exercised

or expiration. At September 30, 2007, fair value of the warrants was \$3.9 million. During the three and nine months ended September 30, 2007, the Company recognized the change in the value of warrants of approximately \$1.0 million and \$2.8 million, as a gain on the consolidated statement of operations.

14

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Table of Contents

The following table summarizes information about warrants outstanding at September 30, 2007:

| Issued in Connection With | Expiration | Date      | Common Shares | Issuable             | Weighted Average | Exercise Price | Acquisition of Xcyte |
|---------------------------|------------|-----------|---------------|----------------------|------------------|----------------|----------------------|
| March 2006                | 2008       | 431       | \$ 15.29      | Acquisition of Xcyte | March 2006       | 2009           | 431                  |
| April 2006                | 2013       | 2,571,429 | 7.00          | February 2007        | stock issuance   | 2014           | 1,062,412            |
| Total                     |            | 3,634,703 | \$ 7.42       |                      |                  |                |                      |

During the second quarter of 2007, 25,508 shares of common stock were issued from the exercise of stock options resulting in proceeds of \$0.2 million. There were no exercises of stock options during the third quarter of 2007.

7. RECENT ACCOUNTING PRONOUNCEMENTS

In July 2006, the FASB issued FASB Interpretation No. 48, ‘‘Accounting for Uncertainty in Income Taxes’’, an interpretation of SFAS 109, ‘‘Accounting for Income Taxes’’ (‘‘FIN 48’’). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in a company’s financial statements by prescribing a minimum probability threshold that a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides related guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and the Company adopted FIN 48 as of January 1, 2007. Due to the relatively simple operational nature of the Company, as well as the fact that the Company has incurred net operating losses since inception, the Company believes that its tax filing positions and deductions are more likely than not to be sustained on audit and does not anticipate any adjustments that will result in a material change in its financial position. Therefore, no reserves for uncertain tax positions have been recorded pursuant to FIN 48. In addition, the Company did not record a cumulative effect adjustment related to the adoption of FIN 48, nor has the Company recognized any interest or penalties related to uncertain tax positions in the statement of operations for the three and nine months September 30, 2007. Although no interest and penalties have been recognized, the Company, upon adoption of FIN 48, has elected a policy to classify any future interest and penalties as a component of interest expense. Tax years that remain subject to examination by the taxation authorities include:

- 2005 and 2006 in the UK
- 2006 in the US

In September 2006, the FASB issued SFAS No. 157, ‘‘Fair Value Measurements’’ (‘‘SFAS 157’’). SFAS 157 defines fair value, establishes a framework for measuring fair value and requires enhanced disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years and will be adopted by the Company as of January 1, 2008. SFAS 157 may impact the Company’s balance sheet and statement of operations in areas including the fair value measurements for short-term investments, derivative instruments and warrants. The Company is currently reviewing the provisions of SFAS 157 and has not yet determined the effect, if any, that adoption of SFAS 157 will have.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities” (“SFAS 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. SFAS 159 will be effective on January 1, 2008. The Company is currently evaluating the impact of adopting SFAS 159 on its financial position, cash flows and results of operations.

15

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Table of Contents

8. Subsequent Event

On October 5, 2007, Cyclacel, through its renamed wholly-owned subsidiary ALIGN Pharmaceuticals, LLC acquired substantially all of the assets of ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC. The closing of the acquisition occurred simultaneously with the execution of Asset Purchase Agreement. See Note 1 to the Notes to Condensed Consolidated Financial Statement for further information.

16

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## Table of Contents

### 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, 2006, 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 judgement 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. We, through our wholly-owned subsidiary, ALIGN Pharmaceuticals, LLC ("ALIGN") markets directly in the U.S. Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. Three Cyclacel drugs are in clinical development. Sapacitabine, an orally-available, cell cycle modulating nucleoside analog, is in Phase II for the treatment of cutaneous T-cell lymphoma and in Phase I in patients with hematologic malignancies. Seliciclib, an orally-available CDK (cyclin dependent kinase) inhibitor, is in Phase II for the treatment of lung cancer and is also being evaluated for nasopharyngeal cancer. CYC116, an orally-available, Aurora kinase and VEGFR2 inhibitor, is in Phase I in patients with solid tumors. Several additional programs are at an earlier stage. Our strategy is to build a diversified biopharmaceutical business focused in oncology, hematology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Our core area of scientific expertise is in cell cycle biology, or the processes by which cells divide and multiply. We focus primarily on the discovery and development of orally available anticancer agents that target the cell cycle with the aim of slowing the progression or shrinking the size of tumors, and enhancing quality of life and improving

survival rates of cancer patients. We are generating several families of anticancer drugs that act on the cell cycle including Cyclin Dependent kinase (CDK) and Aurora kinase (AK) inhibitors. We are advancing three of our anticancer drug candidates,

