

Cyclacel Pharmaceuticals, Inc.  
Form 10-K  
March 13, 2008

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

FOR THE YEAR ENDED DECEMBER 31, 2007

OR

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

Commission file number 0-50626

CYCLACEL PHARMACEUTICALS, INC.  
(Exact name of Registrant as Specified in Its Charter)

Delaware

91-1707622 (State or Other Jurisdiction  
of Incorporation or Organization) (I.R.S. Employer  
Identification No.) 200 Connell Drive  
Suite 1500, Berkeley Heights,  
NJ 07922 07922 (Address of principal executive offices) (Zip Code)  
Registrant's telephone number, including area code: (908) 517-7330

Securities registered under Section 12(b) of the Exchange Act:

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Each Class	Name of Each Exchange on Which Registered	Title of
Common Stock, \$0.001 par value	The NASDAQ Stock	
Market LLC Preferred Stock, \$0.001 par value	Market LLC	

Indicate by check mark if the registrant is a well known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes      No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes      No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendments to this Form 10-K .

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

Large accelerated filer	Accelerated filer	Non-accelerated filer
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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 March 11, 2008 there were 20,433,129 shares of the registrant's common stock outstanding.

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### PART I

#### Item 1. Business

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

##### General

Cyclacel Pharmaceuticals, Inc. “Cyclacel” or the “Company” was incorporated in the state of Delaware in 1996 and is headquartered in Berkeley Heights, New Jersey with research facilities located in Dundee, Scotland and Cambridge, England. Cyclacel is a development-stage biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. We market directly in the U.S. Xclair™ Cream for radiation dermatitis and Numoisyn™ Liquid and Numoisyn™ Lozenges for xerostomia through our wholly-owned subsidiary ALIGN Pharmaceuticals, LLC. 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.

##### 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 or ALIGN, a wholly-owned subsidiary of Cyclacel, entered into a definitive asset purchase agreement with ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC collectively, the Sellers to acquire substantially all of the Sellers’ assets. The transaction closed on the same date.

Notably, we 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 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 our strategy to build a diversified biopharmaceutical business. Please refer to Note 4 of the consolidated financial statements for details of the transaction.

##### Corporate information

Our corporate headquarters are located at 200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922, and our telephone number is 908-517-7330. This is also where our medical and regulatory functions are located. Our primary research facility is located in Dundee, Scotland which is also the center of our structure-based drug design and development programs. A second research facility located in Cambridge, England, is focused on exploring the mechanism of mitosis or cell division in addition to discovering the function of new cancer genes and validating their use as potential druggable targets.

##### Overview

We are a diversified biopharmaceutical business dedicated to the discovery, development and commercialization of novel, targeted drugs to treat cancer and other serious disorders. Our strategy is focused on leading edge therapeutic

management of cancer patients based on a portfolio of three medicines marketed by our ALIGN subsidiary and a deep development pipeline. Our core area of expertise is in cell cycle biology, or the processes by which cells divide and multiply. We focus primarily on the discovery and development of orally available anticancer agents that target the cell cycle with the aim of slowing the progression or shrinking the size of tumors, and enhancing the quality of life and improving survival rates of cancer patients. We have been focused on the cell cycle since our inception.

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Three orally-available drugs are in clinical development: sapacitabine, in two randomized Phase 2 studies for the treatment of elderly acute myeloid leukemia, or AML and cutaneous T-cell lymphoma, or CTCL; seliciclib, in two randomized Phase 2 studies for the treatment of non-small cell lung cancer, or NSCLC and nasopharyngeal cancers, or NPC and CYC116, in Phase 1 in patients with solid tumors. We were founded by Professor Sir David Lane, a recognized leader in the field of tumor suppressor biology who discovered the p53 protein, which operates as one of the body's own anticancer "drugs" by inhibiting cell cycle targets. Our Chief Scientist, Professor David Glover, is a recognized leader in the biology of mitosis or cell division. Professor Glover discovered, among other cell cycle targets, the mitotic kinases, Polo and Aurora, enzymes that act in the mitosis phase of the cell cycle.

We are advancing our three anticancer drug candidates, sapacitabine, seliciclib and CYC116, through in-house research and development activities. 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.

Our expertise in cell cycle biology is at the center of our business strategy 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.

We have executed our strategy through the following activities during 2007:

Advancing our research and development programs

Sapacitabine Phase 2 CTCL initiation

initiation in patients with solid tumors

NPC initiation

APPRAISE Phase 2b NSCLC update

1 in patients with advanced leukemias or myelodysplastic syndromes or MDS data presented at the 2007 Annual Meeting of the American Society of Hematology.

2 elderly AML initiation

Developing our commercial platform

the sales and marketing assets of ALIGN in October 2007

Strengthening our financial position

proceeds of approximately \$33.4 million through a registered direct offering in February 2007

- 
- CYC116 Phase 1
- Seliciclib Phase 2
- Seliciclib
- Sapacitabine Phase
- Sapacitabine Phase
- Acquired
- Raised net
- Entered into a

Committed Equity Financing Facility or CEFF for up to \$60.0 million in December 2007

approximately \$58.8 million of cash and cash equivalents and short-term investments

Enhancing our management team

Gregory R. Reyes, M.D., Ph.D., Senior Vice President, Research

Collins, General Manager, ALIGN

Commercial products

On October 5, 2007, we acquired, through ALIGN the exclusive rights to sell and distribute three products in the United States used primarily to manage the effects of radiation or chemotherapy in cancer

- Ended 2007 with

- Named

- Named William C.

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patients: Xclair™ Cream, Numoisyn™ Liquid and Numoisyn™ Lozenges. All three products are approved in the United States under FDA 510 (k) or medical device registrations. All three products were launched in the United States in January 2006.

### Xclair™ Cream

Xclair™ is an aqueous cream containing sodium hyaluronate, or hyaluronic acid and glycyrrhetic acid that is formulated to relieve symptoms associated with radiation dermatitis. Sodium hyaluronate is the key water-regulating substance in human skin. Sodium hyaluronate has high viscoelasticity and lubricity. When sodium hyaluronate solution is applied on the surface of skin, it forms an air permeable layer that keeps skin moist and smooth. Small molecular weight sodium hyaluronate can penetrate into the dermis where it combines with water to promote microcirculation, nutrient absorption, and metabolism. Glycyrrhetic acid reduces inflammation and is believed to have immunomodulatory properties.

### Numoisyn™ Liquid

Numoisyn™ Liquid is an oral solution used to replace natural saliva when salivary glands are damaged. The viscosity of Numoisyn™ Liquid is similar to that of natural saliva. Linseed extract in Numoisyn™ Liquid contains mucins that provide superior viscosity and reduced friction compared to water or carboxymethylcellulose or CMC solutions. Linseed extract significantly reduces the symptoms of dry mouth, an effect that increases over time while Numoisyn™ Liquid is used.

### Numoisyn™ Lozenges

Numoisyn™ Lozenges dissolve slowly while moved around in the mouth. They contain sorbitol and malic acid to stimulate normal salivation and provide temporary relief of dry mouth in patients who have some residual secretory function and taste perception. Numoisyn™ Lozenges support saliva's natural protection of teeth so that teeth are not damaged with repeated use of the lozenges. They are sugar free and buffered with calcium to protect teeth. Numoisyn™ Lozenges have been demonstrated to be safe and effective for long-term use and are well tolerated by patients. Use of Numoisyn™ Lozenges improves subjective symptoms of dry mouth and does not cause bacteria or plaque formation or loss of tooth enamel hardness.



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### Research and Development Pipeline

The table below summarizes our current clinical and preclinical programs.

Program	Indication	Development Status	Target	Cell Cycle Mechanism	Oncology	
Sapacitabine, CYC682	Elderly AML	Phase 2 randomized trial on-going	DNA polymerase	G2 and S phase	Sapacitabine, CYC682	
Sapacitabine, CYC682	CTCL	Phase 2 randomized trial on-going	DNA polymerase	G2 and S phase	Sapacitabine, CYC682	
Advanced leukemias and MDS		Phase 1 trial on-going	DNA polymerase	G2 and S phase	Seliciclib, CYC202	
NSCLC	Phase 2b randomized trial on-going	CDK2/A, 2/E, 7, 9	G1/S	checkpoint and others	Seliciclib, CYC202	
NPC	Phase 2 randomized trial on-going	CDK2/A, 2/E, 7, 9	G1/S	checkpoint and others	CYC116	
Cancer	Phase 1 trial on-going	Aurora kinase & VEGFR2	Mitosis CDK Inhibitors, Second Generation	Cancer	Preclinical	CDK G1/S
checkpoint and others	Clotrimazole Analogs	Cancer	Preclinical	Cyclin expression blocker	G1 phase Plk Inhibitors	Cancer
Preclinical	Plk	G2/M	checkpoint	Hdm2 Inhibitors	Cancer	Preclinical
Hdm2	G1 phase	Cyclin Binding Groove Inhibitors	Cancer	Preclinical	Cyclin binding groove	G1 phase
Other therapeutic areas	Cell Cycle Inhibitors	Inflammatory Kidney Diseases	Phase 1 trial completed	CDK	G1/S	checkpoint and others
Cell Cycle Inhibitors	HIV/AIDS	Preclinical	CDK	Several GSK-3 Inhibitors	Type 2 Diabetes	Preclinical
GSK-3	N/A	Market opportunity in oncology				

Cancer remains a major life-threatening disease in the United States with approximately 3.2 million people afflicted by cancer and approximately 1.4 million new cases diagnosed every year. Five common solid cancer types: non-small cell lung, breast, ovarian, prostate and colorectal cancers, represent over 50% of all new cases of cancer in the United States each year and account for more than 50% of all cancer deaths in the United States.

Acute myeloid leukemia or AML is one of the most common types of leukemia or cancer in the blood and bone marrow. According to the American Cancer Society approximately 44,000 cases of leukemia are diagnosed annually in the United States of which about 13,400 are classified as AML. Leukemia is a deadly disease with an estimated 9,000 deaths annually in the United States, almost all in adults. The average age of a patient with AML is 67 and about two-thirds of AML patients are above 60 years old. The prognosis of AML in the elderly is poor.

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Lung cancer is a cancer starting in the lungs that often takes many years to develop. About 85% to 90% of all lung cancers are of the non-small cell type or NSCLC. According to the American Cancer Society an estimated 215,000 patients are diagnosed annually with non-small cell lung cancer in the United States. An estimated 380,000 new cases are diagnosed annually in the European Union. Non-small cell lung cancer is a deadly disease with an estimated 162,000 deaths annually in the United States.

Lymphoma is a cancer of lymphoid tissue, a part of the lymphatic system. Lymphoid tissue is formed by several types of immune system cells that work together mainly to resist infections. About 5% of all lymphomas start in the skin often staying there without spreading to internal organs and are called cutaneous lymphomas. The main cell types found in lymphoid tissue are B lymphocytes and T lymphocytes resulting in B-cell or T-cell lymphoma or CTCL. CTCL causes disfiguring skin lesions and severe itching. According to the American Cancer Society an estimated 3,000 patients are diagnosed annually with lymphoma in the skin in the United States.

Nasopharyngeal cancer or NPC develops in the nasopharynx, an area in the back of the nose toward the base of the skull. Although it is sometimes considered a head and neck or an oral cancer, nasopharyngeal cancer is different from these cancers. It is frequently fatal, spreads widely and has different risk factors such as Epstein-Barr virus or EBV infection. High EBV viral titers are considered an indicator of poor prognosis. According to the American Cancer Society an estimated 2,100 patients are diagnosed annually with nasopharyngeal cancer in the United States. An estimated 2,500 are diagnosed annually in the European Union but an estimated 70,000 new cases are diagnosed annually in the Asia Pacific region.

## Oncology Development Programs

We are generating several families of anticancer drugs that act on the cell cycle including nucleoside analogues, cyclin dependent kinase or CDK inhibitors and Aurora kinase/Vascular Endothelial Factor Receptor 2 or AK/VEGFR2 inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitor, AK and/or VEGFR inhibitor drugs, we believe that our drug candidates, are differentiated in that they are orally available and interact with unique target profiles and mechanisms. For example we believe that our sapacitabine is the only orally available nucleoside analogue presently being tested in Phase 2 trials in AML, seliciclib is the only orally available CDK inhibitor currently in Phase 2 trials and CYC116 is the only AK inhibitor in clinical trials that also interacts with VEGFR2.

In our development programs, we have been an early adopter of biomarker analysis to help evaluate whether our drug candidates are having their intended effect through their assumed mechanisms at different doses and schedules. Biomarkers are proteins or other substances whose presence in the blood can serve as an indicator or marker of diseases. Biomarker data from early clinical trials may also enable us to design subsequent trials more efficiently and to monitor patient compliance with trial protocols. We believe that in the longer term biomarkers may allow the selection of patients more likely to respond to its drugs for clinical trial and marketing purposes and increase the benefit to patients.

Our approach to drug discovery and development relies on proprietary genomic technology to identify gene targets, which are then progressed by means of structure-based drug design techniques through to the development stage. This approach is exemplified by our Aurora kinase, or AK, and Polo-like kinase, or Plk, inhibitor programs. Fundamentally, this approach to drug discovery and design aims to improve our ability to select promising drug targets in the early stages of the process so as to decrease compound attrition rates during the later, more expensive stages of drug development. We devote more resources initially to enrich the target selection process, so that we focus our efforts on targets that have a higher probability of yielding successful drug candidates. To this end, we have

assembled an integrated suite of sophisticated discovery and design technologies, together with highly skilled personnel.

#### Sapacitabine

Our lead drug candidate, sapacitabine, is an orally available prodrug of CNDAC, which is a novel nucleoside analog, or a compound with a structure similar to a nucleoside. A prodrug is a compound that

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has a therapeutic effect after it is metabolized within the body. CNDAC has a significantly longer residence time in the blood when it is produced in the body through metabolism of sapacitabine than when it is given directly. Sapacitabine acts through a dual mechanism whereby the compound interferes with DNA synthesis by causing single-strand DNA breaks and induces arrest of the cell division cycle at G2 phase. A number of nucleoside drugs, such as gemcitabine, or Gemzar® from Eli Lilly cytarabine, also known as Ara-C, are in wide use as conventional chemotherapies. Both sapacitabine and its major metabolite, CNDAC, have demonstrated potent anti-tumor activity in both blood and solid tumors in preclinical studies. In a liver metastatic mouse model, sapacitabine was shown to be superior to gemcitabine or 5-FU, two widely used nucleoside analogs, in delaying the onset and growth of liver metastasis.

Two Phase 1 studies of sapacitabine were completed in the United States by Daiichi-Sankyo Co., Ltd of Japan, from which we in-licensed sapacitabine, evaluating 87 patients in refractory solid tumors. A Phase 1b dose escalation clinical trial was completed in the United States for the treatment of patients with refractory solid tumors or lymphomas. Preliminary results were reported at the meeting of the 18th EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics in November 2006. The primary objective of the study was to evaluate the safety profile of sapacitabine administered twice daily for 14 consecutive days or 7 consecutive days every 21 days. Of the 37 treated patients, 28 received the drug twice daily for 14 days and 9 received the drug twice daily for 7 days. The dose-limiting toxicity was reversible myelosuppression. One patient treated at the maximum tolerated dose died of candida sepsis in the setting of grade 4 neutropenia and thrombocytopenia. Non-hematological toxicities were mostly mild to moderate. The best response by investigator assessment was stable disease in 13 patients, five with non-small cell lung cancer, two with breast cancer, two with ovarian cancer and one each with colorectal cancer, adenocarcinoma of unknown primary, gastrointestinal stroma tumor, and parotid acinar carcinoma.

In December 2007, at the 49th Annual Meeting of the American Society of Hematology or ASH, we reported updated interim results from a Phase 1 clinical trial of sapacitabine in patients with advanced leukemias and myelodysplastic syndromes, or MDS. Data from this study demonstrated that sapacitabine had a favorable safety profile and promising anti-leukemic activity in patients with relapsed and refractory acute myeloid leukemia or AML and MDS when administered by two different dosing schedules. The primary objective of the study is to determine the maximum tolerated dose, or MTD of sapacitabine administered twice daily for seven consecutive days every 21 days or three consecutive days per week for two weeks every 21 days. The MTD was reached at 375 mg on the seven-day schedule and 475 mg on the three-day schedule. Dose-limiting toxicity was gastrointestinal which included abdominal pain, diarrhea, small bowel obstruction and neutropenic colitis. One patient treated at the MTD of 375 mg on the seven-day schedule died of complications from neutropenic colitis. Among 46 patients, 42 with AML and 4 with MDS, in this dose escalating study, the best responses were complete remission or CR or complete remission without platelet recovery or CRp in six patients for an Overall Response Rate of 13%. In addition, 15 patients had a significant decrease in bone marrow blasts including seven with blast reduction to 5% or less. The study is ongoing at The University of Texas M. D. Anderson Cancer Center and is led by Dr. Hagop Kantarjian, Professor of Medicine and Chairman of the Leukemia Department and Dr. William Plunkett, Professor and Chief, Section of Molecular and Cellular Oncology, Department of Experimental Therapeutics.

In December 2007, we initiated an open-label, multicenter, randomized Phase 2 clinical trial of oral sapacitabine in elderly patients with AML who are previously untreated or in first relapse. This study follows the encouraging anti-leukemic activity observed in the Phase 1 trial of oral sapacitabine described above. The Phase 2 study is led by Dr. Hagop Kantarjian. The primary objective of this study is to evaluate the 1-year survival rate of three dosing schedules of sapacitabine in elderly patients with previously untreated or first relapsed AML. Secondary objectives are to assess the number of patients who have achieved a CR or CR without blood count recovery, or CRi, duration of CR or CRi, transfusion requirements, number of hospitalized days and safety.

The study uses a selection design with the objective of identifying a dosing schedule among three different schedules which produces a better one-year survival rate in the event that all three dosing schedules are active. The three dosing schedules are: 200 mg twice daily for seven days every 21 days, 300 mg twice daily for seven days every 21 days and 400 mg twice daily for three days per week for

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two weeks every 21 days The trial will enroll a total of approximately 60 patients or approximately 20 patients in each arm. The study uses a Bayesian continuous monitoring rule to stop accrual in one or more arms of the study in the event that a dosing schedule does not appear to have a sufficient number of responses.

In April 2007, we initiated a Phase 2 clinical trial in patients with advanced CTCL, a cancer of T-lymphocytes, or white blood cells, which causes disfiguring skin lesions and severe itching. The primary objective of the study is to evaluate tolerability and response rate of 50 mg and 100 mg regimens of sapacitabine both twice a day for three days per week for two weeks in a three week cycle in approximately 32 patients with progressive, recurrent, or persistent CTCL on or following two systemic therapies. The study uses a selection design to choose an optimal dose if both are active. Secondary objectives are to assess response duration, time to response, time to progression and relief of pruritus or itching.

This study has enrolled five patients to date at two hospital centers. According to recently available and preliminarily analyzed data, the best response by investigator assessment is partial response in one and stable disease in four patients. The partial response patient was crossed over from the 50 mg to the 100 mg regimen. As both regimens are well tolerated with no grade 2 toxicities, the protocol has been amended to increase dosing to 100 mg and 200 mg respectively using the same schedule as that used previously. The study is being expanded to include additional centers.

We have retained worldwide rights to commercialize sapacitabine with the exception of Japan where Daiichi-Sankyo has a right of first refusal to market the drug under terms to be negotiated.

## Selaciclib

Our second drug candidate, selaciclib, is a novel, first-in-class, orally available, CDK inhibitor. The compound selectively inhibits multiple kinase enzyme targets, specifically CDK2/E, CDK2/A, CDK7 and CDK9 that are central to the process of cell division and cell cycle control. Preclinical studies have shown that the drug works by inducing cell apoptosis, or cell suicide, in multiple phases of the cell cycle. To date, selaciclib has been evaluated in approximately 300 patients in several Phase 1 and 2 uncontrolled studies and has shown early signs of anti-cancer activity.

We have completed two Phase 1 trials that enrolled 24 healthy volunteers and three Phase 1 trials that enrolled a total of 84 cancer patients testing different doses and schedules. The primary toxicities observed were of a non-hematological nature including asthenia or weakness, elevation of liver enzymes, hypokalemia or decreased potassium levels, nausea and vomiting and elevation in creatinine. Although these trials were designed to test safety rather than efficacy of selaciclib given alone as monotherapy in patients with solid tumors who failed multiple previous treatments, several of these patients appeared to have benefited from selaciclib treatment.