17

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## Table of Contents

sapacitabine, seliciclib and CYC116 through in-house research and development activities. Sapacitabine, our orally available nucleoside analog, has completed Phase I studies in approximately 160 patients at five centers in the United States including two Phase I studies evaluating 87 patients in refractory solid tumors. We are currently conducting a Phase Ib dose escalation clinical trial with sapacitabine for the treatment of patients with advanced malignancies with approximately 35 patients as of June 30, 2007. Interim results from this trial were presented in a poster at the 43rd annual meeting of the American Society of Clinical Oncology, or ASCO. We plan to evaluate sapacitabine in Phase II studies in both hematological cancers and solid tumors and we announced the first study on April 30, 2007, when we initiated a Phase II clinical trial in patients with advanced cutaneous T-cell lymphoma. Seliciclib is currently being studied in a Phase IIb, multi-center, randomized, double-blinded trial, called APPRAISE, to evaluate the efficacy and safety of seliciclib as a third line treatment in patients with non-small cell lung cancer, or NSCLC. The APPRAISE study builds on the observation of prolonged stable disease experienced by heavily-pretreated NSCLC patients enrolled in a Phase I study of single agent seliciclib. We also plan to commence in the coming months a Phase II study of single agent seliciclib in nasopharyngeal carcinoma. We are also developing CYC116, a novel inhibitor of Aurora kinases A and B and VEGFR2 for the treatment of cancer. We began a multicenter Phase I pharmacologic clinical trial of orally-available CYC116 in patients with advanced solid tumors in June 2007. We have worldwide rights to commercialize sapacitabine, seliciclib and CYC116 and our business strategy is to enter into selective partnership arrangements with these programs. We are also progressing further novel drug series, principally for cancer, which are at earlier stages. Taken together, our pipeline covers all four phases of the cell cycle, which we believe will improve the chances of successfully developing and commercializing novel drugs that work on their own or in combination with approved conventional chemotherapies or with other targeted drugs to treat human cancers.

The ALIGN business, acquired in October 2007, provides us with the foundation to build a commercial organization focused on cancer that is complementary to our oncology/hematology products in development and is part of Cyclacel's strategy to build a diversified biopharmaceutical business. William C. Collins, who was the Seller's Chief Executive Officer and manager, has become General Manager of ALIGN Pharmaceuticals, LLC.

Our corporate headquarters is located in Berkeley Heights, New Jersey, with our research facilities located in the United Kingdom. From our inception in 1996 through September 30, 2007, 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, 2007, our accumulated deficit during the development stage was \$151.0 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 general and administrative costs.

As of September 30, 2007, we have not generated any product revenue but have financed our operations and internal growth through private placements of our common stock and preferred securities, licensing revenue, interest on investments, government grants and research and development tax credits. Our revenue has consisted of collaboration and grant revenue. We have not generated any revenue from sales of commercial products; however, following the acquisition of ALIGN in October, 2007 we expect to generate modest product revenue during the remainder of 2007.

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

On October 5, 2007, Achilles Acquisition, LLC (renamed immediately following the acquisition to ALIGN Pharmaceuticals, LLC ("ALIGN")), a wholly-owned subsidiary of Cyclacel entered into a definitive asset purchase agreement (the "Agreement") with ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC (together, the "Sellers"), to acquire substantially all of the Sellers' assets (the "Transaction"). The closing of the Transaction occurred simultaneously with the execution of the Agreement (the "Closing Date").



Table of Contents

Cyclacel through ALIGN, 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.

As consideration for the Transaction and pursuant and subject to the terms of the Agreement, we, through ALIGN, paid \$3,331,428 in cash to the Sellers and shall pay an additional aggregate amount of \$452,464 within 130 business days from the Closing Date, in cash, shares of the Company's common stock, or a combination thereof, as further described in the Agreement. In addition, the Company may be required to issue to the Sellers a maximum number of shares of common stock, in an amount equal to \$1,116,108, issuable at a price per share of \$6.06 (the average closing price of Cyclacel's common stock on the 90 trading days immediately before the Closing Date), which issuance is contingent upon the achievement of certain operational and financial milestones and subject to satisfaction of any outstanding indemnification obligations by the Sellers. The Company will issue the shares of common stock only to the extent that the milestones are achieved. The results of operations of Cyclacel will include the results of operations from ALIGN from the Closing Date. The assets and liabilities of ALIGN will be recorded as of the Closing Date at their estimated fair values. The transaction is expected to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code.

Results of Operations

On March 27, 2006, Xcyte Therapeutics, Inc. completed the Stock Purchase Agreement with Cyclacel Group plc whereby Xcyte acquired all of the outstanding shares of common stock of Cyclacel Limited, from Cyclacel Group plc. Xcyte changed its name to Cyclacel Pharmaceuticals, Inc., or Cyclacel, and Cyclacel was listed on the Nasdaq Global Market under the ticker symbol CYCC. As explained in detail in Note 5 of the unaudited Condensed Consolidated Financial Statements, the transaction with Xcyte was accounted for as a reverse merger and Cyclacel Limited was considered to have acquired Xcyte on March 27, 2006. As a consequence, the comparative period for the nine months ended September 30, 2006 includes the three-month period to March 31, 2006 which reflects the results of Cyclacel Limited only, while the current nine month period ended September 30, 2007 reflects the results of the combined companies from January 1, 2007 through September 30, 2007.

Three Months Ended September 30, 2006 and 2007

Revenues

The following table summarizes the components of our revenues for the three months ended September 30, 2006 and 2007:

| Three months ended September 30, | 2006 | 2007    | Difference | Difference    | (\$000s) | %  | Collaboration and |    |
|----------------------------------|------|---------|------------|---------------|----------|----|-------------------|----|
| research and development revenue | 27   | — (27)  | 100        | Grant revenue | 56       | 33 | (23)              | 41 |
| revenue                          | 83   | 33 (50) | 60         |               |          |    |                   |    |

Collaboration and research and development revenue is 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.

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

19

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Table of Contents

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;
- regulator-related costs;
- and identification of drug candidates;
- and materials;
- costs;
- and facility expenses for our laboratories; and
- fees.
- clinical trial and
- pre-clinical studies;
  - screening
- laboratory supplies
- technology license
  - rent
- scientific consulting

The following table provides information with respect to our research and development expenditure for the three months ended September 30, 2006 and 2007:

| Three months ended September 30,     | 2006  | 2007  | Difference | Difference | (\$000s)                                | % Sapacitabine | 448  |
|--------------------------------------|-------|-------|------------|------------|---|----------------|------|
| 477                                  | 29    | 6     | Seliciclib | 1,061      | 758                                     | (303)          | (29) |
|                                      |       |       | CYC116     | 1,679      | 672                                     | (1,007)        | (60) |
| Other research and development costs | 871   | 2,542 | 1,671      | 192        | Total research and development expenses |                |      |
| 4,059                                | 4,449 | 390   | 10         |            |   |                |      |

Total research and development expenses represented 60% and 70% of our operating expenses for the three months ended September 30, 2006, and 2007, respectively.