Selaciclib was shown in a further Phase 1 study sponsored and conducted by independent investigators to have clinical antitumor activity in patients with nasopharyngeal cancer or NPC, measured as a decrease in the size of primary tumor and involved lymph nodes, as well as an increase in tumor cell death by biomarker analyses.

Four Phase 2 trials have been conducted in cancer patients to evaluate the tolerability and antitumor activity of selaciclib alone or in combination with standard chemotherapies used in the treatment of advanced NSCLC, or breast cancer. Interim data from two Phase 2 open-label studies of a total of 54 patients with NSCLC, suggest that selaciclib treatment did not aggravate the known toxicities of standard first and second-line chemotherapies nor appear to cause unexpected toxicities, although these trials were not designed to provide statistically significant comparisons. The

combination of seliciclib with standard dose of capecitabine was not well tolerated in patients with advanced breast cancer.

Seliciclib is currently being investigated in the Phase 2 APPRAISE study as a treatment for patients with advanced NSCLC. APPRAISE is a double-blinded, randomized study of single agent seliciclib versus best supportive care in patients with NSCLC treated with at least two prior systemic therapies. APPRAISE is led by Chandra P. Belani, M.D. at Milton S. Hershey Medical Center, Penn State University and Alan B. Sandler, M.D. at Vanderbilt-Ingram Cancer Center. The study's main objective is

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to learn the anti-tumor activity of seliciclib as a single agent in refractory NSCLC and help determine further development strategies. The study design is randomized discontinuation. All patients receive seliciclib at a dose of 1200 mg twice a day for three days for at least three cycles of two weeks each. Patients who achieve stable disease after three cycles will be randomized to continue on seliciclib or receive placebo with best supportive care. Patients in the placebo arm who progress will be given the option to cross-over and again receive seliciclib. The primary efficacy endpoint of APPRAISE is progression free survival, or PFS which will be measured in the randomized portion of the study. To detect a 100% increase in PFS from two to four months 80 randomized patients are required. An interim assessment of safety and efficacy will be performed after approximately 40 patients have been randomized. Approximately 160 patients will be enrolled. Calculation of the sample size was based on the assumption that approximately 50% will achieve stable disease during the initial six week treatment and undergo randomization.

According to recently available and preliminarily analyzed data 120 patients have been enrolled and 26 randomized. The major reason for discontinuation prior to randomization is progression of disease. In particular, 76% of enrolled patients have failed at least three prior treatment regimens and 75% progressed on the last treatment immediately prior to enrollment. A likely cause of the lower than assumed randomization rate may be that seliciclib does not have a high level of activity as a single agent in this population of patients with refractory NSCLC. Following consultation with the chair and co-chair of the study, Cyclacel intends to continue enrollment until 160 patients are enrolled or approximately 40 are randomized, whichever occurs first. A committee of independent experts will then be convened to review the blinded data and recommend whether the study should be continued in order to adequately assess the antitumor effect of seliciclib in this patient population. This will allow the Company to make an informed decision based on the study's objectives and available data.

In November 2007, we commenced a Phase 2 multicenter, international, blinded randomized study of oral seliciclib as a single agent in patients with nasopharyngeal cancer, or NPC. The primary objective is to evaluate 6-month progression free survival, or PFS, of two dosing schedules of seliciclib in approximately 75 patients with previously treated NPC. Secondary objectives are overall survival, response rate, response duration, safety and tolerability. The first part of the study is designed to confirm safety and tolerability of 400 mg twice a day for four days per week or 800 mg once a day for four days per week of seliciclib. It is open to approximately 12 to 24 patients with advanced solid tumors as well as patients with NPC. The second part of the study is designed to detect major differences between the two dosing schedules of seliciclib and a placebo group in terms of 6-month PFS in approximately 51 patients. The study uses a selection design to choose an optimal dosing schedule if both seliciclib dosing schedules are active.

We have retained worldwide rights to commercialize seliciclib.

## CYC116

In June 2007, we initiated a multicenter Phase 1 pharmacologic clinical trial of CYC116, an orally-available inhibitor of Aurora kinase A and B and VEGFR2, in patients with advanced solid tumors. The multicenter Phase 1 trial is designed to examine the safety and tolerability of CYC116 in patients with advanced solid tumors. The primary objective of the study is to determine the maximum tolerated dose. Secondary objectives are to evaluate the pharmacokinetic and pharmacodynamic effects of the drug and to document anti-tumor activity. We expect to report data from this Phase 1 pharmacologic clinical trial during the second half of 2008. We also expect to initiate a Phase I trial of CYC116 in hematological cancers. Aurora kinases, or AK, are a family of serine/threonine protein kinases that are only expressed in actively dividing cells and are crucial for the process of cell division, or mitosis. These proteins, which have been found to be over-expressed in many types of cancer, have generated significant scientific and commercial interest as cancer drug targets. The Aurora kinases were discovered by Professor David Glover, our Chief



Scientist. VEGFR2 is a receptor protein that plays a key regulatory role in the angiogenesis pathway, or blood vessel formation. VEGFR is targeted by recently approved drugs such as bevacizumab and sorafenib indicated for the treatment of several solid cancers, such as breast, colorectal, kidney, liver and lung. We have retained worldwide rights to commercialize CYC116.

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### Other Oncology Programs

#### Second Generation CDK Inhibitors

We have discovered over 600 novel CDK inhibitors that are members of a different chemical family than seliciclib. Based on their observed properties in preclinical tests, we believe that these second-generation compounds may prove to be more potent anticancer agents than seliciclib.

#### Clotrimazole Analogs

We have licensed from Lorus Therapeutics, Inc. a group of compounds based on CYC381, an orally available analog of clotrimazole, a commonly used antifungal drug. Investigators at Harvard Medical School observed that clotrimazole analogs exhibit anticancer activity by inhibiting internal calcium channels in cells and blocking the expression of important cell cycle targets called cyclins. Extensive preclinical testing prior to our licensing CYC381 suggested that it may be active in slowing the progression of several solid tumors in vivo. CYC381 is a racemic mixture or a combination of two different chemicals, called enantiomers, which cannot be easily separated. Before progressing into further development we must reproduce evidence of anticancer activity by one or more enantiomers with that reported by others before we in-licensed CYC381.

#### Plk Inhibitors

Our Plk inhibitor program targets the mitotic phase of the cell cycle with the objective of identifying potent and selective compounds which inhibit Plk1, a kinase active during mitosis. Inhibition of Plk1 results in cell cycle arrest at the G2/M checkpoint and induces apoptosis in cancer cells. Our Plk inhibitor program represents the first target gene that has emerged through the target validation process at our Cambridge laboratory and progressed to the drug discovery and chemistry stage. Because little was known about the nature and structure of Plk1 at the inception of the program we relied on advanced computer modeling and software-based design techniques to identify a series of compounds which selectively inhibit Plk.

#### Hdm2 Inhibitors

One of the key cell cycle regulatory proteins is p53, a protein discovered by our founder, Professor Sir David Lane. When active, p53 causes cell arrest at the G1/S checkpoint, inducing apoptosis in cancer cells. Under normal circumstances, p53 is held in an inactive form by binding to another regulatory protein, Hdm2. In this program, we have investigated ways of disrupting the interaction between Hdm2 and p53, thus activating p53. Through virtual screening technologies, we have identified two small molecule groups capable of breaking the binding between p53 and Hdm2.

#### Cyclin Binding Groove Inhibitors

The activity of CDK can be inhibited by two methods, either by blocking the ATP site, as is the case with seliciclib, or by inhibiting the substrate binding site on the cyclin protein. Preventing the cyclin from binding results in cell cycle arrest and induces apoptosis in cancer cells. We are currently investigating such cyclin binding groove inhibitors, continuing a program that was the subject of a two-year collaboration with AstraZeneca that concluded in mid-2003. We have retained all intellectual property rights associated with this program.

### Non-oncology Programs

## Cell Cycle Inhibitors in Inflammatory Kidney Disease

Preclinical results from several independent investigators suggest that cell cycle inhibitors such as seliciclib may also have a therapeutic benefit in the treatment of patients with inflammatory kidney diseases, which are sometimes referred to as glomerulonephritis. Because seliciclib acts to arrest the progress of the cell cycle, we believe it may be particularly effective in treating those forms of glomerulonephritis characterized by excessive cell proliferation. The most common forms of these are IgA nephritis and lupus nephritis.

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We entered into an evaluation and option agreement with Genzyme Corporation under which Genzyme evaluated two preclinical stage CDK inhibitors for development as drugs for renal disease. The agreement was terminated in 2007; Genzyme has no residual rights in relation to Cyclacel's compounds.

## CDK Inhibitors in Virology

Cell cycle inhibitors may be useful in the treatment of viral diseases to the extent that drugs can be developed that prevent the replication of virus-infected host cells and cause their death by apoptosis while sparing most uninfected cells. If this is proven in humans, cell cycle inhibitors may have significant potential in this area, as they do not interfere with viral targets and are less likely to induce viral resistance, a major cause of failure of currently available antiviral drugs. We have investigated a number of compounds in this program, some of which appear to reduce HIV levels in biological tests and induce antiviral effects that may be equivalent or more potent than many existing HIV/AIDS therapeutic agents. We intend to progress this program through collaboration with groups that specialize in virology research.

## GSK-3 Inhibitors in Type 2 Diabetes

Inhibition of Glycogen Synthase Kinase-3 or GSK-3 is an essential element in the body's regulation of blood sugar. GSK-3 regulates the glycogen synthase enzyme that indirectly controls glucose levels. In health humans insulin controls the regulation of energy conversion and storage by interacting with its receptor which results in the activation of PI-3 kinase that in turn inhibits GSK-3. In patients with adult onset or Type 2 Diabetes GSK-3 inhibition does not occur resulting in failure of glucose control and the energy storage mechanism. We believe that GSK-3 inhibitor drugs may be suitable for development as Type 2 Diabetes therapies. GSK-3 is a target that is structurally very similar to CDK. One of our objectives in discovering novel and highly specific CDK inhibitors for oncology indications is to avoid inhibition of GSK-3. The opposite is true for diabetes indications in which it is desirable to discover highly specific GSK-3 inhibitors that do not inhibit CDK. We have identified four chemical families of GSK-3 inhibitors some of which are potent at picomolar concentrations which we believe are among the most potent GSK-3 inhibitors disclosed in the literature. We have selected two lead compounds from the series, both of which have achieved proof-of-concept in the standard Zucker rat model of diabetes, demonstrating stimulation of glycogen synthase, improvement in glucose tolerance and regulation of triglycerides. We intend to progress this program through collaboration with groups that specialize in diabetes research.

## Technology and expertise

Our approach to drug discovery and development relies on proprietary genomic technology to identify gene targets, which are then progressed by means of structure-based design techniques through to the development stage. This approach is exemplified by our AK and Plk inhibitor programs. Fundamentally, this approach to drug discovery and design aims to improve our ability to select promising drug targets in the early stages of the process so as to decrease compound attrition rates during the later, more expensive stages of drug development. We devote more resources initially to enrich the target selection process, so that we focus our efforts on targets that have a higher probability of yielding successful drug candidates. To this end, we have assembled an integrated suite of sophisticated discovery and design technologies, together with highly skilled personnel.

## Business Strategy

Focus on the cell cycle and cancer

We are and intend to remain strongly focused on the development of novel, cell cycle-based therapies for the treatment of cancer and other serious disease indications:

- Our core area of expertise is in cell cycle biology and our scientists include recognized leaders in this field. In addition, our senior management has extensive experience in research, preclinical and clinical development and sales and marketing. Thus, we believe that we are well placed to exploit the significant opportunities that this area offers for new drug discovery and development.

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mechanism-targeted cell cycle drugs we are developing are designed to be highly selective in comparison to conventional chemotherapies, potentially inducing death in cancer cells while sparing most normal cells which may give rise to fewer side-effects.

- The novel, sapacitabine is the only orally available nucleoside analogue presently being tested in Phase 2 trials in AML, seliciclib is the only orally available CDK inhibitor currently in Phase 2 trials and CYC116 is the only AK inhibitor in clinical trials that also interacts with VEGFR2. We believe that with a deep pipeline of preclinical stage drug candidates, we are well positioned to realize some of the market potential of such drugs.
- We believe that our

Develop anticancer drug candidates in all phases of the cell cycle and multiple compounds for particular cell cycle targets

Targeting a broad development program focused on multiple phases of the cell cycle allows us to minimize risk while maximizing the potential for success and also to develop products that are complementary to one another.

Enter into partnering arrangements selectively, while developing our own sales and marketing capability

We currently retain all virtual all marketing rights to the compounds associated with our current clinical-stage drug programs. To optimize our commercial return, we intend to both enter into selected partnering arrangements, and to leverage our sales and marketing capability by retaining co-promotion rights as appropriate. Historically, we have developed compounds through the Phase 2 proof-of-efficacy stage before seeking a partner. We may be prepared to enter into partnering arrangements earlier than Phase 2 proof-of-concept trials in connection with drug programs outside our core competency in oncology.

## Patents, Proprietary Technology and Collaborations

We consider intellectual property rights to be vital and use a variety of methods to secure, protect and evaluate these rights. These include:

Ownership and enforcement of patent rights;

covering our own inventions in fields that we consider important to its business strategy;

with third parties granting us rights to patents in fields that are important to its business strategy;

assignment agreements with our employees and consultants;

agreements with our key employees and consultants;

agreements with our employees, consultants, and others having access to its proprietary information;

for the maintenance of laboratory notebooks to establish priority of our inventions;

studies from patent counsel;

agreements; and

- Patent applications
- License agreements
- Invention
- Non-compete
- Confidentiality
- Standard policies
- Freedom to use
- Material transfer

- Trademark

protection

In addition to our 31 U.S. patents, we own 17 patents that were granted by the European Patent Office, or EPO, for designated European countries, and 19 issued patents in other countries. The European granted patents expire between 2015 and 2023. In addition to the licenses we hold under the 17 patents issued in the United States, we hold licenses under 73 issued patents worldwide, 17 granted by the EPO for designated European countries and 56 issued in other countries. The licensed European granted patents expire between 2011 and 2022. Our patent strategy is to file patents on compounds and

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technologies in countries and jurisdictions that we consider important to our business. We usually file first in the United Kingdom and then extend our applications to other countries through the Patent Cooperation Treaty or PCT. In some cases, we file directly in the United States.

We give priority to obtaining substance of matter claims in the United States, the EPO, Japan and other important markets if such protection is available. We prefer substance of matter claims because they give us rights to the compounds themselves, and not merely a particular use. In addition to substance of matter claims, we seek coverage for medical uses, combination therapies, pharmaceutical forms of our compounds and synthetic routes where available and appropriate. Claims covering combination therapies and pharmaceutical forms can be valuable because the therapeutic effect of pharmaceuticals used in the anticancer field is often enhanced when individual therapeutics are used in particular combinations. The availability of protection in these areas can, however, vary from jurisdiction to jurisdiction and combination claims are particularly difficult to obtain for many inventions. We own 29 patent applications pending in the United States, 22 before the EPO, 12 pending PCT applications still in the international application phase, and over two hundred pending patent applications in other countries. Seven of this last group of pending patent applications were first filed, and have an earliest priority date, within the last twelve months. No assurances can be given that patents will be issued with respect to the pending applications, nor that the claims will provide equivalent coverage in all jurisdictions. Under the terms of our agreements with several universities and research institutions we also have the right to apply for patents in the name of those universities and institutions for inventions in which license rights are held. This gives us the ability to control the prosecution of certain patents that directly relate to business strategy. In addition to the pending patent applications referred to above that we own, there are 44 pending patent applications worldwide to which we have a license or an option to take a license.

Our patent filings for the second-generation CDK inhibitor research program exemplify our patent strategy. Out of over 600 compounds under investigation in this program we have filed patent applications seeking substance of matter protection that may be roughly grouped into 12 patent families. Of these, we have made a European application designating all European Patent Convention member states and direct national filings in the United States, Japan and several additional countries covering the compounds that we believe to be the most promising from a commercial standpoint. We have made additional PCT filings covering derivative compounds, medical uses and related technology. The first patent application from this family have resulted in the issuance of two U.S. patents with substance of matter claims covering a specific genus of compounds showing activity in preclinical and discover programs. Although issuance of a substance of matter claim in the United States is an indication that other countries may grant similar protection, the pending applications may not result in additional patent protection.

We hold patents to several technology-based systems, including families of patents covering our Fluorescence fluorescent assay techniques Penetratin, a drug delivery system. In addition, we have filed a portfolio of patents claiming the use of over one hundred specific genes as drug targets based on the identification of their function in mitosis.

Since publications in the scientific or patent literature often lag behind actual discoveries, we are not certain of being first to make the inventions covered by each of its pending patent applications or the first to file those patent applications. Generally, patent applications in the United States are maintained in secrecy for a period of 18 months or more, which increases the uncertainty we face. Moreover, the patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. As a result, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of



our products, any related patent may expire, or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent and the commercial opportunity of the product.

If patents are issued to others containing valid claims that cover our compounds or their manufacture or use or screening assays related thereto, we may be required to obtain licenses to these patents or to

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develop or obtain alternative technology. We are aware of several pending patent applications, and understand that others may exist, that could support claims that, if granted, would cover various aspects of our developmental programs, including in some cases particular uses of our lead drug candidates, sapacitabine, seliciclib, CYC116, 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 uses of sapacitabine and seliciclib that are not part of our current clinical programs for those compounds. Although we intend to continue to monitor these applications, it is not possible to predict whether these claims will ultimately be allowed or if they were allowed what their breadth would be. In addition, we may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would create substantial costs. In one case we have opposed a granted European patent related to human aurora kinase. We are also aware of a corresponding US 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. If competitors prepare and file patent applications in the United States that claim technology that we also claim, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office to determine which invention has priority. These proceedings could result in substantial costs, even if the eventual outcome is favorable to us. An adverse outcome in litigation could subject us to significant liabilities to third parties and require us to seek licenses of the disputed rights from third parties or to cease using the technology, even a therapeutic product, if such licenses are unavailable or too expensive.

## Licenses

Several of our programs are based on technology licensed from others. Our breach of an existing license or failure to obtain a license to technology required to develop, test and commercialize our products may seriously harm our business.

## Sapacitabine

We have entered into a license agreement with Daiichi-Sankyo Co., Ltd. of Japan or Daiichi-Sankyo with respect to patents and patent applications covering the sapacitabine compound. We have filed patent applications claiming polymorphic forms of sapacitabine and methods for its preparation and use as well as related know-how and materials. The Daiichi-Sankyo agreement has a commencement date of September 10, 2003. The issued patents for the sapacitabine compound cover the United States, EPO, Japan and 20 other countries. These patents expire between 2012 and 2014. The issued patents for the polymorphic forms cover the United States, EPO, Japan and six other countries, with patents pending in a further seven countries. These patents expire in 2022. It may be possible to extend the term of a patent in the United States or Europe for up to five years to the extent it covers the sapacitabine compound upon regulatory approval of that compound in the United States or Europe, but there is no assurance that we will be able to obtain any such extension. The license grants us the exclusive right to exploit and sublicense the sapacitabine compound and any other products covered by the patents and patent applications owned by Daiichi-Sankyo. The license originally was subject to certain third party rights related to certain countries but the license has been extended and is now worldwide. The license agreement also grants us nonexclusive, sublicensed rights in CNDAC, both the precursor compound and initial metabolite of sapacitabine.

We are under an obligation to use reasonable endeavors to develop a product and we have agreed to pay Daiichi-Sankyo an up-front fee, reimbursement for Daiichi-Sankyo's enumerated expenses, milestone payments and royalties on a country-by-country basis. Under this agreement, aggregate milestone payments totaling \$11.7 million could be payable subject to achievement of all the specific contractual milestones and our decision to continue with these projects. The up-front fee and certain past reimbursement have been paid. Royalties are payable in each country for the term of patent protection in the country or for ten years following the first commercial sale of licensed products

in the country, whichever is later. Royalties are payable on net sales. Net sales are defined as the gross amount invoiced by us or our affiliates or licensees, less discounts, credits, taxes, shipping and bad debt losses. The agreement extends from its commencement date to the date on which no further amounts are owed under it. If we wish to appoint a third party to develop or commercialize a sapacitabine-based product in Japan,

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within certain limitations, Daiichi-Sankyo must be notified and given a right of first refusal to develop and/or commercialize in Japan. In general, the license may be terminated by us for technical, scientific, efficacy, safety, or commercial reasons on six months notice or twelve if after launch of sapacitabine-based product or by either party for material default. On termination, if Daiichi-Sankyo wishes to acquire an exclusive license to sapacitabine intellectual property developed by us during the term of the license, Daiichi-Sankyo may notify us and the parties will meet to negotiate commercial terms in good faith. If agreement cannot be reached, the terms of the exclusive license are to be determined by an expert.