Research and development expenditure increased 10% or \$0.4 million from \$4.0 million for the three months ended September 30, 2006 to \$4.4 million for the three months ended September 30, 2007. In September 2006, we recorded a charge of \$0.1 million for the three months ended September, 2006 in connection with the stock options granted to certain of our employees under FAS123R as compared to \$0.2 million for the three months ended September 30, 2007. During the three months ended September 30, 2006, there were higher costs related to seliciclib with the start of the APPRAISE Phase IIb trial and costs associated with CYC116 as the program was in full pre-clinical studies during 2006 but in Phase I trials in 2007.

The future

We plan to increase our investment 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.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the general and administrative expenses for the three months ended September 30, 2006 and 2007:

20

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## Table of Contents

Three months ended September 30, 2006 2007 Difference Difference (\$000s) % Total general and administrative expenses 2,511 2,064 (447) (18)

Our general and administrative expenditure decreased by \$0.4 million from \$2.5 million for the three months ended September 30, 2006 to \$2.1 million for the three months ended September 30, 2007. The reduction in expenses was primarily attributable to lower costs incurred on audit and accountancy, work related to compliance with the Sarbanes-Oxley in 2006 which is now being sustained at a reduced level of cost and staff recruitment.

## The future

As a public company, we operate in an increasingly demanding regulatory environment that requires us to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, and the Nasdaq Global Market for our common stock and Nasdaq Capital Market for our preferred stock, including those related to expanded disclosures, accelerated reporting requirements and more complex accounting rules. There will be costs incurred with integrating ALIGN into the group as well as expanding the sales team during the remainder of 2007. We expect that our general and administrative expenses will continue to increase in subsequent periods due to these requirements.

## Restructuring charge

As of September 30, 2007 the restructuring liability associated with the exiting Bothell facility was \$1.8 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, 2007.

## Other income (expense)

Other income (expense) is comprised of the change in valuation of the derivative, change in value of liability classified warrants, interest income and interest expense. The following table summarizes the other income (expense) for the three month ended September 30, 2006 and 2007:

| Three months ended September 30, | 2006  | 2007  | Difference | Difference | (\$000s) | %   | Change in valuation of |
|----------------------------------|-------|-------|------------|------------|----------|-----|------------------------|
| derivative                       | (64)  | (19)  | 45         | 70         | —        | 951 | 951                    |
| Change in valuation of warrants  | 793   | 955   | 162        | 20         | 951      | 951 | 100                    |
| Interest income                  | 1,833 | 1,156 | 171        |            |          |     |                        |
| Interest expense                 |       |       | (52)       | (54)       | (2)      | (4) |                        |
| Total other income (expense)     |       |       |            |            |          |     | 677                    |

The change in valuation of the derivative of \$19,000 for the three months ended September 30, 2007 is associated with the dividend make-whole payment on our outstanding convertible exchangeable preferred stock. For the three months ended September 30, 2006, the derivative valuation expense was \$64,000.

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, we recognized the change in the value of warrants of approximately \$1.0 million, as other income in the consolidated statement of operations.



Table of Contents

The increase in interest income of \$0.2 million to \$1.0 million for the three months ended September 30, 2007 from \$0.8 million for the three months ended September 30, 2006 is primarily attributable to higher average balances of cash and cash equivalents and short-term investments in 2007 as compared to 2006 as a result of our registered direct offering in February 2007.

Interest expense for the three months ended September 30, 2007 increased by \$2,000 from \$52,000 for the three months ended September 30, 2006 to \$54,000 for the three months ended September 30, 2007. During the three months ended September 30, 2006 and 2007 interest expenses resulted primarily from accretion expense associated with the Bothell lease restructuring provision.

The future

The valuations of the dividend make-whole payment and the liability-classified warrants will continue to be re-measured at the end of each reporting period. The valuations of the derivative and warrants are dependent upon many factors, including estimated market volatility, and may fluctuate significantly and could have a significant impact on our statement of operations.

A further \$0.2 million of accretion expense associated with the Bothell lease restructuring charge will be recognized over the remaining life of the lease to December 2010.

Income tax benefit

Credit is taken for research and development tax credits, which are claimed from the United Kingdom's taxation and customs authority, 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, 2006 and 2007:

| Three months ended September 30, | 2006 | 2007 | Difference | Difference | (\$000s) | % Total income tax |
|----------------------------------|------|------|------------|------------|----------|--------------------|
| benefit                          | 603  | 433  | (170)      | (28)       |          |                    |

Research and development tax credits recoverable decreased by \$0.2 million from \$0.6 million for the three months ended September 30, 2006 to \$0.4 million for the three months ended September 30, 2007. This decrease was a reflection of a decrease in income taxes available for recovery as a consequence of the lower eligible research and development expenses in 2007.

The future

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

Nine Months Ended September 30, 2006 and 2007

Revenues

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The following table summarizes the components of our revenues for the nine months ended September 30, 2006 and 2007:

| Nine months ended September 30,  | 2006 | 2007 | Difference | Difference | (\$000s)      | %   | Collaboration and |
|----------------------------------|------|------|------------|------------|---------------|-----|-------------------|
| research and development revenue | 152  | 10   | (142)      | (93)       | Grant revenue | 118 | 107 (11) (9)      |
| Total revenue                    | 270  | 117  | (153)      | (57)       |               |     |                   |

22

Table of Contents

Collaboration and research and development revenue is derived from several agreements under which we provide 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.