## Seliciclib

We have entered into an agreement with Centre National de Recherche Scientifique, or CNRS, and Institut Curie that grants us worldwide rights under the patents jointly owned by CNRS, Institut Curie and the Czech Institute of Experimental Botany covering the seliciclib compound. The effective date of the agreement is February 1, 2002. The license grants exclusive rights in the fields of auto-immune diseases, cardiovascular diseases, dermatological diseases, infectious diseases, inflammatory diseases, and proliferative diseases, including cancer. Non-acute chronic diseases of the central nervous system, neurological diseases and diseases of the peripheral nervous system are specifically excluded. The license runs for the term of the patents in each country, or for ten years from the first commercial sale in each country, whichever is later. We paid an up-front fee and yearly payments and milestone payments until the patents covering the seliciclib compound, particular uses of the compound, and particular uses and derivatives of the compound were published as granted in either the United States or by EPO which occurred in 2001 and 2003, respectively. Milestones are also paid on the first commercialization of a product that consists of a new chemical entity that is covered by one of the licensed patents.

We pay royalties based on our net sales of products covered by the patents. Royalties are payable on a country-by-country basis for the term of patent protection in each country or ten years from the first commercial sale of royalty-bearing products in that country, whichever is later. Royalties are payable on net sales. Net sales are defined as the gross amount invoiced by us or by our affiliates for the products, less normal trade discounts, credits for returned products, taxes and shipping charges. There is one royalty rate for products that are covered by valid licensed patent claims and a second, lower royalty rate for all other products that require a license under the licensed patents. The royalties payable under the agreement are reduced if we are required to pay royalties with respect to patents other than the ones licensed under this agreement and the total amount of royalties that we are required to pay exceeds a fixed percentage amount. The amount of reduction depends on the amount by which our total royalties exceed the fixed amount. We must also pay a portion of sublicensing revenues. The portion of sublicensing revenues that we are required to pay is reduced if we have taken the sublicensed product into human clinical trials. Although the license permits us to grant sublicenses, we cannot assign the license without the consent of the CNRS and Institut Curie, which may not be unreasonably withheld. Under the agreement, assignment is defined to include many transactions of the type that we might wish to pursue, such as a merger or an acquisition by another company, as well as certain takeovers. This restriction may prevent us from pursuing attractive business opportunities. Moreover, the occurrence of a majority takeover or a similar transaction that we may be unable to control could cause a default under the license agreement, which could lead to its termination.

We have also purchased from the Czech Institute of Experimental Botany patents and patent applications covering the use of seliciclib and related compounds. The issued patents are in the United States and Australia. Under the purchase agreement, we will pay royalties to the Czech Institute upon sales of products covered by those patents, but only if there are no royalties paid by us to CNRS for those sales under the license agreement with CNRS and Institut Curie covering seliciclib that is described above.

Patents covering the seliciclib compound are owned jointly by the Czech Institute of Experimental Botany and CNRS. The patents have been issued in the United States and by the EPO and expire in 2016. It may be possible to extend the term of a patent in the United States or Europe for up to five years to the extent it covers the seliciclib compound upon regulatory approval of that compound in the United States or Europe, but there is no assurance that we will be able to obtain any such extension. Under agreements between CNRS and the Czech Institute of Experimental Botany, CNRS has the exclusive

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right to enter into license agreements covering the patents. The agreement reserves to both CNRS and the Czech Institute of Experimental Botany certain rights, including the right to patent improvements and to use the patents for internal research purposes.

### Clotrimazole Analogs and CYC381

We have entered into a license agreement with NuChem Pharmaceuticals, Inc., or NuChem and its parent Lorus Therapeutics, Inc. with respect to our license of patents and patent applications covering the CYC381 compound in the United States, the EPO, Japan and other countries, as well as related know-how, materials and technology. The effective date of the agreement is September 22, 2003. Patents containing substance of matter claims covering the compound have been issued in the United States, Australia, China New Zealand and Singapore. These patents and patent applications if and when granted will expire in 2017 and 2018. It may be possible to extend the term of a patent in the United States or Europe for up to five years to the extent it covers the CYC381 compound upon regulatory approval of that compound in the United States, or Europe, but there is no assurance that we will obtain any such extension.

The license grants us worldwide rights in the technology owned by and licensed to NuChem related to a class of compounds including CYC381 and two other chemical classes of compounds that may have similar effects. The license is limited to the diagnosis and treatment of cancer including leukemias, Kaposi's sarcoma and actinic keratosis. To the extent that the patents and related technology are owned by or exclusively licensed to NuChem, the license is exclusive. It is nonexclusive for patents and technology that are nonexclusively licensed to NuChem. We have the right to sublicense these patents and technology to others. Improvements to the licensed patents are owned by NuChem and licensed back to us. On termination, NuChem may obtain, on commercially reasonable terms, a license of the results of the research and development that we perform on CYC381. We are responsible for prosecution, maintenance and defense of the licensed patents, including all associated costs. NuChem co-owns certain of the patents with Harvard University and Ion Pharmaceuticals and Harvard University retains certain rights to use the patents for research purposes. No warranty is given under the agreement as to the validity of the licensed patents or that 'any of the NuChem IP can be practiced or exploited without infringing other patents.' We are obligated to use commercially reasonable efforts to develop and commercialize the patents. The agreement extends from its commencement date to the date on which no further amounts are owed under it. The agreement may be terminated by us for convenience on four months' notice, by either party if the other defaults, and by NuChem if we do not actively pursue the licensed technology. We paid NuChem an up-front fee. We agreed to make milestone and royalty payments on a country-by-country basis and to pay NuChem a portion of any sublicensing fees.

We have entered into a license agreement with Johnson Matthey Pharmaceutical Materials, Inc. or Johnson Matthey with respect to United States and EPO patents as well as patent applications pending in Japan and certain other jurisdictions that claim the synthetic route for CYC381. The effective date of the agreement is September 1, 2003. These patents and applications if and when granted will expire between 2017 and 2018. The license grants us the exclusive worldwide right to manufacture and sell products under the Johnson Matthey patents. The license includes the right to sublicense. We paid an up-front fee and agreed to make minimum annual payments, including with respect to each sublicense and to pay a royalty on the net cost of goods manufactured under the license. We also agreed to give Johnson Matthey the right to bid for any contract to manufacture products under the license. The license runs for the term of the patents. We may terminate the license for convenience, and either party may terminate it for the default of the other.

Sinclair Pharma plc

Through the acquisition of ALIGN we acquired from Sinclair Pharma plc, or Sinclair, United States licensing rights to the three commercial drugs marketed by ALIGN Xclair™ Cream, Numoisyn™ Liquid and Numoisyn™ Lozenges. All three products were launched in the United States in January 2006. Each of the agreements covering these three drugs expire in June 2015. Under these agreements, we have obligations to pay certain quarterly royalties and other amounts pursuant to the agreement which may be reduced or lapse if we exceed certain sales levels.

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### Manufacturing

We have no in-house manufacturing capabilities and have no current plans to establish manufacturing facilities for significant clinical or commercial production. We have no direct experience in manufacturing commercial quantities of any of our products, and we currently lack the resources or capability to manufacture any of our products on a clinical or commercial scale. As a result, we are dependent on corporate partners, licensees or other third parties for the manufacturing of clinical and commercial scale quantities of all of our products. We believe that this strategy will enable us to direct operational and financial resources to the development of our product candidates rather than diverting resources to establishing a manufacturing infrastructure.

Sinclair contracts with third party manufacturers to supply finished goods that meet our needs with respect to Xclair™ Cream, Numoisyn™ Liquid and Numoisyn™ Lozenges. If any of Sinclair's third party manufacturers 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.

### Sales and Marketing

We currently have a 12 person pharmaceutical commercial sales organization. We expect to expand our sales and commercialization group to support products we develop to treat other oncology diseases and other therapeutic areas. We expect to expand our sales and commercialization group to support our products that may be commercialized for oncology/hematology indications and possibly other therapeutic areas. We intend to market and sell directly products for indications addressing modest patient populations. For products with indications addressing large patient populations we may partner with other pharmaceutical companies. In addition, we may accelerate the expansion of our commercial organization to take advantage of any product in-licensing and acquisition opportunities that we may elect to pursue.

### Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture, marketing and distribution of drugs. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our drug candidates and commercialized drugs.

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act and implementing regulations. The process required by the FDA before our drug candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, all performed in accordance with the FDA's good laboratory practice, or GLP, regulations;

- submission to the FDA of an IND application which must become effective before clinical trials may begin;

- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication;



- submission of a new drug application, or NDA, to the FDA;

completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with current good manufacturing practice GMP, or cGMP, regulations;

approval of the NDA prior to any commercial marketing, sale or shipment of the drug; and

commercial marketing and sale of drugs.

- satisfactory
- FDA review and
- Regulation of

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This testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all. Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND, or those of our collaborators, may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the clinical trial until completed. The FDA, the IRB or the clinical trial sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, regulations and regulations for informed consent.

**Clinical Trials:** For purposes of an NDA submission and approval, clinical trials are typically conducted in the following three sequential phases, which may overlap:

Phase 1: The clinical trials are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients. Phase 1 clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently approved drugs.

- Phase 2: These clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trial.

- Phase 3: These clinical trials are commonly referred to as pivotal clinical trials. If the Phase 2 clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase 3 clinical trials are then undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In some cases, the FDA may condition approval of an NDA for a drug candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval.

**New Drug Application.** The results of drug candidate development, preclinical testing and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. Once the submission has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or an additional pivotal Phase 3 clinical trial. Even if

such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators do. Once issued, the FDA may withdraw a drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In

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addition, the FDA may require further testing, including Phase 4 clinical trials, and surveillance programs to monitor the effect of approved drugs which have been commercialized. The FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to a drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

**Fast Track Designation.** The FDA's fast track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug concurrent with or after the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

If fast track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the time period specified in the Prescription Drug User Fees Act, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In some cases, a fast track designated drug candidate may also qualify for one or more of the following programs:

- **Priority**

**Review.** Under FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. We cannot guarantee any of our drug candidates will receive a priority review designation, or if a priority designation is received, that review or approval will be faster than conventional FDA procedures, or that FDA will ultimately grant drug approval.

- **Accelerated**

**Approval.** Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses, and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. In rare instances FDA may grant accelerated approval of an NDA based on Phase 2 data and require confirmatory Phase 3 studies to be conducted after approval and/or as a condition of maintaining approval. We can give no assurance that any of our drugs will be reviewed under such procedures.

When appropriate, we and our collaborators intend to seek fast track designation or accelerated approval for our drug candidates. We cannot predict whether any of our drug candidates will obtain a fast track or accelerated approval designation, or the ultimate impact, if any, of the fast track or the accelerated approval process on the timing or likelihood of FDA approval of any of our drug candidates.

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Satisfaction of FDA regulations and requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a drug candidate is intended to treat a chronic disease, as is the case with some of our drug candidates, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of drug candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our drug candidates on a timely basis, if at all. Even if a drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our drug candidates would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

510(k). Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers to notify FDA, at least ninety days in advance, of their intent to market a medical device. This is known as Premarket Notification and also PMN or 510(k). It allows the FDA to determine whether the device is equivalent to a device already placed into one of three classification categories. Medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.

Other regulatory requirements. Any products manufactured or distributed by us or our collaborators pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a product from distribution, or withdraw approval of that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

## Competition

The biotechnology and biopharmaceutical industries are rapidly changing and highly competitive. We are seeking to develop and market drug candidates that will compete with other products and therapies that currently exist or are being developed. Other companies are actively seeking to develop products that

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have disease targets similar to those we are pursuing. We face competition from many different sources, including commercial, pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. In addition, competitors compete in the areas of recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses.

We believe that we are currently the only company that has an orally available CDK-specific agent in Phase 2 clinical trials. A large number of drug candidates are in development for the treatment of leukemias, lymphomas, lung cancer and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs on the market or in clinical trials for oncology indications, including Eli Lilly, Genzyme, GlaxoSmithKline and Mayne Pharma. We believe that we are currently the only company that has an orally available CDK inhibitor in Phase 2 clinical trials. We believe that several companies are developing drugs targeting cancer that may compete with our candidates. We believe a number of companies, including AstraZeneca, Eisai, Pfizer, Roche, Schering AG, and Sunesis are developing CDK inhibitors in early stage clinical trials in cancer patients. Although Aventis, a predecessor of Sanofi-Aventis, had previously announced that it has ceased Phase 2 development of alvocidib or flavopiridol, a CDK inhibitor, we believe that the National Cancer Institute's Cancer Therapy Evaluation Program is continuing to enroll patients in a Phase 2 trial and that Sanofi-Aventis has reinitiated development of alvocidib in Phase 3 clinical trials in patients with chronic leukemia. A number of companies are pursuing discovery and research activities in each of the other areas that are the subject of our research and drug development programs. We believe that AstraZeneca, Merck, jointly with Vertex, Merck-Serono, Millennium and Sunesis have commenced Phase 2 or Phase 1 clinical trials of Aurora kinase inhibitors in patients with advanced cancers. Several companies have reported selection of Aurora kinase inhibitor candidates for development and may have started or are expected to start clinical trials within the next twelve months. We believe that Boehringer Ingelheim, GlaxoSmithKline and Onconova have commenced Phase 1 or Phase 2 clinical trials with Plk inhibitor candidates for oncology indications. We believe that Beiersdorf, Daiichi-Sankyo, Eisai, Johnson & Johnson, MPM Medical and other companies market products for radiation dermatitis and xerostomia.

## Employees

As of February 15, 2008, we had 83 full-time employees, comprised of 54 employees in research and development and 29 employees in selling, general and administration. From time to time, we also employ independent contractors to support our administrative organizations. We believe we have been successful in attracting skilled and experienced management and scientific personnel. Our employees are not represented by any collective bargaining agreements, and management considers relations with our employees to be good.

## Web Site Access to SEC Filings/Available information

We have filed reports, proxy statements and other information with the SEC. Copies of Cyclacel's reports, proxy statements and other information may be inspected and copied at the public reference facilities maintained by the SEC at SEC Headquarters, Public Reference Section, 100 F Street, N.E., Washington D.C. 20549. The public may obtain information on the operation of the SEC's public reference facilities by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy statements and other information regarding Cyclacel. The address of



the SEC website is <http://www.sec.gov>. We will also provide copies of our Forms 8-K, 10-K, 10-Q, Proxy and Annual Report at no charge available through our website at [www.cyclacel.com](http://www.cyclacel.com) as soon as reasonably practicable after filing electronically such material with the SEC. Copies are also available, without charge, from Cyclacel Pharmaceuticals, Inc., 200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922.

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### Item 1A. Risk Factors

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

We 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 and we do not anticipate material revenues from the ALIGN products in the foreseeable future. We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA, and other regulatory authorities in the United States, the European Union and elsewhere. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. Sapacitabine and seliciclib, our most advanced drug candidates for the treatment of cancer, are currently our only drug candidates in Phase 2 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 selling, general and administrative costs associated with our operations, and we may never achieve profitability. As of December 31, 2007, our accumulated deficit was \$162.3 million. Our net loss attributable to common shareholders for the years ended December 31, 2006 and 2007 was \$32.1 million and \$24.1 million respectively. Our net loss attributable to common shareholders from inception through December 31, 2007 was \$200 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 our drugs. We expect to incur continued losses for several years, as we continue our research and development of our initial drug candidates, seek regulatory approvals, 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.

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

We have funded all of our operations and capital expenditures with proceeds from the issuance of public equity securities, private placements of our securities, interest on investments, government grants,

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research and development tax credits. In order to conduct the lengthy and expensive research, preclinical testing and clinical trials necessary to complete the development and marketing of our drug candidates, we will require substantial additional funds. Based on our current operating plans, we expect our existing resources to be sufficient to fund our planned operations for at least the next 12 months. To meet these financing requirements, we may raise funds through public or private equity offerings, debt financings or strategic alliances. Raising additional funds by issuing equity or convertible debt securities will cause our shareholders to experience substantial dilution in their ownership interests and new investors may have rights superior to the rights of our other stockholders. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities and options. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights to our drug discovery and other technologies, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. Additional funding may not be available to us on favorable terms, or at all. If we are unable to obtain additional funds, we may be forced to delay or terminate our clinical trials and the development and marketing of our drug candidates.

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

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

- fund research and development and clinical trials connected with our research;
- fund clinical trials and seek regulatory approvals;
- build or access manufacturing and commercialization capabilities;
- implement additional internal control systems and infrastructure;
- commercialize and secure coverage, payment and reimbursement of our drug candidates, if any such candidates receive regulatory approval;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional management, sales and scientific personnel.

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

with establishing sales and marketing capabilities;

acquiring or investing in businesses, products and technologies;

competing technological and market developments; and

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

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If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or future commercialization efforts.

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If we fail to enter into and maintain successful strategic alliances for our drug candidates, we may have to reduce or delay our drug candidate development or increase our expenditures.

An important element of our strategy for developing, manufacturing and commercializing our drug candidates is entering into strategic alliances with pharmaceutical companies or other industry participants to advance our programs and enable us to maintain our financial and operational capacity.

We face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. In addition, these alliances may be unsuccessful. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our drug development or research programs. If we elect to fund drug development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

Our committed equity financing facility with Kingsbridge may not be available to us if we elect to make a draw down, may require us to make additional “blackout” or other payments to Kingsbridge, and may result in dilution to our stockholders.

On December 10, 2007, we entered into the committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge. The CEFF entitles us to sell and obligates Kingsbridge to purchase the lesser of 4,084,590 shares of common stock or \$60 million of common stock from Cyclacel during the next three years, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; effectiveness of the registration statement of which this prospectus is a part; and the continued listing of our stock on The NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 days from the date Kingsbridge provides us notice of such material and adverse event. If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

We are entitled, in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement of which this prospectus is a part and prohibit Kingsbridge from selling shares under this prospectus. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement is not effective in circumstances not permitted by the agreement, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of the number of shares held by Kingsbridge exclusive of shares that Kingsbridge may hold pursuant to exercise of the Kingsbridge warrant and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout or other payment could be significant.

Should we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to 10 percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

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

Clinical trials are expensive and complex and can take many years and have uncertain outcomes. We estimate that clinical trials of our most advanced drug candidates will continue for several years, but may take significantly longer to complete. The designs used in some of our trials have not been used widely

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by other pharmaceutical companies. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future drug candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for our clinical trials;
- delays in obtaining institutional review board, or IRB, and other regulatory approvals to commence a clinical trial;
- slower than anticipated rates of patient recruitment and enrollment, or reaching the targeted number of patients;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues;
- introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

If we suffer any significant delays, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue development of our drug candidates or generate revenue and our development costs could increase significantly.

Adverse events have been observed in our clinical trials and may force us to stop development of our product candidates or prevent regulatory approval of our product candidates.

Adverse or inconclusive results from our clinical trials may substantially delay, or halt entirely, any further development of our drug candidates. Many companies have failed to demonstrate the safety or effectiveness of drug candidates in later stage clinical trials notwithstanding favorable results in early stage clinical trials. Previously unforeseen and unacceptable side effects could interrupt, delay or halt clinical trials of our drug candidates and could result in the FDA or other regulatory authorities denying approval of our drug candidates. We will need to demonstrate safety and efficacy for specific indications of use, and monitor safety and compliance with clinical trial protocols throughout the development process. To date, long-term safety and efficacy has not been demonstrated in clinical trials for any of our drug candidates. Toxicity and ‘severe adverse effects’ as defined in trial protocols have been noted in preclinical and clinical trials involving certain of our drug candidates. For example, elevations of liver enzymes and decrease in potassium levels have been observed in some patients receiving our drug candidate seliciclib and neutropenia was observed in patients receiving sapacitabine. In addition, we may pursue clinical trials for sapacitabine and seliciclib in more than one indication. There is a risk that severe toxicity observed in a trial for one indication could result in the delay or suspension of all trials involving the same drug candidate. We are currently conducting Phase 2 clinical trials to test the safety and efficacy of sapacitabine in CTCL and elderly AML and



seliciclib in the treatment of NSCLC and NPC and Phase 1 clinical trials to test the safety of CYC116 in patients with solid tumors. If these trials or any future trials are unsuccessful, our business and reputation could be harmed and our share price could be negatively affected.

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

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significant delay in completing clinical trials for our drug candidates, or in receiving regulatory approval for the commercialization of our drug candidates, may severely harm our business and reputation.

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

We have programs to develop small molecule inhibitors of CDK and AK. One of our drug candidates, seliciclib, is a CDK inhibitor, and CYC116 is an AK and VEGFR2 inhibitor, based on our understanding of CDK and AK inhibitors. Although a number of pharmaceutical and biotechnology companies are attempting to develop CDK or AK inhibitor drugs for the treatment of cancer, no CDK or AK inhibitor has yet reached the market. Our seliciclib program relies on our understanding of the interaction of CDKs with other cellular mechanisms that regulate key stages of cell growth. If our understanding of the role played by CDKs or AK inhibitors in regulating the cell cycle is incorrect seliciclib and CYC116 may fail to produce therapeutically relevant results hindering our ability to pursue our clinical and regulatory strategy.

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

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

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

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

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

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

Although we are not currently party to any collaboration arrangement or strategic alliance that is material to our business, in the future we expect to be dependent upon collaborative arrangements or

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strategic alliances to complete the development and commercialization of some of our drug candidates particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our drug candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

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

- we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete our obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

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

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates under development or our commercial products. We currently lack the resources or the capacity to manufacture any of our products on a clinical or commercial scale. We anticipate future reliance on a limited number of third party manufacturers until we are able, or decide, to expand our operations to include manufacturing capacities. Any performance failure on the part of manufacturers could delay late stage clinical development or regulatory approval of our drug, the commercialization of our drugs or our ability to sell our commercial products, producing additional losses and depriving us of potential product revenues.

If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities. To date, our drug candidates have been manufactured in small quantities for preclinical testing and clinical trials and we may not be able to successfully increase the manufacturing capacity, whether in collaboration with third party manufacturers or on our own, for any of our drug candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA and other regulatory bodies must review and approve. If we are unable to successfully increase the manufacturing capacity for a drug candidate whether for late stage clinical trials or for commercial sale, the drug development, regulatory approval or commercial launch of any related drugs may be delayed or there may be a shortage in supply. Even if any third party manufacturer makes improvements in the manufacturing process for our drug candidates, we may not own, or may have to share, the intellectual property rights to such innovation.

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

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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.

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

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

The clinical development, manufacturing, selling and marketing of our drug candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States, the European Union and elsewhere. These regulations also vary in important, meaningful ways from country to country. We are not permitted to market a potential drug in the United States until we receive approval of an NDA from the FDA. We have not received an NDA approval from the FDA for any of our drug candidates.

Obtaining an NDA approval is expensive and is a complex, lengthy and uncertain process. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are the Phase 3 clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, an NDA may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In addition, failure to comply with FDA and other applicable foreign and U.S. regulatory requirements may subject it to

administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve either pending NDAs, or supplements to approved NDAs.

Despite the substantial time and expense invested in preparation and submission of an NDA or equivalents in other jurisdictions, regulatory approval is never guaranteed. The FDA and other regulatory

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authorities in the United States, the European Union and elsewhere exercise substantial discretion in the drug approval process. The number, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the drug candidate, the disease or condition for which the drug candidate is intended to be used and the regulations and guidance documents applicable to any particular drug candidate. The FDA or other regulators can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to:

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

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 products.

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.

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

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



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

We are engaged in a rapidly changing and highly competitive field. We are seeking to develop and market products that will compete with other products and drugs that currently exist or are being developed. We compete with companies that are developing small molecule drugs, as well as companies that have developed drugs or are developing alternative drug candidates for cancer or other serious

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disorders where there is abnormal cell proliferation. We believe that several companies are developing drugs targeting cancer that may compete with our candidates. A large number of drug candidates are in development for the treatment of leukemias, lymphomas, lung cancer and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs on the market or in clinical trials for oncology indications, including Eli Lilly, Genzyme, GlaxoSmithKline and Mayne Pharma. We believe that we are currently the only company that has an orally available CDK inhibitor in Phase 2 clinical trials. We believe a number of companies, including AstraZeneca, Eisai, Pfizer, Roche, Schering AG and Sunesis are developing CDK inhibitors in early stage clinical trials in cancer patients. Although Aventis, a predecessor of Sanofi-Aventis, had previously announced that it has ceased Phase 2 development of alvocidib or flavopiridol, a CDK inhibitor, we believe that the National Cancer Institute's Cancer Therapy Evaluation Program is continuing to enroll patients in a Phase 2 trial and that Sanofi-Aventis has reinitiated development of alvocidib in Phase 3 clinical trials in patients with chronic leukemia. A number of companies are pursuing discovery and research activities in each of the other areas that are the subject of our research and drug development programs. We believe that AstraZeneca, Merck, jointly with Vertex, Merck-Serono, Millennium and Sunesis have commenced Phase 2 or Phase 1 clinical trials of Aurora kinase inhibitors in patients with advanced cancers. Several companies have reported selection of Aurora kinase inhibitor candidates for development and may have started or are expected to start clinical trials within the next twelve months. We believe that Boehringer Ingelheim, GlaxoSmithKline and Onconova have commenced Phase 1 or Phase 2 clinical trials with Plk inhibitor candidates for oncology indications. We believe that Beiersdorf, Daiichi-Sankyo, Eisai, Johnson & Johnson, MPM Medical and other companies market products for radiation dermatitis and xerostomia.

Our competitors, either alone or together with collaborators, may have substantially greater financial resources and research and development staff. Our competitors may also have more experience:

developing drug candidates;

preclinical and clinical trials;

approvals; and

product candidates.

- 
- conducting
- obtaining regulatory
- commercializing

Our competitors may succeed in obtaining patent protection and regulatory approval and may market drugs before we do. If our competitors market drugs that are less expensive, safer, more effective or more convenient to administer than our potential drugs, or that reach the market sooner than our potential drugs, we may not achieve commercial success. Scientific, clinical or technical developments by our competitors may render our drug candidates obsolete or noncompetitive. We anticipate that we will face increased competition in the future as new companies enter the markets and as scientific developments progress. If our drug candidates obtain regulatory approvals, but do not compete effectively in the marketplace, our business will suffer.

The commercial success of 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;

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severity of adverse side effects; and

advantages over alternative treatment methods.

- prevalence and
- other potential

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

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

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

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.

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 United States and international markets is substantially dependent on whether third party coverage and reimbursement is available. The United States 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.

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Following the acquisition of ALIGN, we now have the right to 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 maintain such insurance on acceptable terms with adequate coverage, or at a reasonable cost. There is also a risk that third parties that we have agreed to indemnify could incur liability. Even if we were ultimately successful in product liability litigation, the litigation would consume substantial amounts of our financial and managerial resources and may exceed insurance coverage creating adverse publicity, all of which would impair our ability to generate sales of the litigated product as well as our other potential drugs.

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

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

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

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

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

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

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

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

Our commercial success depends in large part on obtaining and maintaining patent and trade secret protection for our drug candidates, the methods used to manufacture those drug candidates and the methods for treating patients using those drug candidates. Specifically our two lead drug candidates have composition of matter patents that expire at the earliest case in 2016 and 2014. Failure to obtain, maintain or extend the patents could adversely affect our business. We will only be able to protect our drug candidates and our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

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

Even if patents are issued regarding our drug candidates or methods of using them, those patents can be challenged by our competitors who may argue such patents are invalid and/or unenforceable. Patents also will not protect our drug



candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The U.S. Federal Food, Drug and Cosmetic, or FD&C, Act and FDA regulations and policies and equivalents in other jurisdictions provide incentives to manufacturers to challenge patent validity or create modified, noninfringing versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage manufacturers to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor.

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

Intellectual Property Rights of third parties may increase our costs or delay or prevent us from being able to commercialize our drug candidates 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. 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 sapacitabine and seliciclib that are not part of our current clinical programs for these compounds. Numerous third-party United States and foreign issued patents and pending applications exist in the area of kinases, including CDK, AK and Plk for which we have research programs. For example, some pending patent applications contain broad claims that could represent freedom to operate limitations for some of our kinase programs should they be issued unchanged. Although we intend to continue to monitor these applications, we cannot predict what claims will ultimately be allowed and if allowed what their scope would be. In addition, because the patent application process can take several years to complete, there may be currently pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our drug candidates. If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that the owner asserts that we infringe its patents. In one case we have opposed a European patent relating to human aurora kinase. 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;

some of our screening work outside Europe;

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

- decide to move

- be required to pay

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

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

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

We have limited experience attempting to comply with public company obligations. Attempting to comply with these requirements will increase our costs and require additional management resources, and we still may fail to comply.

As a public company, we face and will continue to face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. Compliance with the Sarbanes Oxley Act of 2002, as well as other rules of the SEC, the Public Company Accounting Oversight Board and the Nasdaq Global Market has resulted in a significant initial cost to us as well as an ongoing increase in our legal, audit and financial compliance costs. As a public company, we are subject to Section 404 of the Sarbanes Oxley Act relating to internal control over financial reporting. We have completed a formal process to evaluate our internal controls for purposes of Section 404, and we concluded that as of December 31, 2007, our internal control over financial reporting is effective. As our business grows and changes, there can be no assurances that we can maintain the effectiveness of our internal controls over financial reporting.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed. We have completed a formal process to evaluate our internal control over financial reporting. However, guidance from regulatory authorities in the area of internal controls continues to evolve and substantial uncertainty exists regarding our on-going ability to comply by applicable deadlines. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our common stock may have a volatile public trading price.

An active public market for our common stock has not developed. Our stock can trade in small volumes which may make the price of our stock highly volatile. The last reported price of our stock may not represent the price at which you would be able to buy or sell the stock. The market prices for securities of companies comparable to us have been

highly volatile. Often, these stocks have experienced significant price and volume fluctuations for reasons that are both related and unrelated to the operating performance of the individual companies. Factors giving rise to this volatility may include:

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

- disclosure

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developments in both the United States and abroad;	• regulatory
concerning proprietary rights, including patents and litigation matters;	• developments
about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;	• public concern
concern about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;	• public
announcements by our competitors or others; and	• general market
conditions and comments by securities analysts and investors.	

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

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

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

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

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

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

Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years

unless, among other possibilities, the board of directors approves the transaction. Our board of directors could use this provision to prevent changes in management. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

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

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

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issuance of preferred stock that can be created and issued by the board of directors without prior stockholder approval, commonly referred to as ‘blank check’ preferred stock, with rights senior to those of our common stock;

- authorize the
- provide for the

board of directors to be divided into three classes; and

- require that

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

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

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

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

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

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

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

- additions

to or departures of our key personnel;

- announcements of
- announcements
- new regulatory
- general and

technological innovations or new products or services by us or our competitors;

concerning our competitors or the biotechnology industry in general;

pronouncements and changes in regulatory guidelines;

industry-specific economic conditions;



estimates or recommendations by securities analysts;  
quarterly results;  
about our collaborators or licensors; and  
accounting principles.

- changes in financial
- variations in our
- announcements
- changes in

The market prices of the securities of biotechnology companies, particularly companies like us without product revenues and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the performance of particular companies. In the

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past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Moreover, market prices for stocks of biotechnology-related and technology companies frequently reach levels that bear no relationship to the performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our financial condition and results of operations.

The future sale of our common and convertible preferred stock, and future issuances of our common stock upon conversion of our convertible preferred stock could negatively affect our stock price.

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

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

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

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

We may automatically convert the convertible preferred stock into common stock if the closing price of our common stock has exceeded \$35.30, which is 150% of the conversion price of the preferred stock for at least 20 trading days during a 30-day trading period ending within five trading days prior to the notice of automatic conversion. You should be aware that there is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred and the automatic conversion date.

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

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

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

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

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

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

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 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 contracts with third party manufacturers to supply the finished goods to us to meet our needs. If any of Sinclair's third party manufacturers service providers do not meet our or our licensor's requirements for quality, quantity or timeliness, or do not achieve and maintain compliance with all applicable regulations, demand for our products or our ability to continue supplying such products could substantially decline. As the third party manufacturers are the sole supplier of the products any delays may impact our sales.

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

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

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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. 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.

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 hired trained and deployed additional marketing personnel and a national oncology specialty sales force. We may increase or decrease the size of our sales force in the future, depending on many factors, including the effectiveness of the sales force, the level of market acceptance of Xclair™ Cream, Numoisyn™ Liquid and Numoisyn™ Lozenges and the results of our clinical trials. 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 2 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 Canada 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.

### Item 1B. Unresolved Staff Comments

None.

### Item 2. Properties

In October 2006, we entered into a five-year lease for office space of approximately 6,500 square feet in Berkeley Heights, New Jersey, which is our corporate headquarters.

In October 2000, we entered into a 25-year lease for our research and development facility in Dundee, Scotland. We also leased a second research facility at the Babraham Research Campus, Cambridge, England for five years beginning in August 2005.

Additionally, we lease approximately 40,500 square feet of space in Bothell, Washington, with monthly payments of approximately \$0.1 million. The lease term on this space expires December 2010. However, activities were discontinued at the Bothell facility during the third quarter of 2005 and we are exploring options for the sub-leasing of this facility.

We believe that our existing facilities will be adequate to accommodate our business needs.

Item 3. Legal Proceedings

From time to time, we may be involved in routine litigation incidental to the conduct of our business. As of December 31, 2007, we were not a party to any material legal proceedings.

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

No matters were submitted to a vote of the shareholders during the fourth quarter of 2007.

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PART II

Item 5.

Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Price Range of Common Stock

Our common stock began trading March 16, 2004 and is traded on the Nasdaq Global Market. As of March 27, 2006, in connection with the name change from Xcyte to Cyclacel, we changed the symbol under which our common stock trades to "CYCC", previously "XCYT". Our preferred stock currently trades on the Nasdaq Capital Market under the symbol "CYCCP", previously "XCYTP". The following table summarizes, for the periods indicated, the high and low sales prices for the common stock of Xcyte prior to March 27, 2006 and of Cyclacel after March 27, 2006, as reported by the Nasdaq Global Market, as adjusted to reflect the effect of a 1-for-10 reverse split of our common stock on March 27, 2006:

				High	Low	2007	Quarter
ended March 31, 2007	\$ 8.64	\$ 6.70	Quarter ended June 30, 2007	\$ 9.50	\$ 6.00	Quarter ended	
September 30, 2007	\$ 6.50	\$ 4.33	Quarter ended December 31, 2007	\$ 5.93	\$ 4.90	2006	Quarter
ended March 31, 2006	\$ 8.70	\$ 5.60	Quarter ended June 30, 2006	\$ 8.30	\$ 5.50	Quarter ended	
September 30, 2006	\$ 6.91	\$ 4.35	Quarter ended December 31, 2006	\$ 7.95	\$ 4.31		

Holders of Common Stock

On March 11, 2008 we had approximately 110 registered holders of record of our common stock. On March 11, 2008, the closing sale price of our common stock as reported on the Nasdaq Global Market was \$3.13 per share.



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### Performance Graph

The comparative stock performance graph below compares the cumulative total stockholder return from investing \$100 on March 27, 2006 (the date of the reverse merger with Xcyte) or on February 28, 2006 in index-including reinvestment of dividends of fiscal year ending December 31, 2007.

#### COMPARISON OF 21 MONTH CUMULATIVE TOTAL RETURN\*

Among Cyclacel Pharmaceuticals, Inc., The NASDAQ Composite Index,  
The RDG MicroCap Biotechnology Index And The NASDAQ Biotechnology Index

\* \$100

invested on 3/27/06 in stock or 2/28/06 in index-including reinvestment of dividends. Fiscal year ending December 31.

Name	March 27,							
2006	December 31,							
2006	December 31,							
2007 Cyclacel	100.00	85.86	68.59	Nasdaq Composite	100.00	107.56	117.24	RDG MircroCap
Biotechnology	100.00	57.75	29.63	NASDAQ Biotechnology	100.00	93.30	94.18	

For 2007 and beyond, the Company changed its performance indexes from the RDG MicroCap Biotechnology Index to the NASDAQ Biotech Index. The Company believes that the NASDAQ Biotech Index is more indicative of other companies with similar business models.

Performance Graph and related information shall not be deemed “soliciting material” or to be “filed” with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that the Company specifically incorporates it by reference into such filing.

### Dividends

We have never declared nor paid any cash dividends on our common stock and do not currently anticipate declaring or paying any cash dividends on our outstanding shares of common stock in the

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foreseeable future. We are, however, required to make or accrue quarterly dividend payments on our convertible preferred stock. Our ability to pay dividends on our common stock may be limited if we fail to pay accrued dividends on our convertible preferred stock. Except for dividends we are paying on the convertible preferred stock, we currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and other factors that our board of directors may deem relevant. Pursuant to the terms of our outstanding preferred stock, we currently pay dividends to the holders of our preferred stock.

## Recent sales of unregistered securities

None.

## Securities Authorized for Issuance Under Equity Compensation Plans

The information called for by this item is incorporated by reference from our definitive proxy statement which will be filed with the SEC within 120 days after the end of 2007 fiscal year pursuant to regulation 14A for our annual meeting to be held on May 14, 2008.

## Item 6.

## Selected Financial Data

This section presents our historical financial data. The consolidated statement of operations data for the years ended December 31, 2005, 2006 and 2007 and for the period from August 13, 1996 (inception) to December 31, 2007 and the consolidated balance sheet data as of December 31, 2006 and 2007 have been derived from our audited financial statements included elsewhere in this Form 10-K. The statement of operations data for the year ended 2003 and 2004 and the balance sheet data as of December 31, 2003, 2004 and 2005 have been derived from our audited financial statements that are not included in this Form 10-K. Historical results are not necessarily indicative of future results.

The information contained in the following tables should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements included in this Form 10-K.

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Years Ended December 31, Period from  
August 13,  
1996

(inception) to

December 31,

2007	2003	2004	2005	2006	2007	(in thousands except share and per share amounts)						Consolidated					
Statements of Operations:						Revenues:				Collaboration and							
research and development income					\$ 1,250	\$ 102	\$ 245	\$ 231	\$ 10	\$ 3,000	Grant income		941				
823	111	156	119	3,596	2,191	925	356	387	129	6,596	Operating expenses:						
Research and development						20,091	20,332	15,841	21,205	19,569	141,544						
Selling, general and administrative costs					2,597	3,554	5,290	12,319	11,543	47,496	Other restructuring						
					—	—	—	225	1,554	1,779	Total operating expenses		22,688	23,886	21,131	33,749	
32,666					190,819	Operating loss		(20,497 )	(22,961 )	(20,775 )	(33,362 )	(32,537 )	(184,223 )				
Interest and other income (expense)					558	(2,237 )	827	1,859	6,443	7,369	Loss before taxes						
(19,939 )					(25,198 )	(19,948 )	(31,503 )	(26,094 )	(176,854 )	Income tax benefit		4,397	2,456				
1,900					2,245	2,041	14,525	Net loss		(15,542 )	(22,742 )	(18,048 )	(29,258 )	(24,053 )			
(162,329 )					Dividends on preferred shares		(4,654 )	(11,053 )	(11,876 )	(2,827 )	—		(38,123 )	Net			
loss applicable to common shareholders					\$ (20,196 )		\$ (33,795 )		\$ (29,924 )		\$ (32,085 )		\$ (24,053 )		\$		
(200,452 )					Net loss per share – basic and diluted		\$ (22.01 )		\$ (5.10 )		\$ (4.50 )		\$ (2.40 )		\$ (1.21 )		
Shares used in computing basic and diluted net loss per share								917,555	6,627,831	6,656,732	13,390,933						
19,873,911																	

As of December 31,	2003	2004	2005	2006	2007	(in thousands) Consolidated Balance Sheet							
Data:	Cash and cash equivalents					\$ 4,335	\$ 7,766	\$ 3,117	\$ 44,238	\$ 30,987			
Short-term investments	29,345	15,152	10,690	9,764	27,766	Working capital	34,383	20,909					
2,152	50,244	49,065	Total assets	42,800	31,176	19,071	63,276	75,912	Long-term debt, net				
of current portion	(495 )	(368 )	(78 )	(1,436 )	(3,231 )	Total stockholders' equity	37,648						
23,953	4,119	53,919	57,969										

In connection with the stock purchase agreement with Xcyte Therapies Inc. or Xcyte in March 2006, Cyclacel Limited was considered to be the acquiring company for accounting purposes. Accordingly, the assets and liabilities of Xcyte were recorded, as of March 27, 2006, at their respective fair values and added to those of Cyclacel Limited. The results of operations and balance sheet data for 2006 reflect the results of the combined companies from March 28, 2006 through December 31, 2006. Additionally, the historical results of operations and balance sheet data shown for comparative purposes in this Form 10-K reflect those of Cyclacel Limited prior to the reverse acquisition.