Research and development expenses

The following table provides information with respect to our research and development expenditure for the nine months ended September 30, 2006 and 2007:

|                                      | Nine months ended September 30, 2006 | 2007  | Difference | Difference | (\$000s)                                | %      | Sapacitabine | 1,367   |        |       |       |         |      |
|--------------------------------------|--------------------------------------|-------|------------|------------|---|--------|--------------|---------|--------|-------|-------|---------|------|
|                                      | 1,862                                | 495   | 36         | Seliciclib | 2,027                                   | 2,405  | 378          | 19      | CYC116 | 5,230 | 1,564 | (3,666) | (70) |
| Other research and development costs | 8,572                                | 6,911 | (1,661)    | (19)       | Total research and development expenses | 17,196 | 12,742       | (4,454) | (26)   |       |       |         |      |

Total research and development expenses represented 64% and 65% of our operating expenses for the nine months ended September 30, 2006 and 2007, respectively.

Research and development expenses decreased by 26% or \$4.5 million from \$17.2 million for the nine months ended September 30, 2006 to \$12.7 million for the nine months ended September 30, 2007. The overall reduction relates primarily to a decrease in the charge for stock-based compensation of \$5.5 million from \$6.1 million for the nine months ended September, 30 2006 to \$0.6 million for the nine months ended September 30, 2007 as a result of the stock options granted during June 2006 being two-thirds vested immediately upon grant. Additionally, there was a decrease in expenditure on CYC116 as the program was in full pre-clinical studies during 2006, offset by higher costs related to sapacitabine and seliciclib with ongoing Phase I and Phase II trials during 2007.

General and administrative expenses

The following table summarizes the general and administrative expenses for the nine months ended September 30, 2006 and 2007:

|  | Nine months ended September 30, 2006 | 2007  | Difference | Difference | (\$000s) | % | Total general and administrative expenses |
|--|--------------------------------------|-------|------------|------------|----------|---|---|
|  | 9,456                                | 6,883 | (2,573)    | (27)       |          |   |   |

Total general and administrative expenses represented 35% of our operating expenses for the nine months ended September 30, 2006 and 2007, respectively.

Our general and administrative expenditure decreased by \$2.6 million from \$9.5 million for the nine months ended September 30, 2006 to \$6.9 million for the nine months ended September 30, 2007. The reduction in expenses was primarily attributable to a decrease in the charge for stock based compensation of \$2.6 million from \$3.3 million for the nine months ended September, 30 2006 to \$0.7 million for the nine months ended September 30, 2007.



## Table of Contents

## Restructuring charge

The following table summarizes the restructuring charges for the nine months ended September 30, 2006 and 2007:

| Nine months ended September 30, | 2006 | 2007  | Difference | Difference | (\$000s) | % Total restructuring charge |
|---------------------------------|------|-------|------------|------------|----------|------------------------------|
| 225                             | 81   | (144) | (64)       |            |          |                              |

In March 2006, the Company assumed an accrued restructuring liability in relation to the Bothell manufacturing facility, calculated as the net present value of the difference between the remaining lease payments due less the estimate of net sublease income and expenses. In September 2006, the Company entered into an Exclusive Subleasing Agency Agreement in an attempt to achieve the successful sublet of the facility and the market assessment from our real estate agent was that it was difficult to lease space in the Bothell area and the original estimate of obtaining an early tenant was optimistic. On the basis of continued market review we assessed that the facility may have a possibility of being sublet by the beginning of 2008, albeit at a reduced capacity. As a result of this, we have recorded an additional provision in the first quarter of 2007 of \$0.1 million in recognition of reduced projected sublease income under a sublease agreement. 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, 2007.

## Other income (expense)

The following table summarizes the other income (expense) for the nine months ended September 30, 2006 and 2007:

| Nine months ended September 30, | 2006  | 2007  | Difference | Difference                      | (\$000s) | % Change in valuation of |
|---------------------------------|-------|-------|------------|---------------------------------|----------|--------------------------|
| derivative (162)                | (89)  | 73    | 45         | Change in valuation of warrants | —        | 2,815                    |
| income 1,565                    | 2,769 | 1,204 | 77         | Interest expense                | (178)    | (154)                    |
| (expense) 1,225                 | 5,341 | 4,116 | 336        |                                 | 24       | 13                       |
|                                 |       |       |            | Total other income              |          |                          |

The change in derivative value of \$162,000 and \$89,000, respectively for the nine months ended September 30, 2006 and 2007 is associated with the dividend make-whole payment on our outstanding convertible exchangeable preferred stock.

The change in valuation of warrants relates to the issue of warrants to purchase shares of 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, we recognized the change in the value of warrants of approximately \$2.8 million, as other income in the consolidated statement of operations.

The increase in interest income of \$1.2 million to \$2.8 million for the nine months ended September 30, 2007 from \$1.6 million for the nine months ended September 30, 2006, is primarily attributable to higher average balances of cash and cash equivalents and short-term investments in 2007 as compared to 2006 as a result of the Company's financing activities.

Interest expense for the nine months ended September 30, 2007 decreased by \$24,000 as compared to the same period in 2006. During the nine months ended September 30, 2006 interest expenses resulted

24

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Table of Contents

primarily from interest associated with a government loan, the principal of which was repaid in the fourth quarter of 2005. During the nine months ended September 30, 2007 interest expense resulted primarily from accretion expense associated with the Bothell lease restructuring provision. During the nine months ended September 30, 2007, accretion expense amounted to approximately \$0.1 million.