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain statements that may be deemed 'forward-looking statements' within the meaning of United States securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in



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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. Certain factors that could cause results to differ materially from those projected or implied in the forward looking statements are set forth in this Annual Report on Form 10-K for the year ended December 31, 2007 under the caption “Item 1A — Risk factors”.

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

## Overview

We are a development-stage biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Our strategy is focused on leading edge therapeutic management of cancer patients based on a portfolio of three medicines marketed by our ALIGN subsidiary and a deep development pipeline. We market directly in the U.S. Xclair™ Cream for radiation dermatitis and Numoisyn™ Liquid and Numoisyn™ Lozenges for xerostomia. We have three orally-available drugs that are in clinical development: sapacitabine in two randomized Phase 2 studies for the treatment of elderly acute myeloid leukemia or AML, and cutaneous T-cell lymphoma or CTCL; seliciclib in two randomized Phase 2 studies for the treatment of non-small cell lung cancer or NSCLC and nasopharyngeal cancers or NPC and CYC116 in a Phase 1 study in patients with solid tumors. Our core area of expertise is in cell cycle biology, or the processes by which cells divide and multiply. We focus primarily on the discovery and development of orally available anticancer agents that target the cell cycle with the aim of slowing the progression or shrinking the size of tumors, and enhancing the quality of life and improving survival rates of cancer patients. We are generating several families of anticancer drugs that act on the cell cycle including nucleoside analogues, cyclin dependent kinase or CDK inhibitors and Aurora kinase/Vascular Endothelial Factor Receptor 2 or AK/VEGFR2 inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitor and AK inhibitor drugs, we believe that our drug candidates are differentiated in that they are orally available and interact with unique target profiles and mechanisms. For example we believe that our sapacitabine is the only orally available nucleoside analogue presently being tested in Phase 2 trials in AML, seliciclib is the only orally available CDK inhibitor currently in Phase 2 trials and CYC116 is the only AK inhibitor in clinical trials that also interacts with VEGFR2.

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.

Our corporate headquarters is located in Berkeley Heights, New Jersey, while our main research facility is located in Dundee, Scotland, and a second research facility located in Cambridge, England.

From our inception in 1996 through December 31, 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 December 31, 2007, our accumulated deficit during the development stage was approximately \$162.3 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. Our operating expenses comprise research and development expenses and selling and general and administrative expenses.

To date, we have not generated product revenue but have financed our operations and internal growth through private placements, licensing revenue, interest on investments, government grants and

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research and development tax credits. Our revenue has consisted of collaboration and grant revenue and in 2008 will include sales of our medical devices following the ALIGN acquisition. We have not reported any revenue from sales of our commercial products in 2007, in accordance with our accounting policies, but expect to do so in 2008. We have recognized revenues from inception through December 31, 2007 of \$6.6 million of which \$3.0 million is derived from fees under collaborative agreements and \$3.6 million of grant revenue from various United Kingdom government grant awards. We have also recognized amounts receivable from the United Kingdom's tax authority, H.M. Revenue & Customs of \$14.5 million for research and development tax credits since inception.

## Recent Events

### Acquisition of ALIGN Pharmaceuticals, Inc.

On October 5, 2007, Achilles Acquisition, LLC renamed immediately following the acquisition to ALIGN Pharmaceuticals, LLC, or ALIGN, a wholly-owned subsidiary of Cyclacel, entered into a definitive asset purchase agreement with ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC or Sellers, to acquire substantially all of the Sellers' assets. The transaction closed on the same date.

Notably, we acquired the Sellers' exclusive rights to sell and distribute three products in the United States used potentially 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 primarily complementary to Cyclacel's oncology/hematology products in development and is part of our strategy to build a diversified biopharmaceutical business.

As consideration for the asset purchase and pursuant and subject to the terms of the agreement, we paid \$3.3 million in cash to the Sellers and may pay an additional aggregate amount of \$0.5 million within 130 business days from the closing date of the asset acquisition, in cash, shares of our common stock, or a combination thereof. In addition, we may be required to issue to the Sellers a maximum number of 184,176 shares of common stock. Issuance is contingent upon the achievement of certain operational and financial milestones and subject to satisfaction of any outstanding indemnification obligations by the Sellers. We will issue the shares of our common stock only to the extent that the milestones are achieved. We are also committed, as part of securing long term supply arrangements, to make future payments of approximately \$0.6 million in 2009 and \$0.7 million in 2010.

The transaction has been accounted for as a business combination and the consolidated results of operations of Cyclacel will include the results of operations of 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. William C. Collins, the former chief executive officer and manager of the Sellers, was appointed as the general manager of ALIGN.

### Acquisition Purchase Price

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

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







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.

The future

Beginning in 2008, we expect to receive modest product revenues from the ALIGN business acquired in October 2007.

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### Research and development expenses

To date, we have focused on drug discovery and development programs, with particular emphasis on orally available anticancer agents. Research and development expense represents costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for sapacitabine, seliciclib and CYC116 to advance product candidates toward clinical trials, to develop in-house research and preclinical study capabilities and to advance our biomarker program and technology platforms. We expense all research and development costs as they are incurred. Research and development expenses primarily include:

- payroll
- and personnel-related expenses, including consultants and contract research;
- clinical trial and
- regulatory-related costs;
- preclinical studies;
- screening
- and identification of drug candidates;
- laboratory supplies
- and materials;
- technology license
- rent
- costs;
- and facility expenses for our laboratories; and
- scientific consulting
- fees.

The following table provides information with respect to our research and development expenditure for the years ended December 31, 2005, 2006 and 2007:

	Years ended	\$Differences	% Differences	2005	2006	2007	2005 to 2006	2006 to 2007
2005 to 2006	2006 to 2007	(in thousands)	Sapacitabine	\$ 2,236	\$ 1,841	\$ 3,326	\$ (395 )	\$ 1,485
(18 )%	81 %	Seliciclib	4,777	3,126	3,270	(1,651 )	144	(35 )%
6,712	2,626	1,315	(4,086 )	24 %	(61 )%	Other costs related to research and development		
programs, management and exploratory research			3,431	9,526	10,347	6,095	821	178 %
Total research and development expenses			\$ 15,841	\$ 21,205	\$ 19,569	\$ 5,364	\$ (1,636 )	34 %
								(8 )%

Research and development expenses represented 75%, 63% and 60% of our operating expenses for the years ended December 31, 2005, 2006 and 2007.

Fiscal 2007 as compared to fiscal 2006. Research and development costs decreased 8% or \$1.6 million from \$21.2 million in the year ended December 31, 2006 to \$19.6 million in the year ended December 31, 2007. Significant components of the change relate to a decrease in the charge for stock-based compensation of \$5.4 million from \$6.2 million during 2006 to \$0.8 million during 2007 as a result of the stock options granted during June 2006 being two-thirds vested immediately upon grant. This decrease was offset by an increase in costs of \$1.6 million related to sapacitabine and seliciclib as we increased the number of Phase 2 trials in 2007. Additionally, CYC116 expenses decreased by \$4.1 million from \$6.7 million for the year ended December 31, 2006 to \$2.6 million for the same period

in 2007. The decreases in expenses were attributable to the CYC116 program being in full pre-clinical studies during 2006 and then moving to a Phase 1 study in 2007.

Fiscal 2006 as compared to fiscal 2005. Research and development costs increased 34% or \$5.4 million from \$15.8 million in the year ended December 31, 2005 to \$21.2 million in the year ended December 31, 2006. The overall increase primarily relates to an increase in the charge for stock-based compensation of \$6.5 million offset by the effects of the phasing of our clinical trials with the completion stages of Phase 2a clinical trials of seliciclib in 2005 followed by a period of reduced spending prior to the

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start of the Phase 2b trial in the second quarter of 2006. Expenditure increased gradually as our efforts focused on initiating the recruited sites for the Phase 2b trials during the second half of 2006 together with an increase in research and development expenditure on CYC116 as activities focused on IND-directed studies on this program culminating in the filing of the IND as scheduled in December 2006.

### 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.

### Selling, general and administrative expenses

Selling, general and administrative expenses include costs for sales and marketing operations, administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the total selling, general and administrative expenses for the years ended December 31, 2005, 2006 and 2007:

Years ended	\$Differences	% Differences	2005	2006	2007	2005 to 2006	2006 to 2007	
2005 to 2006	2006 to 2007	(in thousands)	Total selling, general and administrative expenses				\$ 5,290	\$
12,319	\$ 11,543	\$ 7,029	\$ (776 )	133 %	(6 )%			

Total selling, general and administrative expenses represented 25%, 37% and 35% of our operating expenses for the years ended December 31, 2005, 2006 and 2007 respectively.

Fiscal 2007 as compared to fiscal 2006. Selling, general and administrative expenditure decreased 6% or \$0.8 million from \$12.3 million in the year ended December 31, 2006 to \$11.5 million in the year ended December 31, 2007. The reduction in expenses was primarily attributable to a decrease in the charge for stock based compensation of \$2.5 million from \$3.4 million during 2006 to \$0.9 million during 2007 offset by sales and marketing expenditure of \$0.8 million related to the new ALIGN acquisition and Delaware taxation, recruitment costs, legal costs that each have increased by \$0.2 million.

Fiscal 2006 as compared to fiscal 2005. Selling, general and administrative expenditure increased 133% or \$7.0 million from \$5.3 million in the year ended December 31, 2005 to \$12.3 million in the year ended December 31, 2006. The increase arose primarily from the new combined business entity and our increased costs of operating as a public company and increased compensation and benefit expenses. The charge for stock-based compensation increased \$3.4 million in the year ended December 31, 2006 compared to the same period in 2005. Salary and benefit expense increased by \$1.4 million in the year ended December 31, 2006 compared with the same period in 2005. This increase was due primarily to the incorporation of payroll costs relating to the remaining support staff of Xcyte as of March 28, 2006, increased bonus payments and United Kingdom payroll taxes incurred in connection with the issue of Group Preferred D shares to certain directors and officers in March 2006 prior to the Stock Purchase. Regulatory, corporate and advisors costs together with insurances have increased \$1.2 million, of which approximately \$0.2 million relates to compliance costs for Section 404 of the Sarbanes Oxley Act, in the year ended December 31, 2006 compared with the same period in 2005. Rental and maintenance of the Seattle office and Bothell manufacturing facilities together with our corporate headquarters in New Jersey have given rise to \$0.7 million of additional costs in the year ended December 31, 2006. There were no comparable expenses recognized in the year ended December 31, 2005.

The future

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

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## Stock-based compensation expenses

We adopted FAS 123R on January 1, 2006 using the modified prospective application method. Previously we recognized stock-based compensation in accordance with the provisions of APB No. 25 “Accounting for Stock Issued to Employees” or APB No. 25. Prior period figures have not been restated and therefore are not comparable to the current year presentation. Stock-based compensation expenses includes charges/(credits) related to options issued to employees, directors and non-employees.

The following table summarizes the components of our stock-based compensation for the years ended December 31, 2005, 2006 and 2007:

Years ended			\$ Differences	% Differences	2005	2006	2007	2005 to 2006	2006 to 2007		
2005 to 2006	2006 to 2007		(in thousands)		Research and development			\$ (295 )	\$ 6,230	\$ 837	\$
6,525	\$ (5,393 )	2,212 %	(87 )%	Selling, general and administrative			(39 )	3,370	896	3,409	
(2,474 )	8,741 %	(73 )%	Total stock based compensation			\$ (334 )	\$ 9,600	\$ 1,733	\$ 9,934	\$	
(7,867 )	2,974 %	(82 )%									

For the year ended December 31 2005 we recognized a stock-based compensation credit of \$0.3 million. The credit recognized arose from an up-date of the market value of the underlying common stock under APB No. 25.

As required by the provisions of FAS No. 123R “Share-Based Payment” or FAS 123R we recorded a stock-based compensation charge of \$9.6 million for the year ended December 31, 2006. The stock-based compensation charge was comprised of (i) \$5.2 million related to restricted stock granted to certain employees and directors (ii) \$1.8 million due to the acceleration of vesting of options due to the Stock Purchase and (iii) \$2.6 million relating to the options granted in the second, third and fourth quarters of 2006 under the 2006 Plan. In the second quarter of 2006, we granted 829,079 stock options under the 2006 Plans, of which two-thirds were fully vested on grant. The remaining unvested options were fully vested in June 2007. In the third quarter of 2006, we granted 16,667 stock options under the 2006 Plans which vest rateably over three years to August 1, 2009. In the fourth quarter of 2006 we granted 488,333 stock options under the 2006 Plans of which approximately 8,333 vest rateably over three years to October 31, 2009, 40,000 vest rateably over four years to October 31, 2010 and 390,000, of which one-quarter vested in December 2007 with the balance vesting rateably over three years to December 21, 2010, and 50,000 fully vested on December 31, 2007.

## Restructuring charge

The following table summarizes the restructuring charges for years ended December 31, 2005, 2006 and 2007:

Years ended		\$ Differences	% Differences	2005	2006	2007	2005 to 2006	2006 to 2007	2005
to 2006	2006 to 2007	(in thousands)	Total restructuring charge	\$ —	\$ 225	\$ 1,554	\$ 225	\$ 1,329	
100 %	591 %								

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. As a result of the agreement, we recorded an additional provision in the third quarter of 2006 of \$0.2 million in recognition of commissions payable upon successful conclusion of a sublease agreement.

For the year ended December 31, 2007, a charge of approximately \$1.6 million has been recognized in the consolidated statement of operations to reflect the reduced likelihood of any sublet income as a result of a deterioration in commercial real estate market conditions in the Bothell area.



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### Future

As of December 31, 2007, the restructuring liability associated with exiting the Bothell facility was \$3.0 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. These changes can be material.

### Other income (expense)

The following table summarizes the other income (expense) for years ended December 31, 2005, 2006 and 2007:

Years ended	\$ Differences	% Differences	2005	2006	2007	2005 to 2006	2006 to 2007	2005
to 2006	2006 to 2007	(in thousands)	Change in valuation of derivative			\$ —	\$ (215 )	\$ (93 )
) \$ 122	(100 )%	57 %	Change in valuation of warrants liability			—	—	3,205
% Interest income	887	2,328	3,554	1,441	1,226	163 %	53 %	Interest expense (60 )
(254 )	(223 )	(194 )	31	(323 )%	12 %	Total other income,net	\$ 827	\$ 1,859
1,032	\$ 4,584	125 %	247 %				\$ 6,443	\$

Fiscal 2007 as compared to fiscal 2006. Total other income, net, increased to \$6.4 million in 2007 from \$1.9 million in 2006.

The change in derivative value of \$0.2 million and \$0.1 million, respectively for the year ended December 31, 2006 and 2007 is associated with the dividend make-whole payment on our outstanding convertible exchangeable preferred stock.

The change in valuation of warrants liability 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 have been classified as a liability in accordance with EITF 00-19 “Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock.” or 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 year ended December 31, 2007, we recognized the change in the value of warrants of approximately \$3.2 million, as other income in the consolidated statement of operations.

The increase in interest income of \$1.3 million to \$3.6 million for the year ended December 31, 2007 from \$2.3 million for the year ended December 31, 2006, is primarily attributable to higher average balances of cash and cash equivalents and short-term investments in 2007 as compared to 2006 primarily as a result of the receipt of \$33.4 million in net proceeds received from the registered direct financing described above.

Interest expense for the year ended December 31, 2007 decreased by \$0.1 million as compared to the same period in 2006. During the year ended December 31, 2006 interest expenses resulted primarily from interest associated with a government loan, the principal of which was repaid in the fourth quarter of 2005. During 2007 interest expense resulted primarily from accretion expense associated with the Bothell lease restructuring provision which amounted to approximately \$0.2 million.

Fiscal 2006 as compared to fiscal 2005. The increase in interest income from \$0.9 million in 2005 to \$2.3 million in 2006 is primarily attributable to higher average balance of cash and cash equivalents and short-term investments in 2006 following receipt of \$42.6 million in net proceeds of our private placement during the second quarter of 2006 and the \$21.1 million of cash and cash equivalents and short-term investments assumed in the Stock Purchase. The increase in interest expense to \$0.3 million in 2006 as compared to \$60,000 in 2005 resulted primarily from accretion expense associated with the Bothell lease restructuring provision. During the year ended December 31, 2006 we recognized accretion expense of \$0.2 million. No such accretion expense was recognized in the year ended December 31, 2005.

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### The future

The valuation of the warrant liability will continue to be re-measured at the end of each reporting period. The valuation of the warrants is dependent upon many factors, including our stock price, and may fluctuate significantly, which may have a significant impact on our statement of operations.

A further accretion expense of approximately \$0.4 million associated with the Bothell lease restructuring charge will be recognized over the remaining life of the lease through November 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 years ended December 31, 2005, 2006 and 2007:

Years ended			\$ Differences	% Differences	2005	2006	2007	2005 to 2006	2006 to 2007	
2005 to 2006	2006 to 2007		(in thousands)		Total income tax benefit			\$ 1,900	\$ 2,245	\$ 2,041
\$ 345	\$ (204 )	18 %	(9 )%							

Fiscal 2007 as compared to fiscal 2006. Research and development tax credits recoverable decreased 9% or \$0.2 million from \$2.2 million in 2006 to \$2.0 million in 2007. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year but restricted to income taxes paid by the Company in that same year. This decrease was a reflection of the increased income taxes available to recover in 2006 compared to 2007.

Fiscal 2006 as compared to fiscal 2005. Research and development tax credits recoverable increased 18% or \$0.3 million from \$1.9 million in 2005 to \$2.2 million in 2006. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year but restricted to income taxes paid by the Company in that same year. This increase was a reflection of the increased income taxes available to recover from the taxes paid in connection with the issue of Group Preferred D shares to certain directors and officers in March 2006, prior to the Stock Purchase.

### Future

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

### Liquidity and Capital Resources

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

December 31, 2006	December 31, 2007	\$ Difference	% Difference	(in thousands)	Cash and cash equivalents	\$ 44,238	\$ 30,987	\$
(13,251 )	(30 )%				Short-term investments, available for sale	9,764	27,766	18,002
					and cash equivalents and short-term investments	\$ 54,002	\$ 58,753	\$ 4,751
					9 %			9 %
					Current assets			\$
					58,165	\$ 63,777	\$ 5,612	10 %
					Current liabilities	7,921	14,712	6,791
					85 %			85 %
					Working capital			
					\$ 50,244	\$ 49,065	\$ (1,179 )	( 2 )%

Since our inception, we have not generated any significant revenues 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

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research and development tax credits. We have incurred significant losses since our inception. As of December 31, 2007, we had an accumulated deficit of \$162.3 million.

We believe that existing funds together with cash generated from the revenues of ALIGN and financing activities are sufficient to satisfy our planned working capital, capital expenditures, debt service and other financial commitments through to at least the next 12 months.

At December 31, 2006, we had cash and cash equivalents and short-term investments of \$54.0 million as compared with \$58.8 million at December 31, 2007. This higher balance at December 31, 2007 was primarily due to the February 2007 registered direct financing of \$33.4 million in gross proceeds.

The following is a summary of our contractual obligations and other commitments relating to our facilities, equipment leases and purchases as at December 31, 2007, and the effect such obligations could have on our liquidity:

Payments due by period				Total	Less than				
1 year	1-3 years	4-5 years	After 5 years	(in thousands)	Capital lease obligations	\$ 10	\$ 10	\$ —	\$ —
\$ —	Operating lease obligations	8,077	2,146	4,195	1,215	521	Other long term payables	1,307	—
1,307	—	—	Other obligations	1,594	1,594	—	—	Total	\$ 10,988
1,215	\$ 521					\$ 3,750	\$ 5,502	\$	

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

We are obligated to pay or accrue quarterly dividends of \$0.3 million on our convertible preferred stock.

The Company, as part of securing long term supply arrangements has commitments to make future payments of approximately \$0.6 million in 2009 and \$0.7 million in 2010. We are also required to purchase approximately \$1.4 million of products.

Cash provided by (used in) operating, investing and financing activities for the years ended December 31, 2005, 2006 and 2007, is summarized as follows:

Year ended December 31,	2005	2006	2007	(in thousands)	Net cash used in operating activities	\$ (15,141 )
	\$ (20,172 )	\$ (23,140 )			Net cash provided by (used by) investing activities	\$ 2,745
						\$ 3,911
						\$ (22,693 )
					Net cash provided by financing activities	\$ 8,354
						\$ 57,400
						\$ 32,208

Fiscal 2007 as compared to fiscal 2006. Net cash used in operating activities increased by \$2.9 million, to \$23.1 million for the year ended December 31, 2007 from \$20.2 million during the year ended December 31, 2006. Net cash used in operating activities during 2007 of \$23.1 million resulted primarily from our net loss of \$24.1 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 \$1.7 million and net increase in working capital of \$1.2 million due to an decrease in prepaid expenses combined with a net increase in accounts payable and accrued expenses.

Net cash provided by investing activities decreased \$26.6 million, to a use of \$22.7 million for the year ended December 31, 2007 from a source of \$3.9 million for the year ended December 31, 2006. During

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2007, we incurred cash expenditures of \$3.8 million for the acquisition of ALIGN on October 5, 2007. During 2007, we purchased short-term investments totaling \$154.0 million which was offset by maturities of \$136.4 million in short term investments. During 2006 and 2007, we purchased fixed assets of \$0.7 million and \$1.8 million, respectively.

Net cash provided by financing activities decreased \$25.2 million, from \$57.4 million for the year ended December 2006 to \$32.2 million for the year ended December 31, 2007. During 2007 the net cash provided by financing activities related primarily to gross proceeds received from the registered direct financing of \$33.4 million offset by payment of our preferred stock dividend of \$1.2 million and payment of capital lease obligations of \$0.1 million. During 2007 and 2006, we received stock option exercises of \$0.2 million and \$0, respectively. During 2006, we received net proceeds of \$42.6 million from the April 2006 private placement of common stock and common stock purchase warrants.

In February 2007, we raised \$36.0 million in gross proceeds, before deducting placement agent fees and offering expenses of \$2.6 million, in a “registered direct” offering through the sale of shares of our common stock and warrants. We sold approximately 4.2 million units, each unit consisting of one share of our common stock and a seven-year warrant to purchase 0.25 shares of our common stock, at a purchase price of \$8.47125 per unit. The purchase price for the shares and the exercise price for the warrants was \$8.44 per share, the closing bid price for our common stock on February 12, 2007. Investors paid \$0.125 per warrant. The Company issued 4,249,668 shares of common stock and warrants to purchase 1,062,412 shares of common stock. 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 December 31, 2007, the warrants issued to the investors were classified 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 December 31, 2007, fair value of the warrants was \$3.5 million. During 2007, the Company recognized the change in the value of warrants of approximately \$3.2 as a gain on the consolidated statement of operations.

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

In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 175,000 shares of common stock at an exercise price of \$7.17 per share which represents a 30% premium over the average of the closing bid prices of our common stock during the 5 trading days preceding the signing of the agreement. The warrant will become

exercisable six months from the date of the agreement and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. As of December 31, 2007, the warrants issued to the investors are classified as equity in accordance with EITF 00-19.



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Fiscal 2006 as compared to fiscal 2005. Net cash used in operating activities increased \$5.1 million, from \$15.1 million in 2005 to \$20.2 million in 2006. Net cash used in operating activities during 2006 of \$20.2 million resulted primarily from our net loss of \$29.3 million. Net cash provided by investing activities increased \$1.2 million, from \$2.7 million in 2005 to \$3.9 million in 2006. Net cash provided by investing activities resulted primarily from the sale and maturity of short-term investments, the proceeds of which were used to fund our operating activities. Net cash provided by financing activities increased \$49.1 million, from \$8.3 million in 2005 to \$57.4 million in 2006. During 2006 the net cash provided by financing activities related primarily to proceeds received from the private placement of \$42.6 million and the \$17.9 million of cash and cash equivalents assumed on the Stock Purchase offset by payment of our preferred stock dividend of \$0.9 million, costs associated with the Stock Purchase of \$2.0 million and the payment of capital lease obligations of \$0.3 million.

During the year ended December 31, 2005, the net cash provided by financing activities related to \$9.2 million received from our former parent company offset by payment of capital lease obligations.

Capital spending is vital to our research and development initiatives and to maintain our operational capabilities. During the years ended December 31, 2006 and 2007 we used cash of \$0.3 million in 2006 to develop our research facilities in Cambridge, England, and \$0.7 million in 2006 to refurbish our new corporate offices in New Jersey and to acquire smaller, but key items, of research and development equipment and replacement items essential to support our information technology function. In 2007 \$1.8 million has been used to invest in key laboratory equipment in both the research & development facilities.

## Operating Capital and Capital Expenditure Requirements

We expect to continue to incur substantial operating losses in the future. While we expect to receive modest product revenues from ALIGN we cannot guarantee that we will generate any additional product revenues until a product candidate has been approved by the FDA or similar regulatory agencies in other countries and successfully commercialized. We currently anticipate that our cash, cash equivalents, marketable securities and proceeds from the private placement will be sufficient to fund our operations at least through the next 12 months. Consequently, we will need to raise substantial additional funds to continue our operations. We cannot be certain that any of our programs will be successful or that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in development, should they succeed. Additionally, we plan to continue to evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

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

- the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;
- the costs associated with establishing manufacturing and commercialization capabilities;
- the costs of acquiring or investing in businesses, product candidates and technologies;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the effect of

competing technological and market developments; and

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

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

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development programs. In addition, we may have to partner one or more of our product candidate programs at an earlier stage of development, which would lower the economic value of those programs to us.

## Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other 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.

## Revenue Recognition

### Product sales

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

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

## Stock-based Compensation

On January 1, 2006, we adopted FAS 123R using the modified prospective application method. 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.

## Warrants liability

## February 2007 Financing

EITF 00-19 requires freestanding contracts that are settled in our own stock, including common stock warrants to be designated as an equity instrument, asset or liability. Under the provisions of EITF 00-19, a contract designated as an asset or a liability must be carried at fair value until exercised or expired, with any changes in fair value recorded in the results of operations. A contract designated as an equity instrument must be included within equity, and no subsequent fair value adjustments are required. We review the classification of the contracts at each balance sheet date. Pursuant to EITF 00-19, since we are

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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 2007 was \$3.2 million with regards to the February 2007 financing.

## Goodwill

Goodwill represents the difference between the purchase price and the fair value of net tangible and identifiable intangible assets acquired in the business combination. We recorded goodwill in March 2006 with respect to the merger with Xcyte and in October 2007 with respect to the acquisition of ALIGN. Under FAS No. 142, "Goodwill and Other Intangible Assets," goodwill and intangible assets with indefinite lives are no longer amortized but are reviewed annually (or more frequently if there are indicators such assets may be impaired) for impairment. Separable intangible assets that are not deemed to have indefinite lives will continue to be amortized over their estimated useful lives. There were no triggering events calling into question the recoverability of goodwill during 2007.

## Recent Accounting Pronouncements

In December 2007, FASB ratified the consensus reached by EITF on EITF Issue 07-1, "Accounting for Collaborative Arrangements" or EITF 07-1. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)." EITF 07-1 will be effective beginning on January 1, 2009. We believe that the adoption of EITF 07-1 will not have a material impact on our consolidated financial statements.

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

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

In February 2007, FASB issued Statement No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115” or FAS 159. FAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, FAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets

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and liabilities. FAS 159 is effective for the Company beginning on January 1, 2008. The adoption of FAS 159 is not expected to have a material effect on our consolidated financial statements based on our current and forecasted business activities.

In September 2006, the FASB issued FAS No. 157, "Fair Value Measurements," or FAS 157, which establishes a framework for measuring fair value, and expands disclosures about fair value measurements. The FASB partially deferred the effective date of FAS 157 for nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis while the effective date for nonfinancial and financial assets and liabilities that are recognized on a recurring basis is effective beginning January 1, 2008. The adoption of FAS 157 is not expected to have a material effect on our consolidated financial statements based on our current and forecasted business activities.

### Item 7A. 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 December 31, 2007 consisted of \$18.5 million in corporate bonds and \$9.3 million in federal agency obligations with contractual maturities of one year or less. Due to the short-term nature of our investments, we believe that our exposure to market interest rate fluctuations is minimal. The corporate bonds in which we invest are rated 'A' or better by both Moody's and Standard and Poor's. Our cash and cash equivalents are held primarily in highly liquid money market accounts. A hypothetical 10% change in short-term interest rates from those in effect at December 31, 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 period. We currently do not engage in extensive 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 December 31, 2007 differences on foreign currency translation of \$0.1 million are shown as a movement in other comprehensive income. In the year ended December 31, 2007 exchange rate differences of \$0.5 million were charged in the consolidated statements of operations.

#### Common Stock Price Risk

In February 2007, we issued common stock and warrants. Pursuant to EITF 00-19, we recorded the fair value of the warrants as a current liability. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the condensed consolidated statements of operations. The change in fair value recognized in the financial statements during 2007 was \$3.2 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.

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



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Item 8. Financial Statements and Supplementary Data

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CYCLACEL PHARMACEUTICALS, INC.  
(A Development Stage Company)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders  
Cyclacel Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Cyclacel Pharmaceuticals, Inc. (a development stage company) as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007 and the period from August 13, 1996 (inception) to December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cyclacel Pharmaceuticals, Inc.(a development stage company) at December 31, 2007 and 2006, and the consolidated results of its operations and its consolidated cash flows for each of the three years in the period ended December 31, 2007 and for the period from August 13, 1996 (inception) to December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As described in Note 2 to the consolidated financial statements, the Company adopted the provisions of Financial Accounting Standards Board Interpretation No.48, "Accounting for Uncertainty in Income Taxes (an interpretation of FASB Statement No. 109)," on January 1, 2007 and the provisions of Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment," on January 1, 2006.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cyclacel Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

London, England  
March 13, 2008

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CYCLACEL PHARMACEUTICALS, INC.  
(A Development Stage Company)

## CONSOLIDATED BALANCE SHEETS

December 31, 2006	2007	(In \$000s, except share amounts)	ASSETS		Current assets:		Cash
and cash equivalents	44,238	30,987	Short-term investments	9,764	27,766	Inventory	— 213
Prepaid expenses and other current assets	4,163	4,811	Total current assets	58,165	63,777	Property, plant and equipment (net)	2,121 3,016
Deposits and other assets	241	196	Intangible assets (net)	—	4,305	Goodwill	2,749 4,618
Total assets	63,276	75,912	LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:			Accounts payable	2,175	4,958	Accrued liabilities	3,324
Other current liabilities	290	1,279	Derivative liability	1,135	—	Warrants liability	— 3,545
Current portion of other accrued restructuring charges	908	905	Current portion of equipment financing	89	10	Total current liabilities	7,921 14,712
Other accrued restructuring charges, net of current	1,436	2,090	Other long term payables	—	1,141	Total liabilities	9,357 17,943
Commitments and contingencies (Note 11)	Stockholders' equity:		Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2006 and 2007, respectively; 2,046,813 shares issued and outstanding at December 31, 2006 and 2007, respectively. Aggregate preference in liquidation of \$20,673,000 at December 31, 2006 and December 31, 2007				
2	Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2006 and 2007, respectively; 16,157,953 and 20,433,129 shares issued and outstanding at December 31, 2006 and 2007, respectively		16	20	Additional paid-in capital		
194,714	222,906	Accumulated other comprehensive loss	(2,537 )	(2,630 )	Deficit accumulated during the development stage		
(138,276 )	(162,329 )	Total stockholders' equity	53,919	57,969	Total liabilities and stockholders' equity	63,276	75,912

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



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CYCLACEL PHARMACEUTICALS, INC.  
(A Development Stage Company)CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)  
(In \$000s, except share and per share amounts)

Preferred Stock   Common Stock   Additional  
paid-in  
capital  
\$000   Accumulated  
other  
comprehensive  
income/(loss)  
\$000   Deferred  
compensation  
\$000   Deficit  
accumulated  
during  
development  
stage  
\$000   Total

\$000	No.	\$000	No.	\$000	On incorporation,	—	—	—	—	—	—	—	—	—	Issue of shares for cash	—
—	—	1	—	—	1	Translation adjustment	—	—	—	—	(4)	—	—	(4)	Loss for the	—
period	—	—	—	—	—	(290)	(290)	Comprehensive loss for the period	—	—	—	—	—	—	—	—
—	—	(294)	Balance at March 31, 1997	—	—	—	1	(4)	—	(290)	(293)	Issue of shares	—	—	—	—
for cash, net of issuance costs	—	—	266,778	—	4,217	—	—	—	4,217	Issue of shares for IP rights	—	—	—	—	—	—
agreement	—	—	—	262	—	—	—	262	Deferred stock-based compensation	—	—	—	—	—	—	—
2,002	—	(2,002)	—	—	Amortization of deferred stock-based compensation	—	—	—	—	—	—	—	—	—	302	—
—	302	Translation adjustment	—	—	—	—	55	—	—	55	Loss for the year	—	—	—	—	—
—	—	(2,534)	(2,534)	Comprehensive loss for the year	—	—	—	—	—	—	—	—	—	(2,479)	Balance	—
at March 31, 1998	—	—	266,778	—	6,482	51	(1,700)	(2,824)	2,009	Amortization of	—	—	—	—	—	—
deferred stock-based compensation	—	—	—	—	—	—	406	—	406	Translation adjustment	—	—	—	—	—	—
—	—	11	—	—	11	Loss for the year	—	—	—	—	—	(3,964)	(3,964)	Comprehensive	—	—
loss for the year	—	—	—	—	—	—	—	(3,953)	Balance at March 31, 1999	—	—	266,778	—	—	—	—
—	6,482	62	(1,294)	(6,788)	(1,538)	—	—	—	—	—	—	—	—	—	—	—

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



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CYCLACEL PHARMACEUTICALS, INC.  
(A Development Stage Company)CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (contd)  
(In \$000s, except share and per share amounts)

Preferred Stock paid-in capital \$000	Accumulated other comprehensive income/(loss) \$000	Deferred compensation \$000	Deficit accumulated during development stage \$000	Total \$000	No.	\$000	No.	\$000	Issue of shares for cash, net of issuance costs	—	—	5,451	—	—	—	—
—	—	—	—	—	—	—	—	—	106	—	—	—	106	Issue of shares for license	—	—
agreement	—	—	4,510	—	183	—	—	—	183	Fair value of warrants issued to shareholders	—	—	—	—	—	—
—	—	1,215	—	—	—	—	—	1,215	Deferred stock-based compensation	—	—	—	363	—	(363)	—
—	—	—	—	—	—	—	—	—	672	—	672	Translation	—	—	—	—
adjustment	—	—	—	—	—	—	—	191	—	—	—	—	—	—	—	(14,853)
(14,853)	—	—	—	—	—	—	—	—	—	—	—	—	(14,662)	Balance at March 31,	—	—
2002	—	—	917,555	1	23,777	(407)	(738)	(37,709)	(15,076)	Exercise of share options	—	—	—	—	—	—
for cash	—	—	—	—	12	—	—	—	12	Deferred stock-based compensation	—	—	—	—	(84)	—
84	—	—	—	—	—	—	—	—	—	—	—	—	305	—	305	—
Translation adjustment	—	—	—	—	—	—	—	(1,846)	—	—	—	(1,846)	Loss for the year	—	—	—
—	—	(15,542)	(15,542)	—	—	—	—	—	—	—	—	—	—	—	—	(17,388)
Balance at March 31, 2003	—	—	917,555	1	23,705	(2,253)	(349)	(53,251)	(32,147)	—	—	—	—	—	—	—

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







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—	—	—	(93 )	—	—	(93 )	Comprehensive loss for the year	—	—	—	—	—	—	—	—	(24,146 )
Balance at December 31, 2007	2,046,813	2	20,433,129	20	222,906	(2,630 )	—	(162,329 )	57,969							

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

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CYCLACEL PHARMACEUTICALS, INC.  
(A Development Stage Company)

## CONSOLIDATED STATEMENTS OF CASH FLOWS (contd)

Year ended											
December 31,											
2005 Year ended											
December 31,											
2006 Year ended											
December 31,											
2007 Period from											
August 13, 1996											
(inception) to											
December 31,											
2007	\$000	\$000	\$000	\$000	Financing activities:				Payments of capital lease obligations		
(294 )	(269 )	(89 )	(3,709 )		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	33,357	75,983			Proceeds from the exercise of stock options and issue of warrants, net of issuance costs						
— —	163	163			Payment of preferred stock dividend				(921 )	(1,223 )	(2,144 )
Repayment of government loan				(455 )	—	—	(455 )	Government loan received		—	—
Cyclacel Group plc				9,103	—	—	9,103	Proceeds of committable loan notes issued from shareholders		—	—
— 8,883					Loans received from shareholders				—	—	—
purchase of Xcyte				— 17,915	—	17,915	Costs associated with stock purchase		— (1,951 )	— (1,951 )	
) Net cash provided by financing activities				8,354	57,400	32,208	196,705	Effect of exchange rate			
changes on cash and cash equivalents				(607 )	(18 )	374	5,739	Net (decrease) increase in cash and cash			
equivalents				(4,042 )	41,139	(13,625 )	25,248	Cash and cash equivalents, beginning of period		7,766	
3,117	44,238	—			Cash and cash equivalents, end of period		3,117	44,238	30,987	30,987	
Supplemental cash flow information:											
Cash received during the period for:											
Interest	769	2,377	2,437	10,922	Taxes	2,441	1,906	2,045	12,884	Cash paid during the	
period for:				Interest	(131 )	(80 )	(858 )	(1,681 )	Schedule of non-cash transactions		
Acquisitions of equipment purchased through capital leases								—	—	—	3,470
Common shares in connection with license agreements								—	—	—	592
conversion of bridging loan								—	—	—	1,638
convertible loan notes and accrued interest								—	—	—	8,893
cash bonus								—	—	—	164
Issuance of other long term payable on ALIGN acquisition								—	—	—	1,122
1,122											

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

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CYCLACEL PHARMACEUTICALS, INC.  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1

ORGANIZATION OF THE COMPANY

Cyclacel Pharmaceuticals, Inc. (“Cyclacel”, or the “Company”) was incorporated in the state of Delaware in 1996 and is headquartered in Berkeley Heights, New Jersey with research facilities located in Dundee, Scotland and Cambridge, England. Cyclacel is a development-stage biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Cyclacel’s strategy is focused on leading edge therapeutic management of cancer patients based on a portfolio of three products marketed by its ALIGN subsidiary and a deep development pipeline. Three orally-available drugs are in clinical development: sapacitabine, in two randomized Phase 2 studies for the treatment of elderly acute myeloid leukemia or AML and cutaneous T-cell lymphoma, or CTCL; seliciclib, in two randomized Phase 2 studies for the treatment of non-small cell lung cancer or NSCLC and nasopharyngeal cancers or NPC and CYC116, in Phase 1 in patients with solid tumors. As a development stage enterprise, substantially all efforts of the Company to date have been devoted to performing research and development, conducting clinical trials, developing and acquiring intellectual properties, raising capital and recruiting and training personnel.

Recent Financial Developments

On December 10, 2007, Cyclacel entered into a Committed Equity Financing Facility or CEFF with Kingsbridge Capital Limited or Kingsbridge, who committed to purchase the lesser of 4,084,590 shares of common stock or \$60 million of common stock from Cyclacel during the next three years. Under the terms of the agreement, Cyclacel will determine the exact timing and amount of any CEFF financings, subject to certain conditions. All amounts “drawn down” under the CEFF will be settled via the issuance of Cyclacel’s common stock. In addition the Company issued approximately 0.2 million of warrants with an exercise price of \$7.17 per warrant.

On February 20, 2007, Cyclacel raised gross proceeds of \$36.0 million through a registered direct financing from the sale of shares of its common stock and warrants, before deducting placement agent fees and estimated offering expenses. 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 in the financing paid \$0.03125 per warrant, for an aggregate purchase price of \$8.47125 for one share of common stock and a warrant to purchase 0.25 of a share of common stock. At closing, the Company issued approximately 4.2 million shares of common stock and warrants to purchase approximately 1.1 million shares of common stock.

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 or ALIGN, a wholly-owned subsidiary of Cyclacel, entered into a definitive asset purchase agreement with ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC collectively, the Sellers to acquire substantially all of the Sellers’ assets. The transaction closed on the same date.