Income tax benefit

Credit is taken for research and development tax credits, which are claimed from the United Kingdom's taxation and customs authority, 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, 2006 and 2007:

|  | Nine months ended September 30, 2006 | 2007  | Difference | Difference | (\$000s) | % Total income tax benefit |
|--|--------------------------------------|-------|------------|------------|----------|----------------------------|
|  | 1,659                                | 1,549 | (110)      | (7)        |          |                            |

Research and development tax credits recoverable decreased by \$0.1 million from \$1.7 million for the nine months ended September 30, 2006 to \$1.6 million for the nine months ended September 30, 2007. This decrease was a reflection of a decrease in income taxes available for recovery as a consequence of the lower eligible research and development expenses in 2007.

Liquidity and Capital Resources

The following is a summary of our key liquidity measures at December 31, 2006 and September 30, 2007:

| December 31, 2006 | September 30, 2007 | (\$000s) | Cash and cash equivalents | 44,238              | 31,113 | Short-term investments, available for sale | 9,764           |        |
|-------------------|--------------------|----------|---------------------------|---------------------|--------|--|-----------------|--------|
| 37,430            | Current assets     | 58,165   | 75,166                    | Current liabilities | 7,921  | 10,901                                     | Working capital | 50,244 |
| 64,265            |                    |          |                           |                     |        |  |                 |        |

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 through 2008.

At September 30, 2007, we had cash and cash equivalents and short-term investments of \$68.5 million as compared to \$54.0 million at December 31, 2006. This higher balance at September 30, 2007 was primarily due to the receipt of net proceeds of \$33.4 million from the registered direct offering in the first quarter of 2007. Since our inception, we have not generated any product revenue and have relied primarily on the proceeds from sales of equity and preferred securities to finance our operations and internal growth. Additional funding has come through interest on investments, licensing revenue, government grants and research and development tax credits. We have incurred significant losses since our inception. As of September 30, 2007, Cyclacel had an accumulated deficit of \$151.0 million.

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In our Annual Report on Form 10-K for the year ended December 31, 2006 under the heading “Liquidity and Capital Resources,” we outlined our contractual obligations and other commitments. For the nine months ended September 30, 2007, there have been no material changes in our contractual obligations and other commitments.

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2006 and 2007, is summarized as follows:

25

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Table of Contents

|                                 |   |        |          |   |        |
|---------------------------------|---|--------|----------|---|--------|
| Nine months ended September 30, | 2006  | 2007   | (\$000s) | Net cash used in operating activities     | 16,781 |
| 17,630                          | Net cash provided by (used in) investing activities | 4,239  | (28,229) | Net cash provided by financing activities | 57,779 |
|                                 |   | 32,512 |          |   |        |

Operating activities

Net cash used in operating activities increased \$0.8 million, to \$17.6 million for the nine months ended September 30, 2007 from \$16.8 million for the nine months ended September 30, 2006.

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 \$12.5 million, adjusted for material non-cash activities comprising amortization of investment premiums (discounts), change in valuation of derivative, change in valuation of liability-classified warrants, depreciation and amortization, non-cash stock based compensation expense and provision for restructuring costs, amounting to \$2.3 million and net increase in working capital of \$2.8 million due to an increase in amounts receivable combined with a net decrease in accounts payable and accrued expenses.

Net cash used in operating activities during the nine months ended September 30, 2006 of \$16.8 million resulted from our net operating loss of \$23.7 million, adjusted for material non-cash activities comprising depreciation and amortization, and non-cash stock based compensation expense amounting to \$10.3 million, and net decrease in working capital of \$3.6 million, primarily due to a net decrease in accounts payable and accrued expenses.

Investing activities

Net cash provided by investing activities for the nine months ended September 30, 2006 was \$1.0 million compared to a use of \$28.2 million for the nine months ended September 30, 2007.

For the nine months ended September 30, 2007, we purchased \$27.4 million of gross marketable securities.

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, 2006 and 2007 totaled approximately \$0.1 million and \$0.8 million respectively, for normal replacements and improvements.

Financing activities

Net cash provided by financing activities decreased by \$28.5 million, from \$61.0 million for the nine months ended September 30, 2006 to \$32.5 million for the nine months ended September 30, 2007.

For the nine months ended September 30, 2007 the net cash provided by financing activities related to \$33.4 million in net proceeds from our registered direct financing, offset by the payment of our preferred stock dividend of \$0.9 million and by payment of capital lease obligations of \$0.1 million.

For the nine months ended September 30, 2006 the net cash provided by financing activities related primarily to the \$17.9 million of cash, and cash equivalents assumed on the Stock Purchase with Xcyte on March 27, 2006 and the April 2006 net proceeds of \$42.6 million from the private placement of common stock in April 2006, offset by costs associated with the Stock Purchase of \$2.0 million and the payment of capital lease obligations of \$0.2 million.

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 in October, 2007 we will not receive any product revenue on our product 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.

## Table of Contents

We currently anticipate that our cash, cash equivalents and marketable securities will be sufficient to fund our operations at least through December 31, 2008. However, we will need to raise substantial additional funds to continue our operations. We cannot be certain that any of our programs will be successful or that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in development, should they succeed 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 and ;

• the costs of acquiring or investing in businesses, product candidates and technologies;

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

• the costs and timing of seeking and obtaining FDA and other regulatory approvals;

• the effect of competing technological and market developments; and

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

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

## 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 financial statements.

## Stock-based Compensation

On January 1, 2006, we adopted SFAS 123R. Under SFAS 123R, the fair value of stock options and other equity-based compensation must be recognized as expense in the statements of operations over the requisite service period of each award. 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, 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.