Cyclacel 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 asset purchase and pursuant and subject to the terms of the agreement, Cyclacel paid \$3.3 million in cash to the Sellers and may pay an additional aggregate amount of

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\$0.5 million within 130 business days from the closing date of the asset acquisition, in cash, shares of the Company's common stock, or a combination thereof. In addition, Cyclacel may be required to issue to the Sellers a maximum number of 184,176 shares of common stock. Issuance is contingent upon the achievement of certain operational and financial milestones and subject to satisfaction of any outstanding indemnification obligations by the Sellers. Cyclacel will issue the shares of its common stock only to the extent that the milestones are achieved. Cyclacel are also committed, as part of securing long term supply arrangements, to make future payments of approximately \$0.6 million in 2009 and \$0.7 million in 2010. In connection with the asset acquisition of ALIGN, Cyclacel recorded the assets and liabilities of ALIGN at their respective fair values on the date of acquisition. Cyclacel included the results of operations for the acquired business in its consolidated statement of operations from October 5, 2007. William C. Collins, the former chief executive officer and manager of the Sellers, was appointed as the general manager of ALIGN.

## Acquisition of Xcyte Therapies Inc.

On March 27, 2006, Xcyte Therapies Inc. (Xcyte) completed a Stock Purchase Agreement (the Stock Purchase Agreement) with Cyclacel Group plc (Group), a public company organized under the laws of England and Wales in which Xcyte agreed to purchase from Group all of the capital stock of Cyclacel Limited (Limited), a private limited company organized under the laws of England and Wales and a wholly-owned subsidiary of Group. For more information please see the Company's December 31, 2006 Annual Report filed on Form 10-K with the SEC.

## Basis of Presentation

The accompanying consolidated financial statements as of December 31, 2006 and 2007, and for each of the three years in the period ended December 31, 2007, have been prepared in accordance with accounting principles generally accepted in the United States. The consolidated financial statements include the financial statements of Cyclacel Pharmaceuticals, Inc. and all of the Company's wholly owned subsidiaries. All intercompany balances and transactions have been eliminated.

## 2 Summary

### of Significant Accounting Policies

### Use of Estimates

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

### Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments which potentially subject the Company to concentrations of risk consist principally of cash and cash equivalents, short-term investments and accounts receivable. At December 31, 2007, the Company did not believe it had any concentration of credit risk.

The Company's cash and cash equivalents are invested in deposits with banks in the United Kingdom and the United States.

Drug candidates developed by the Company may require approvals or clearances from the U.S. Food and Drug Administration or FDA or other international regulatory agencies prior to commercialize sales. There can be no assurance that the Company's drug candidates will receive any of the required approvals or clearances. If the Company was denied approval or clearance or such approval was delayed, it may have a material adverse impact on the Company.



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### Foreign currency and currency translation

Average rates of exchange ruling during the year have been used to translate the statement of operations of the overseas subsidiary from its functional currency. Transactions which do not take place in an entity's functional currency are converted at the spot rate.

Monetary assets and liabilities denominated in foreign currencies are retranslated from their functional currency at balance sheet exchange rates. The balance sheet of the overseas subsidiary is translated at rates ruling at the balance sheet date from their functional currency. Differences on translation arising from changes in the dollar value of overseas net assets and related foreign currency loans at the beginning of the accounting year together with the differences between statements of operations translated at average rates and at balance sheet rates are shown as a movement in other comprehensive income. Other exchange rate differences are dealt with in the statements of operations for the year.

### Segments

The Company has adopted Statement of Financial Accounting Standards or FAS, No.131, "Disclosure about Segments of an Enterprise and Related Information," and related disclosures about products, services, geographic areas and major customers. The Company has determined that it has one reportable segment.

### Cash and Cash Equivalents

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

### Short-term Investments

The Company invests in certain marketable debt securities. Debt securities at December 31, 2006 and 2007 comprise investment-grade government and commercial securities purchased to generate a higher yield than cash equivalents. In accordance with FAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," or FAS 115 such investment securities are classified as available-for-sale and are carried at fair value. Under FAS 115, unrealized gains and losses, net of tax, are reported in a separate component of stockholders' equity until realized. Amortization, accretion, interest and dividends, realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in interest income. For the purpose of computing realized gains and losses, the cost of securities sold is based on the specific-identification method. Investments in securities with maturities of less than one year or which management intends to use to fund current operations are classified as short-term investments.

The Company evaluates whether an investment is other-than-temporarily impaired. This evaluation is dependent upon the specific facts and circumstances. Factors that are considered in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis; the financial condition of the issuer; the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment.

The Company also invests its surplus cash in bank term deposits having a maturity period of between one day and one year. Accordingly, all cash resources with original maturity of three months or less have been classified as cash and cash equivalents and those with original maturity of more than three months as short-term investments.

#### Inventory

Cyclacel values inventories at lower of cost or net realizable value. The Company determines cost using the first-in, first-out method. The Company analyzes its inventory levels quarterly and writes-down

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inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory is disposed of and the related costs are written off. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required.

## Fair Value of Financial Instruments

For financial instruments consisting of cash and cash equivalents, short-term investments, accounts payable and accrued liabilities included in the Company's financial statements, the carrying amounts are reasonable estimates of fair value due to their short maturities.

## Property, Plant and Equipment

Property, plant and equipment is stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets, which are generally three to five years. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related assets, currently between five and fifteen years. Upon sale or retirement of assets, the costs and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected as a component of operating income or loss. Expenditures for maintenance and repairs are charged to operating expenses as incurred.

## 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. Goodwill and intangible assets acquired in a purchase business combination and determined to have an indefinite useful life are not amortized, but instead are tested for impairment at least annually in accordance with the provisions of FAS No. 142, "Goodwill and Other Intangible Assets." or FAS 142.

To test for impairment, the Company must compare the fair value of its reporting units to their respective carrying values, including assigned goodwill. For all years presented in this report, the Company has determined that it has one reporting unit for purposes of applying FAS No. 142. To the extent the carrying amount of the reporting unit exceeds its fair value, Cyclacel would be required to perform the second step of the impairment analysis, as this is an indication that the reporting unit goodwill may be impaired. In this second step, Cyclacel compares the implied fair value of the reporting unit goodwill with the carrying amount of the reporting unit goodwill. The implied fair value of goodwill is determined by allocating the fair value of the reporting unit to all of the assets (recognized and unrecognized) and liabilities of the reporting unit in a manner similar to a purchase price allocation, in accordance with FAS No. 141 "Business Combinations." The residual fair value after this allocation represents the implied fair value of the reporting unit goodwill. To the extent the implied fair value of goodwill of the reporting unit is less than its carrying amount Cyclacel would be required to recognize an impairment loss.

The fair value of the Company's single reporting unit is determined based on the fair market value of Cyclacel's outstanding common stock, preferred stock and common stock warrants. The carrying value of Cyclacel's single reporting unit is represented by the Company's book value net assets. The results of the annual impairment tests, based on values as of September 30, 2006 and 2007, respectively, indicated the fair value of the reporting unit exceeded its carrying value. Based on the results of the annual impairment analysis, no impairment charges were recorded against goodwill.

## Intangibles

As part of the acquisition of ALIGN, Cyclacel acquired rights to a license agreement with Sinclair as well as the various customer relationships. This agreement allows Cyclacel to exclusively sell and distribute Xclair™ Cream, Numoisyn™ Liquid and Numoisyn™ Lozenges in the United States. Cyclacel will amortize the license agreement and customer relationship intangible assets over the remaining life of the contract of approximately seven years. The fair values ascribed to the license agreements and

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customer relationships on October 5, 2007 were \$3.0 million and \$0.5 million, respectively. During 2007, the Company amortized approximately \$0.5 million and \$0.1 million for the license agreement and customer relationships, respectively. The Company expects to amortize \$0.5 million each year for these intangible assets until June 2015.

As part of the acquisition of ALIGN, Cyclacel assumed all rights under its trade name, non-compete agreements signed between ALIGN and its senior managers as well as obtaining a beneficial contract pricing arrangement. Cyclacel will amortize the fair values of these assets acquired in the ALIGN acquisition over 2 years, which represents the approximate time period that the non-compete agreements will remain in effect based on the employment contracts of the existing ALIGN management team. The fair value ascribed to the non-compete agreements, trade name and beneficial contract pricing arrangement on October 5, 2007 was \$0.4 million, \$0.1 million and \$0.4 million respectively. During 2007, the Company amortized approximately \$50,000 for the non-compete agreements, \$10,000 on the trade name and \$15,000 on the beneficial pricing contract. The Company expects to amortize \$0.2 million annually for non-competes, \$0.1 million for the trade name and \$0.2 million for the beneficial pricing contract each year for the next two years; 2008 — 2010.

## Impairment of Long-lived Assets

In accordance with the provisions of FAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets” or FAS 144, the Company reviews long-lived assets, including property, plant and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Under FAS 144, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. Through December 31, 2007 there have been no impairments of long-lived assets.

## Revenue Recognition

### Product sales

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

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

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

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

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

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

## Clinical Trial Accounting

Nearly all of the Company's clinical trials are performed by contract research organizations or CROs or under the supervision of contract research assistants or CRAs and participating clinical trial sites. CRAs and some CROs bill monthly for services performed, and others bill based upon milestones achieved. For outstanding amounts, the Company accrues unbilled clinical trial expenses based on the services performed each period. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as research and development expenses. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial reduced by any initial payment made to the clinical trial site when the first patient is enrolled.

## Research and Development Expenditures

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

## Patent Costs

Costs relating to prosecution are charged to operations as incurred as recoverability of such expenditure is uncertain.

## Leased Assets

The costs of operating leases are charged to operations on a straight-line basis over the lease term.

Where the Company enters into a lease which entails taking substantially all the risks and rewards of ownership of an asset, the lease is treated as a capital lease. The asset is recorded in the balance sheet as an asset and is depreciated in accordance with the aforementioned depreciation policies. The capital elements of future lease payments are recorded as liabilities and the interest is charged to operations over the period of the lease.

## Income Taxes

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

The company adopted FIN48 “Accounting for Uncertainty in Income Taxes” that was an interpretation of SFAS 109 accounting for income taxes, or FIN48. FIN48 clarifies the accounting for uncertainty in income taxes recognized in a company’s financial statements by prescribing a minimum probability threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods as well as disclosure and transition.



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

## Net Loss Per Common Share

The Company calculates net loss per common share in accordance with FAS No. 128 "Earnings Per Share" or FAS 128. Basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. The Company's potentially dilutive shares, which include outstanding common stock options, convertible preferred stock, make-whole dividend payments of common stock on convertible preferred stock and common stock warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

							Years
ended December 31,	2005	2006	2007	Stock options	—	1,335,841	2,592,246
—	870,980	870,980	Make-whole dividend payments of common stock on convertible preferred stock	—			
190,608	—	Cyclacel stock to be issued on October 5, 2008	—	—	46,044	Common stock warrants	—
2,572,653	3,809,703	Total shares excluded from calculation	—	4,970,082	7,318,973		

## Derivative Instruments

The terms of Cyclacel's November 2004 convertible preferred stock offering included a dividend make-whole payment feature. If the Company elected to automatically convert, or the holder elects to voluntarily converted, some or all of the convertible preferred stock into shares of its common stock prior to November 3, 2007, the Company 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 additional payment was payable in cash or, at the Company's option, in shares of its common stock, or a combination of cash and shares of common stock. This dividend make-whole payment feature was considered to be an embedded derivative and has been recorded on the balance sheet at fair value as a current liability. Cyclacel recognized other income (expense) in its statements of operations as the fair value of this derivative fluctuates from period to period.

The accounting for derivatives 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 the Company's results of operations.

## Stock-based Compensation

The Company has various stock-based compensation plans for employees and outside directors, which are described more fully in Note 13 "Stock-Based Compensation Arrangements". The Company accounts for these plans under FAS No. 123R "Share-Based Payment" or FAS 123R effective January 1, 2006 under the modified prospective application method.

Comprehensive Income (Loss)

In accordance with FAS No. 130, “Reporting Comprehensive Income,” all components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the

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

## Recent Accounting Pronouncements

In December 2007, FASB ratified the consensus reached by EITF on EITF Issue 07-1, “Accounting for Collaborative Arrangements” or EITF 07-1. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, “Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor’s Products).” EITF 07-1 will be effective beginning on January 1, 2009. The Company believes that the adoption of EITF 07-1 will not have a material impact on its consolidated financial statements.

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

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

In February 2007, FASB issued Statement No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115” or FAS 159. FAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, FAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. FAS 159 is effective for the Company beginning on January 1, 2008. The adoption of FAS 159 is not expected to have a material effect on the Company’s consolidated financial statements based on our current and forecasted business activities.

In September 2006, the FASB issued FAS No. 157, “Fair Value Measurements,” or FAS 157, which establishes a framework for measuring fair value, and expands disclosures about fair value measurements. The FASB partially

deferred the effective date of FAS 157 for nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis while the effective date for nonfinancial and financial assets and liabilities that are recognized on a recurring basis is effective beginning January 1, 2008. The adoption of FAS 157 is not expected to have a material effect on the Company's consolidated financial statements based on our current and forecasted business activities.

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3 Significant

Contracts

Distribution, Licensing and Research Agreements

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

In respect of Licensing Agreements, additional payments of \$23.4 million would be payable if the Company achieves predefined milestones subject to achievement of all the specific contractual milestones and the Company's decision to continue with these projects. Under these agreements the Company makes annual payments that do not presently exceed \$0.1 million. Moreover, these payments will not exceed \$0.1 million per annum while the defined milestones set out in the related agreements have not been achieved.

In connection with the asset acquisition with ALIGN on October 5, 2007, the Company acquired license agreements for the exclusive rights to sell and distribute three products in the United States. The Company, as part of securing long term supply arrangements has commitments to make future payments of approximately \$0.6 million in 2009 and \$0.7 million in 2010 . Also, the Company is required to purchase approximately \$1.4 million of products.

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Acquisition

ALIGN

On October 5, 2007, Achilles Acquisition, LLC, renamed immediately following the acquisition to ALIGN Pharmaceuticals, LLC or ALIGN, a wholly-owned subsidiary of Cyclacel, entered into a definitive asset purchase agreement with ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC collectively, the Sellers to acquire substantially all of the Sellers' assets. The transaction closed on the same date.

The Company, 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 asset purchase and pursuant and subject to the terms of the agreement, we paid \$3.3 million in cash to the Sellers and shall pay an additional aggregate amount of \$0.5 million within 130 business days from the closing date of the asset acquisition, in cash, shares of our common stock, or a combination thereof. In addition, we may be required to issue to the Sellers a maximum number of 184,176 shares of common stock. Issuance is contingent upon the achievement of certain operational and financial milestones and subject to satisfaction of any outstanding indemnification obligations by the Sellers. We will issue the shares of our common stock only to the extent that the milestones are achieved. We are also committed, as part of securing long term supply arrangements, to make future payments of approximately \$0.6 million in 2009 and \$0.7 million in 2010.

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

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### Acquisition Purchase Price

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

	Cash and equity	\$ 3,571	Acquisition costs	432
Total purchase price	\$ 4,003			
Acquisition Preliminary Purchase Price Allocation				

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

equipment	10	Intangible assets	4,495	Current liabilities	(1,400 )	Current assets	\$ 151	Property, plant and
Goodwill	1,869	\$ 4,003				Non-current liabilities	(1,122 )	
Pro Forma Results of Operations								

The results of operations of ALIGN are included in Cyclacel's consolidated financial statements from the date of the business combination transaction as of October 5, 2007. The following table presents pro forma results of operations and gives effect to the business combination transaction as if the business combination was consummated at January 1, 2006. 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.

								Year ended		
December 31,	2006	2007	\$000	\$000	Revenues	1,398	911	Loss before taxes	(35,983 )	(27,143 )
Net loss applicable to common stockholders					(36,565 )	(25,102 )	Net loss per share – basic and diluted			\$ (2.73 )
Weighted average shares					13,390,933	19,873,911				
Xcyte										

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





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Each Limited and Group stock option and warrant that was not converted prior to the consummation of the Stock Purchase was cancelled.

### 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 of December 15, 2005 of \$4.38 (as adjusted for the 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 option pricing model with the following assumptions: stock price of \$4.38 (as adjusted for the reverse stock split), volatility of 0.97; risk-free interest rate of 4.0%; and an expected life of three months.

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

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

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

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

The results of operations of Xcyte are included in Cyclacel's 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 January 1, 2005. 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.

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									Year ended	
December 31,	2005	2006	\$000	\$000	Revenues	1,169	5,387	Loss before taxes	(49,364 )	(30,660
)	Net loss applicable to common stockholders	(59,340 )	(31,242 )	)	Net loss per share – basic and diluted	\$				
(8.91 )	\$ (2.33 )	Weighted average shares	6,656,732	13,390,933						
5	Cash and Cash Equivalents									

The following is a summary of cash and cash equivalents at December 31, 2006 and 2007:

									December 31,	2006
2007	\$000	\$000	Cash	19,738	5,408	Deposits with original maturity of less than three months	24,500			
25,579	44,238	30,987								
6	Short-term Investments									

The following is a summary of short-term investments at December 31, 2006 and 2007:

December 31, 2006	Amortized									
cost	Gross									
unrealized										
gains	Gross									
unrealized										
losses	Fair value	\$000	\$000	\$000	\$000	Federal agency obligations	1,835	—	(1 )	1,834
Corporate bonds	7,918	15	(3 )	7,930	9,753	15	(4 )	9,764		

December 31, 2007	Amortized									
cost	Gross									
unrealized										
gains	Gross									
unrealized										
losses	Fair									
value	\$000	\$000	\$000	\$000	Federal agency obligations & municipal bonds	9,354	—	—	9,354	
Corporate bonds & commercial paper	18,390	24	(2 )	18,412	27,744	24	(2 )	27,766		

The Company did not dispose of any securities prior to maturity during the year ended December 31, 2006. In 2007, the Company disposed of a short-term security prior to maturity, realizing a loss of \$9,000.

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

All investments held at December 31, 2006 have contractual maturities within one year. At December 31, 2007, the Company had marketable securities at fair value with maturities of one year or less of \$26.3 million and greater than one year of \$1.5 million.



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7 Prepaid

Expenses and Other Current Assets

The following is a summary of prepaid expenses and other current assets at December 31, 2006 and 2007:

							December 31,	2006
2007	\$000	\$000	Research and development tax credit receivable	2,379	2,467	Prepayments	1,371	
1,741			Other current assets	413	603			
				4,163	4,811			
8			Property, Plant and Equipment					

Property, plant and equipment consisted of the following:

								Useful
lives in years								
from date of acquisition	December 31,	2006	2007	\$000	\$000	Leasehold improvements		
Life of lease (15 yrs)	960	996	Research and laboratory equipment	3 to 5 yrs	8,648	9,956	Office	
equipment and furniture	3 to 5 yrs	1,496	2,159	11,104	13,111	Less: accumulated depreciation and		
amortization	(8,983 )	(10,095 )	2,121	3,016				
The depreciation and amortization of property, plant and equipment amounted to \$1.3 million, \$1.1 million and \$1.1 million for the years ended December 31, 2005, 2006 and 2007, respectively. These charges include depreciation of assets held under capital leases.								

Depreciation and amortization expense for the period from inception or August 13, 1996 through to December 31, 2007 was \$10.2 million. Included in property, plant and equipment are assets under capital lease obligations with an original cost of \$3.8 million and approximately \$10,000 as of December 31, 2006 and 2007 respectively. Accumulated depreciation on assets under capital leases was \$3.2 million and \$2,000, as of December 31, 2006 and 2007 respectively.

9 Accrued and Other Current Liabilities

Accrued liabilities consisted of the following:

							December 31,	2006
2007	\$000	\$000	Accrued research and development	3,020	3,681	Other liabilities	304	334
3,324	4,015							
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Other current liabilities consisted of the following:

									December 31, 2006
2007	\$000	\$000	Payroll	290	308	Preferred stock dividends declared	—	307	Deferred consideration
payable in common stock	—	250	Other current liabilities	—	414	290	1,279		
10	Related Party Transactions								

## Fees Paid to Shareholders

Since inception through June 30, 2004, when Cyclacel Limited was acquired by Cyclacel Group plc in an exchange of shares, Cyclacel Limited paid fees to shareholders for the services and expenses of their directors appointed to the Cyclacel Group plc. From July 1, 2004 through becoming a public Company on March 27, 2006, these services were provided to Cyclacel Group plc and the fees were payable by Cyclacel Group plc. Since July 1, 2004 all of these fees have been allocated to Cyclacel Group plc based on assumptions that the directors believe are reasonable under the circumstances. The directors believe these allocations are indicative of the costs that Cyclacel Limited would have incurred if it had operated on a standalone basis or as an entity independent of Cyclacel Group plc.