27

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## Table of Contents

### Derivative Instrument

#### Make-whole provision included in our preferred stock

The terms of our November 2004 convertible preferred stock offering include a dividend make-whole payment feature. If we had elected to automatically convert, or the holder elected to voluntarily convert, some or all of the convertible preferred stock into shares of our common stock prior to November 3, 2007, then we would have made an additional payment on the convertible preferred stock equal to the aggregate amount of dividends that would have been payable on the convertible preferred stock through and including November 3, 2007, less any dividends already paid on the convertible preferred stock. This make-whole payment feature was not exercised prior to 3rd November by either Cyclacel or the preferred stock holders. This additional payment would have been payable in cash or, at our option, in shares of our common stock, or a combination of cash and shares of common stock. This dividend make-whole payment feature is considered to be an embedded derivative and has been recorded on the balance sheet at fair value as a current liability. We will be required to recognize other income (expense) in our statements of operations as the fair value of this derivative fluctuates from period to period. The accounting for derivatives is complex, and requires significant judgments and estimates in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The fair value of the dividend make-whole payment feature is based on various assumptions, including the estimated market volatility and discount rates used in determination of fair value. The use of different assumptions may have a material effect on the estimated fair value amount and our results of operations.

### 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 its 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 and nine months ended September 30, 2007 was \$1.0 million and \$2.8 million, respectively.

### 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.

Under SFAS 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. There were no triggering events calling into question the recoverability of goodwill during the three and nine months ended September 30, 2007.

### 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, 2007 consisted of \$16.0 million in corporate bonds and \$21.4 million in federal agency and municipal obligations with contractual maturities of one year

28

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## Table of Contents

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, 2007 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. As of September 30, 2007 differences on foreign currency translation of \$0.8 million are shown as a component of other comprehensive loss. In the nine months ended September 30, 2007 exchange rate differences of \$0.5 million were charged in the statement of operations.

## Valuation Risk

### Derivate instruments

The Company’s convertible exchangeable preferred stock issued in November 2004 remained in place following completion of the Stock Purchase. The terms of the convertible exchangeable preferred stock include a dividend make-whole payment feature. This feature is considered to be an embedded derivative and was valued on the balance sheet at \$0.3 million at September 30, 2007. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

## Warrants

On February 16, 2007, the Company issued common stock and warrants. Pursuant to EITF 00-19 the Company recorded the fair value of the warrants as long-term liabilities. 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 and nine months ended September 30, 2007 was \$1.0 million and \$2.8 million, respectively. Fair value of the derivative instruments will be affected by estimates of various factors that may affect the respective instrument, including our stock price, the risk free rate of return and expected volatility in the fair value of our stock price. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

## Item 4. Controls and Procedures

### 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 September 30, 2007 our disclosure

controls and procedures are effective.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as such term is defined in SEC Rule 13a-15(e), that are designed to ensure that information required to be disclosed in our Securities Exchange Act of

29

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## Table of Contents

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

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Executive Vice President, 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.

Table of Contents

Part II. Other Information

Item 1. Legal proceedings

None

Item 1A. Risk Factors

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in this Quarterly Report on Form 10-Q. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed above in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere throughout this Quarterly Report on Form 10-Q. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

The Risk Factors included in Part 1, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007 have not materially changed other than as set forth below as a consequence of our acquiring the right to market and promote Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges in October 2007. Accordingly, the Risk Factors set forth below should be read in conjunction with those in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and this Quarterly Report on Form 10-Q.

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

Our customer base is highly concentrated.

Our principal customers are a small number of wholesale drug distributors. These customers comprise a significant part of the distribution network for pharmaceutical products in the United States. Three large wholesale distributors, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation, control a significant share of the market in the United States. Our ability to distribute any product, including Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges, and to recognize revenues on a timely basis is substantially dependent on our ability to maintain commercially reasonable agreements with each of these wholesale distributors and the extent to which these distributors, over whom we have no control, comply with such agreements. Our agreements with wholesaler distributors may contain terms that are not favorable, given our relative lack of market leverage (as a company with only three approved products) or other factors, which could adversely affect our commercialization of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges (collectively, the “ALIGN products”). The loss of any of these customers could materially and adversely affect our ability to distribute our products, resulting in a negative impact on our operations and financial condition.

Our distribution rights to the ALIGN products are licensed from others, and any termination of that license could harm our business.

We have in-licensed from Sinclair Pharmaceuticals, Ltd. the distribution rights to the ALIGN products. This license agreement imposes obligations on us. Although we are currently in compliance with all of our material obligations under this license, if we were to breach any such obligations, Sinclair would be permitted to terminate the license. This would restrict us from distributing the ALIGN products.

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

Our licensor and supplier Sinclair Pharmaceuticals, Ltd., contracts with third party manufacturers to supply the finished goods to us to meet our needs. If any of Sinclair's third party manufacturers

31

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## Table of Contents

service providers do not meet our or our licensor's requirements for quality, quantity or timeliness, or do not achieve and maintain compliance with all applicable regulations, demand for our products or our ability to continue supplying such products could substantially decline.

In all the countries where we sell our products, governmental regulations exist to define standards for manufacturing, packaging, labeling and storing. All of our suppliers of raw materials and contract manufacturers must comply with these regulations. Failure to do so could result in supply interruptions. In the United States, the FDA requires that all suppliers of pharmaceutical bulk material and all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA's cGMP regulations and guidelines. Failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications pre-approved by regulators for the content of the pharmaceutical product. If the operations of one or more of our manufacturers were to become unavailable for any reason, any required FDA review and approval of the operations of an alternative supplier could cause a delay in the manufacture of our products.

If we are unable to compete successfully in our market place, it will harm our business.

There are existing products in the marketplace that compete with our products. Companies may develop new products that compete with our products. Certain of these competitors and potential competitors have longer operating histories, substantially greater product development capabilities and financial, scientific, marketing and sales resources. Competitors and potential competitors may also develop products that are safer, more effective or have other potential advantages compared to our products. In addition, research, development and commercialization efforts by others could render our products obsolete or non-competitive. Certain of our competitors and potential competitors have broader product offerings and extensive customer bases allowing them to adopt aggressive pricing policies that would enable them to gain market share. Competitive pressures could result in price reductions, reduced margins and loss of market share. We could encounter potential customers that, due to existing relationships with our competitors, are committed to products offered by those competitors. As a result, those potential customers may not consider purchasing our products.

We may be required to defend lawsuits or pay damages in connection with the alleged or actual violation of healthcare statutes such as fraud and abuse laws, and our corporate compliance programs can never guarantee that we are in compliance with all relevant laws and regulations.

Our commercialization efforts in the United States are subject to various federal and state laws pertaining to promotion and healthcare fraud and abuse, including federal and state anti-kickback, fraud and false claims laws. Anti-kickback laws make it illegal for a manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase of a product. The federal government has published many regulations relating to the anti-kickback statutes, including numerous safe harbors or exemptions for certain arrangements. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid), claims for reimbursed products or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

Our activities relating to the sale and marketing of our products will be subject to scrutiny under these laws and regulations. It may be difficult to determine whether or not our activities, comply with these complex legal

requirements. Violations are punishable by significant criminal and/or civil fines and other penalties, as well as the possibility of exclusion of the product from coverage under governmental healthcare programs, including Medicare and Medicaid. If the government were to investigate or make allegations against us or any of our employees, or sanction or convict us or any of our employees, for violations of any of these legal requirements, this could have a material adverse

32

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Table of Contents

effect on our business, including our stock price. Our activities could be subject to challenge for many reasons, including the broad scope and complexity of these laws and regulations, the difficulties in interpreting and applying these legal requirements, and the high degree of prosecutorial resources and attention being devoted to the biopharmaceutical industry and health care fraud by law enforcement authorities. During the last few years, numerous biopharmaceutical companies have paid multi-million dollar fines and entered into burdensome settlement agreements for alleged violation of these requirements, and other companies are under active investigation. Although we have developed and implemented corporate and field compliance programs as part of our commercialization efforts, we cannot assure you that we or our employees, directors or agents were, are or will be in compliance with all laws and regulations or that we will not come under investigation, allegation or sanction.

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

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

We are at an early stage of development as a company and have a limited operating history on which to evaluate our business and prospects. While we expect to receive modest product revenues from the ALIGN business acquired in October 2007, since beginning operations in 1996 we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products. We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the Food and Drug Administration, or FDA, and other regulatory authorities in the United States, the European Union and elsewhere. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. Seliciclib and sapacitabine, our most advanced drug candidates for the treatment of cancer, are currently our only drug candidates in clinical trials and we cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

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

We have incurred operating losses in each year since beginning operations in 1996 due to costs incurred in connection with our research and development activities and general and administrative costs associated with our operations, and we may never achieve profitability. As of September 30, 2007, our accumulated deficit was \$150.8 million. Our net



loss for the three months ended September, 2006 and 2007 was \$5.4million and \$4.1 million respectively. Our net loss attributable to ordinary shareholders from inception through September 30, 2007 was \$188.9 million. Our initial drug candidates are in the early stages of clinical testing and we must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of its drugs. We expect to incur continued losses for several years, as we continue our research and development

33

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## Table of Contents

of our initial drug candidates, seek regulatory approvals, commercialize any approved drugs and market and promote Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. If our initial drug candidates are unsuccessful in clinical trials or we are unable to obtain regulatory approvals, or if our drugs are unsuccessful in the market, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, you could lose all or part of your investment.

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

Our successful commercialization of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges in the United States will depend on our ability to establish and maintain an effective sales and marketing organization in the United States. We are in the process of hiring, training and deploying additional marketing personnel and a national sales force. Prior to our launches of these products, we had never sold or marketed any products.

For our product candidates currently under development, our strategy is to develop compounds through the Phase II stage of clinical testing and market or co-promote certain of our drugs on our own. We have limited sales, marketing or distribution capabilities. We will depend primarily on strategic alliances with third parties, which have established distribution systems and sales forces, to commercialize our drugs. To the extent that we are unsuccessful in commercializing any drugs or devices ourselves or through a strategic alliance, product revenues will suffer, we will incur significant additional losses and our share price will be negatively affected.

We may not be able to obtain approval in additional countries to market Numoisyn® Liquid.

Numoisyn® Liquid is currently approved for marketing in the United States and we own the rights to market the drug in Canada. There is no guarantee that we will be able to obtain approval to market Numoisyn® Liquid in Canada and hence market the drug and earn potential sales revenue in Canada.

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

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

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

We are highly dependent on our senior management and key scientific, technical and sales and marketing personnel. Competition for these types of personnel is intense. The loss of the services of any member of our senior management, scientific, technical or sales or marketing staff may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on our business, operating results and financial condition. We also rely on consultants and advisors to assist us in formulating our strategy. All of our

consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us. With the acquisition of ALIGN, the success of the commercialization of those products depends, in large part, on our continued ability to develop and maintain important relationships with leading key distributors and research and medical institutions. Failure to do that could have a material adverse effect on our ability to commercialize the ALIGN products.

34

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## Table of Contents

We intend to expand and develop new drug candidates. We will need to hire additional employees in order to continue our clinical trials and market our drug candidates. This strategy will require us to recruit additional executive management and scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. The inability to attract and retain sufficient scientific, technical and managerial personnel could limit or delay our product development efforts, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

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

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

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

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

It is necessary that our and our distribution partners' products, including Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges achieve and maintain market acceptance. If our drug candidates are approved by the FDA or by another regulatory authority, the resulting drugs, if any, may not gain market acceptance among physicians, healthcare providers and payors, patients and the medical community. The degree of market acceptance of any of our approved drugs or devices will depend on a variety of factors, including:

- timing of market introduction, number and clinical profile of competitive drugs;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- cost-effectiveness;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors;
- prevalence and

severity of adverse side effects; and

advantages over alternative treatment methods.

- other potential

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

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

35

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## Table of Contents

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

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

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

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

Due to the acquisition of ALIGN, we now have the right to commercially market products. We are exposed to additional risks of product liability claims. These risks exist even with respect to those drugs and devices that are approved for commercial sale by the FDA or other regulatory authorities in the United States, the European Union or elsewhere and manufactured in facilities licensed and regulated by the FDA or other such regulatory authorities. We have secured limited product liability insurance coverage, but may not be able to obtain such insurance on acceptable terms with adequate coverage, or at a reasonable cost. There is also a risk that third parties that we have agreed to indemnify could incur liability. Even if we were ultimately successful in product liability litigation, the litigation would consume substantial amounts of our financial and managerial resources and may create adverse publicity, all of which would impair our ability to generate sales of the litigated product as well as our other potential drugs.

If we infringe intellectual property rights of third parties, we may increase our costs or be prevented from being able to commercialize our drug candidates and/or the ALIGN products.

There is a risk that we are infringing or will infringe the proprietary rights of third parties because patents and pending applications belonging to third parties exist in the United States, the European Union and elsewhere in the world in the areas of our research and/or the ALIGN products. Others might have been the first to make the inventions covered by each of our or our licensors’ pending patent applications and issued patents and might have been the first to file patent applications for these inventions. In addition, because the patent application process can take several years to complete, there may be currently pending applications, unknown to us, which may later result in issued patents that

cover the production, manufacture, commercialization or use of our drug

36

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Table of Contents

candidates. In addition, the production, manufacture, commercialization or use of our product candidates may infringe existing patents of which we are not aware. Numerous third-party United States and foreign issued patents and pending applications exist in the area of kinases, including CDK, Aurora and Plk for which we have research programs. Because patent applications can take several years to issue, there may be pending applications that may result in issued patents that cover our technologies or product candidates. For example, some pending patent applications contain broad claims that could represent freedom to operate limitations for some of our kinase programs should they be issued unchanged. If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that the owner asserts that we infringe its patents. In one case we have opposed a European patent relating to human aurora kinase. We are also aware of a corresponding U.S. patent containing method of treatment claims for specific cancers using aurora kinase modulators which, if held valid, could potentially restrict the use of our aurora kinase inhibitors once clinical trials are completed.

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

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder;
- decide to move some of our screening work outside Europe;
- be required to pay substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a competitor's patent or other proprietary rights; or
- be required to redesign the formulation of a drug candidate so it does not infringe, which may not be possible or could require substantial funds and time.

Intellectual property rights of third parties could adversely affect our ability to commercialize our drug candidate and/or the ALIGN products.

If patents issued to third parties contain valid claims that cover our compounds or their manufacture or uses relevant to our development plans, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We are aware of several published patent applications, and understand that others may exist, that could support claims that, if granted, could cover various aspects of our developmental programs, including in some cases particular uses of our lead drug candidate, seliciclib, sapacitabine or other therapeutic candidates, or gene sequences and techniques that we use in the course of our research and development. In addition, we understand that other applications exist relating to potential uses of seliciclib and sapacitabine that are not part of our current clinical programs for these compounds. Although we intend to continue to monitor these applications, we cannot predict what claims will ultimately be allowed and if allowed what their scope would be. If a patent is issued that covers our compounds or their manufacture or uses or screening assays related to our development plans then we may not be in a



position to commercialize the related drug candidate unless we successfully pursue litigation to have that patent invalidated or enter into a licensing arrangement with the patent holder. Any such litigation would be time consuming and costly, and its outcome would not be guaranteed, and we cannot be certain that we would be able to enter into a licensing arrangement with the patent holder on commercially reasonable terms. In either case, our business prospects could be materially adversely affected. In one case we have opposed a granted European patent related to human aurora kinase. We are also aware of a corresponding US

37

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Table of Contents

patent containing method of treatment claims for specific cancers using aurora kinase modulators, which if held valid, could potentially restrict the use of certain of our aurora kinase inhibitors.

Our common stock may have a volatile public trading price.

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

- disclosure of actual or potential clinical results with respect to product candidates we are developing;
- regulatory developments in both the United States and abroad;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;
- concern about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;
- public announcements by our competitors or others; and
- general market conditions and comments by securities analysts and investors.

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

10 .1†

Asset Purchase Agreement by and between ALIGN Pharmaceuticals, LLC, ALIGN Holdings, LLC and Achilles Acquisition, LLC, dated October 5, 2007. 10 .2 Employment Offer Letter by and between Achilles Acquisition, LLC and William C. Collins, dated October 3, 2007. 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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Confidential treatment has been requested as to certain portions, which have been filed separately with the Securities and Exchange Commission.

38

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Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in Berkeley Heights, New Jersey, on November 7, 2007.

CYCLACEL PHARMACEUTICALS, INC. Dated: November 7, 2007 By: /s/ Paul McBarron Paul  
McBarron Executive Vice President, Finance, and  
Chief Operating Officer  
(Authorized Officer and Principal Financial Officer)

39

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