									Year
ended									
December 31,									
2005	Year ended								
December 31,									
2006	Year ended								
December 31,									
2007	\$000	\$000	\$000	Merlin Venture Limited	24	6	—	Invesco	24 6 —
Amounts Receivable from Directors and Officers									

In connection with the issue of Group Preferred D shares to certain directors and officers in March 2006 prior to the Stock Purchase the Company was obliged to withhold payroll taxes of \$0.2 million and remit this amount to the UK tax authorities. As this was a non-cash item the taxes could not be withheld from the payment but had to be recovered from the employee. Under the UK Income and Taxes Act 1988 these payroll taxes were recoverable from the relevant individuals by June 27, 2006 and all amounts had been recovered prior to this date.

## 11 Commitments and contingencies

### General

Please refer to Notes 3 and 4 for a further discussion of certain of the Company's commitments and contingencies.

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## Leases

The following is a summary of the Company's contractual obligations and commitments relating to its facilities and equipment leases as at December 31, 2007:

	Capital									
lease obligations	Operating									
\$000	\$000	2008	10	2,146	2009	—	2,196	2010	—	1,999
537	Thereafter	—	522	10	\$ 8,077	Less amount representing interest	—	Present value of future		
minimum lease payments	10		Less current portion	10		—				
Rent expense, which includes lease payments related to the Company's research and development facilities and corporate headquarters and other rent related expenses, was \$0.7 million, \$1.0 million and \$1.1 million for the years ended December 31, 2005, 2006 and 2007, respectively.										

In October 2000, the Company entered into a 25-year lease for its research and development facility in Dundee, Scotland. The Company also leases a second research facility at the Babraham Research Campus, Cambridge, England. The Company entered into this five-year lease in August 2005.

The Company continues to lease approximately 40,500 square feet of space in Bothell, Washington, with monthly payments of approximately \$0.1 million. The lease term on this space expires December 2010. However, activities were discontinued at the Bothell facility during the third quarter of 2005 and the Company continued to explore options for the future of this facility. Market conditions for subleasing space in Bothell are currently considered poor primarily due to an overabundance of available space. Accordingly, as part of the Stock Purchase on March 27, 2006, the Company recorded an accrued restructuring liability which was computed as the present value of the difference between the remaining lease payments due less the estimate of net sublease income and expenses.

As of December 31, 2007 the accrued restructuring liability was \$3.0 million. This represents the Company's best estimate of the fair value of the liability as determined under FAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." Subsequent changes in the liability due to accretion, or changes in estimates of sublease assumptions, etc. will be recognized as adjustments to restructuring charges in future periods.

In October 2006, the Company entered into a five-year lease for office space in Berkeley Heights, New Jersey which is the location of the Company's corporate headquarters.

## Guarantee

On July 28, 2005, Cyclacel Group plc signed a convertible Loan Note Instrument constituting convertible unsecured loan notes. On July, 28, 2005, it entered into a Facility Agreement with Scottish Enterprise, as lender, whereby Scottish Enterprise subscribed for £5 million, or approximately \$9 million, of the convertible loan notes. Upon the completion of the Stock Purchase, the convertible loan notes held by Scottish Enterprise converted into 1,231,527 preferred D shares in satisfaction of all amounts owed by Group under the convertible loan notes. The number of preferred D shares that Scottish Enterprise received was calculated by dividing the principal amount outstanding under the loan note by £4.06. Scottish Enterprise retains the ability it had under the Facility Agreement to receive a cash

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should the research operations in Scotland be significantly reduced. However, Cyclacel Limited will guarantee approximately \$9 million, the amount potentially due to Scottish Enterprise, which will be calculated as a maximum of £5 million less the market value of the shares held (or would have held in the event they dispose of any shares) by Scottish Enterprise at the time of any significant reduction in research facilities during the period ending on July 28, 2010.

## Purchase Obligations

At December 31, 2007, the Company had minimum purchase obligations of approximately \$1.4 million falling due during 2008 in relation to the purchase of manufactured products within the Align business.

## Legal proceedings

In the ordinary course of business the Company may be subject to legal proceedings and claims. The Company is not currently subject to any material legal proceedings.

## 12 Stockholders' Equity (Deficit)

### 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, August and November 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, July 20, 2007 and October 19, 2007, respectively.

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 December 31, 2006 (after giving effect to the one for ten reverse stock split of Xcyte's common



stock). In the year ended December 31, 2004, holders had voluntarily converted 910,187 shares of Preferred Stock into 3,873,124 shares of common stock. In the year ended December 31, 2005, holders voluntarily converted 33,000 shares of preferred stock into 140,425 shares of common stock. During 2006 and 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

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Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

The Company and the holders elected not to automatically convert some or all of the Preferred Stock into common stock prior to November 3, 2007. If they had done so, the Company would have made an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through November 3, 2007, less any dividends already paid on the Preferred Stock. This additional payment would have been payable in cash or, at the Company's option, in shares of the Company's common stock, or a combination of cash and shares of common stock. As of December 31, 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 Statement of FAS No. 133, "Accounting for Derivative Instruments" or FAS 133, the Company was required to separate and account for, as an embedded derivative, the dividend make-whole payment feature of the Preferred Stock. As an embedded derivative instrument, the dividend make-whole payment feature was measured at fair value and reflected as a liability. Changes in the fair value of the derivative were recognized as a gain or loss in the consolidated statement of operations as a component of other income (expense). As of March 27, 2006 the fair value of the dividend make-whole payment feature was \$1.8 million. The carrying value of this derivative was reduced by \$0.9 million during the year ended December 31, 2006, based on cash dividends paid during the period. At December 31, 2006, the derivative liability was valued at \$1.1 million and subsequently reduced to \$0 on November 3, 2007, the last date of possible conversion. During 2006 and 2007, the Company recorded a charge of \$0.2 million and \$0.1 million, respectively, on the consolidated statement of operations.

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

### March 2006 Stock Purchase Agreement

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

### April 2006 Securities Purchase Agreement

On April 26 2006, the Company entered into a Securities Purchase Agreement pursuant to which it sold to certain investors, for an aggregate purchase price of \$45.3 million, 6,428,572 shares of its common stock and warrants to purchase up to 2,571,429 additional shares of its common stock. The purchase price for the common stock and the exercise price for the warrants is \$7.00 per share. Investors in the financing paid an additional purchase price equal to

\$0.125 per warrant or an additional \$0.05 for each share underlying the warrants. The warrants became exercisable six months after the closing and have an expiration date seven years thereafter. As of December 31, 2007 all warrants are outstanding.

#### February 2007 Registered Direct Offering

On February 16, 2007, the Company raised \$36.0 million in gross proceeds, before deducting placement agent fees and offering expenses of \$2.6 million, in a “registered direct” offering through the

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sale of shares of the Company's common stock and warrants. The Company entered into subscription agreements with these investors pursuant to which it sold approximately 4.2 million units, each unit consisting of one share of common stock and a seven-year warrant to purchase 0.25 shares of common stock, at a purchase price of \$8.47125 per unit. The purchase price for the shares and the exercise price for the warrants was \$8.44 per share, the closing bid price for the Company's common stock on February 12, 2007. Investors paid \$0.125 per warrant. The Company issued 4,249,668 shares of common stock and warrants to purchase 1,062,412 shares of common stock.

The warrants issued to the investors are being accounted for as a liability in accordance with EITF 00-19. At the date of the transaction, the fair value of the warrants of \$6.8 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate — 4.58%, expected volatility — 85%, expected dividend yield — 0%, and a remaining contractual life of 6.88 years. The value of the warrant shares is being marked to market each reporting period as a derivative gain or loss on the consolidated statement of operations until exercised or expiration. At December 31, 2007, the fair value of the warrants was \$3.5 million. During 2007, the Company recognized the change in the value of warrants of approximately \$3.2 as a gain on the consolidated statement of operations.

### December 2007 Committed Equity Financing Facility

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

In connection with the CEFF, Cyclacel issued a warrant to Kingsbridge to purchase up to 175,000 shares of common stock at an exercise price of \$7.17 per share which represents a 30% premium over the average of the closing bid prices of Cyclacel's common stock during the 5 trading days preceding the signing of the agreement. The warrant will become exercisable six months from the date of the agreement and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. As of December 31, 2007, the warrants issued to the investors have been classified as equity in accordance with EITF 00-19. The transaction date fair value of the warrants of \$0.6 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate — 3.605%, expected volatility — 70%, expected dividend yield — 0%, and a remaining contractual life of 5.5 years.



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### Common Stock Warrants

The following table summarizes information about warrants outstanding at December 31, 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	15.29	March 2006 stock issuance	2014	2,571,429	7.00	February 2007 stock issuance			
2014	1,062,412	8.44	December 2007 CEFF	2012	175,000	7.17	Total	3,809,703	\$ 7.41	
Exercise of Stock Options										

During 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 2006 or 2005.

### 13 Stock-Based Compensation Arrangements

The Company adopted FASB Statement No. 123R, “Share Based Payment” (FAS123R) on January 1, 2006. FAS 123R is a revision of FASB Statement No. 123, “Accounting for Stock-Based Compensation” (FAS123) and supersedes Accounting Principles Board or APB Opinion No. 25, “Accounting for Stock Issued to Employees,” and its related implementation guidance. FAS 123R requires the Company to measure all share-based payment awards, including those with employees, granted, modified, repurchased or cancelled after, or that were unvested as of, January 1, 2006 at grant date fair value.. Under FAS 123R, the fair value of stock options and other equity-based compensation must be recognized as expense in the statements of operations over the requisite service period of each award. The Company adopted FAS 123R using the modified prospective method of transition. Accordingly, beginning January 1, 2006, the Company began recognizing compensation expense under FAS 123R for the unvested portions of outstanding share-based awards previously granted under its various plans, over the periods these awards continue to vest. This compensation expense recognized is based on the fair values and attribution methods that were previously disclosed in its prior period financial statements under FAS 123.

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



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Had compensation expense been recognized for stock-based compensation plans in accordance with FAS 123, the Company would have recorded the following net loss and net loss per share amounts for the year ended December 31, 2005:

	Year
ended	
December 31, 2005	\$000, except per share
data and share amounts	Net loss applicable to common shareholders, as reported \$ (29,924 ) Add: Employee stock-based compensation expense included in reported net loss, net of related tax effects (334 ) Deduct: Total stock-based employee compensation expense determined under fair value method for all awards, net of tax effects (1,901 ) Pro forma net loss \$ (32,159 ) Basic and diluted loss per common share As reported \$ (4.50 ) Pro forma \$ (4.83 )

FAS 123R requires compensation expense associated with share-based awards to be recognized over the requisite service period, which for the Company is the period between the grant date and the date the award vests or becomes exercisable. Most of the awards granted by the Company (and still outstanding), vests ratably over four years, with 1/4 of the award vesting one year from the date of grant and 1/48 of the value vesting each month thereafter. However, a large grant of awards issued in June 2006 vested (a) two-thirds upon grant, and (b) one-third over a one-year vesting period. In addition, certain awards made to executive officers vest over three to five years, depending on the terms of their employment with the Company. Effective January 1, 2006, the Company has elected to recognize all share-based awards issued after the adoption of FAS 123R under the straight-line attribution method.

FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. This analysis will be evaluated quarterly and the forfeiture rate will be adjusted as necessary. Ultimately, the actual expense recognized over the vesting period will be based on only those shares that vest.

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

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

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

## Acceleration of Options

### Cyclacel Plans



The vesting of all options granted pursuant to the 1997 Plan, 2000 Plan and Discretionary Plan were accelerated on the members' voluntary liquidation of Cyclacel Group plc. As a result of this acceleration, any holder of options granted pursuant to these Plans had the right to exercise 100% of the options held by such holder pursuant to such plan. However, prior to the completion of the Stock Purchase and liquidation of Cyclacel Group plc all Cyclacel employees waived their rights to exercise any options held by them. The number of options of common stock that would have become fully vested as a result of the

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accelerated vesting provisions of the Plans was 1,369,757. However, as the liquidation of Cyclacel Group plc was probable at the time the options were waived and the liquidation caused the acceleration of the vesting of the options, the previously unrecognized compensation cost associated with these awards was charged as employee compensation immediately prior to the consummation of the Stock Purchase on March 27, 2006. Options granted pursuant to the Senior Executive Incentive Plan only became vested on occurrence of certain trigger events and the passage of time thereafter; moreover, there were no provisions for an acceleration of vesting on liquidation. Directors benefiting from this plan waived their rights to any options held by them and concurrently the directors were issued with restricted stock as detailed below. Accordingly, as the options had never vested and were improbable of vesting even absent the liquidation, no compensation charge associated with these awards has been charged as employee expense in this period. There were no Cyclacel common stock options outstanding on completion of the Stock Purchase or liquidation of Group. As of March 16, 2006, no further options will be granted under the 1997 Plan, 2000 Plan and Discretionary Plan.

## Xcyte Plans

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

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

The vesting of up to 25% of the total options granted under any award pursuant to the 2003 Plan accelerated immediately upon the closing of the Stock Purchase and the asset sale to Invitrogen pursuant to the terms of the 2003 Plan. As a result of this acceleration, any holder of options under the 2003 Stock Plan had the right to exercise the lesser of 25% of the options granted to such holder under the 2003 Stock Plan award or all remaining unvested options granted to the holder under the award pursuant to such plan. The number of shares of the common stock that became fully vested as a result of the accelerated vesting provisions of the 2003 Plan was 21,779.

Since March 16, 2006, no further options were issued under the former Xcyte Plans, those being, 1996 Stock Option Plan, 2003 Stock Plan, 2003 Directors Stock Option Plan and 2003 Employee Stock Purchase Plan.

## 2006 Plans

On March 16, 2006, Xcyte stockholders approved the adoption of 2006 Plans, under which Cyclacel, may make equity incentive grants to its officers, employees, directors and consultants. There are 3,000,000 shares of Cyclacel common stock reserved for issue under the equity incentive plan. In the second quarter of 2006, the Company granted 829,079 stock options under the 2006 Plans, of which two-thirds of the options vested immediately on grant. The remaining unvested options became fully vested 12 months following the date of grant of the options on June 13, 2007. In the third quarter of 2006, we granted 16,667 stock options under the 2006 Plans which vest rateably over three years to August 1, 2009. In the fourth quarter of 2006, the Company granted 488,333 stock options under the 2006 Plans of which approximately 8,333 vest rateably over three years to October 31, 2009, 40,000 vest rateably

over four years to October 31, 2010 and 390,000, of which one-quarter vested in December 2007 with the balance vesting rateably over three years to December 21, 2010, and 50,000 fully vested on December 31, 2007. The total fair value of all options granted in 2006 under the 2006 Plans is \$5.7 million, of which \$4.1 million has been recognized as of December 31, 2007. During 2007, the Company granted 1,317,546 options to employees and directors with a grant date fair value of \$4.8 million, of which \$0.4 million has been expensed. As of December 31, 2007, the total remaining unrecognized compensation cost related to the non-vested stock

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options amounted to approximately \$6.0 million, which will be amortized over the weighted-average remaining requisite service period of 9.15 years. During 2006 and 2007, the Company did not settle any equity instruments with cash.

The Company received \$0.2 million from the exercise of 25,508 stock options during 2007. The total intrinsic value of options exercised during 2007 was approximately \$17,000. The weighted average grant-date fair value of options granted during 2006 and 2007 was \$4.30 and \$3.68, respectively.

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

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

Number of options outstanding	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value	Cyclacel Pharmaceuticals, Inc.	Balance as of December 31, 2005	—	—	—	—	Assumed
on stock purchase	44,491	\$ 34.91	7.82	—	Granted 1,334,079	\$ 6.53	9.45	—	Cancelled/forfeited	
(42,729 )	\$ 30.96	8.28	—	Balance as of December 31, 2006	1,335,841	\$ 6.72	9.44	—	Granted	
1,317,546	\$ 6.07		Exercised (25,508 )	\$ 6.40	Cancelled/forfeited	(35,633 )	\$ 6.02			
Options outstanding at December 31, 2007	2,592,246	\$ 6.39	9.14	53,580	Unvested at					
December 31, 2007	1,688,927	\$ 6.23	9.51	48,337	Vested and exercisable at December 31, 2007					
903,319	\$ 6.69	8.47	5,243	Vested and exercisable at December 31, 2006	1,335,841	\$ 6.72	9.44			

The following table summarizes information about options outstanding at December 31, 2007:

price	Number
outstanding	Weighted Average
remaining	
contractual life	Number

Exercise

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exercisable \$		4.65 – 5.30	58,667	9.55	6,945	5.35 – 5.74	907,156	9.79	3,702	6.30 – 6.95
1,340,673	8.71	870,672	7.80 – 9.20	263,750	9.18	—	15.00 – 45.30	22,000	7.16	22,000
2,592,246		903,319								
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The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option-pricing model as prescribed by FAS 123R using the following assumptions:

	Year ended					
December 31,						
2005	Year ended					
December 31,						
2006	Year ended					
December 31,						
2007 Expected term (years)	3.0	4.65	4.25 – 6.00	Risk free interest rate	4.4%	4.9% 3.28 – 5.07%
Volatility	90%	92%	65 – 80%	Dividends	0.00%	0.00% 0.00%
Resulting weighted average grant date fair value	\$2.37	\$4.46	\$3.68			

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

Due to the Company's limited existence of being a public company, the expected volatility assumption was based on the historical volatility of peer companies over the expected term of the option awards.

The weighted average risk-free interest rate represents interest rate for treasury constant maturities published by the Federal Reserve Board. If the term of available treasury constant maturity instruments is not equal to the expected term of an employee option, Cyclacel uses the weighted average of the two Federal Reserve securities closest to the expected term of the employee option.

In the first quarter of 2006 prior to the completion of the Stock Purchase, 1,750,000 shares of Group preferred stock were granted to certain directors, officers and a former director. These shares converted to 648,412 shares of restricted common stock of the Company on completion of the Stock Purchase. Because the shares granted are not subject to additional future vesting or service requirements, the stock-based compensation expense of \$5.2 million recorded in the first quarter of 2006 constitutes the entire grant-date fair value of this award, and no future period charges will be recorded. The stock is restricted only in that it cannot be sold for a specified period of time. There are no vesting requirements. The fair value of the stock granted was \$7.99 per share based on the market price of the Company's common stock on the date of grant. There were no discounts applied for the effects of the restriction, since the value of the restriction is considered to be de minimis. Certain of the restricted stock was issued as a replacement for the previously held stock-based compensation awards and the incremental fair value of the restricted stock over the original award at the date of replacement has been charged to expense during the year ended December 31, 2006. Of the \$5.2 million charge, \$3.2 million was reported as a component of research and development expense and \$2.0 million was reported as a component of general and administrative expense.

There were no stock option exercises for the year ended December 31, 2006. The Company received \$0.2 million from the exercise of 25,508 options during 2007. No income tax benefits were recorded because FAS 123R prohibits recognition of tax benefits for exercised stock options until such benefits are realized. As Cyclacel presently has tax loss carry forwards from prior periods and expect to incur tax losses in 2007, the Company was not be able to benefit from the deduction for exercised stock option in the current reporting period.

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



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The following table summarizes the components of the Company's stock based compensation for 2005, 2006 and 2007:

						Year
ended						
December 31,						
2005   Year ended						
December 31,						
2006   Year ended						
December 31,						
2007   (\$000s) Research and development    (295 )     6,230     837	Selling, general and administrative	(39 )				
3,370      896 Stock-based compensation costs before income taxes    (334 )     9,600     1,733						
14 Restructuring						

As a result of strategic decisions taken by Xcyte in March 2005 the Company restructured its operations and reduced its workforce. In connection with this restructuring Xcyte recorded charges and made provisions for termination benefits, lease restructuring, asset impairment and sales tax assessment.

The table below presents a summary of and reconciliation of those provisions for the year ended December 31, 2006 and 2007:

Lease restructuring charges							
	Sales tax assessment	Total	\$000	\$000	\$000	Balance at March 27, 2006 (as assumed on Stock Purchase)	2,731
270	3,001	Cash payments	(612 )	—	(612 )	Adjustments for lease-related deferred expenses and liabilities	
225	—	225	Balance at December 31, 2006	2,334	270	2,614	Cash payments (903 ) — (903 )
Adjustments for lease-related deferred expenses and liabilities				1,554	—	1,554	Balance at December 31, 2007
2,995	270	3,265					
Lease restructuring charges							

Under the Stock Purchase agreement Cyclacel assumed the accrued restructuring liability in relation to the Bothell manufacturing facility. The liability is computed as the present value of the difference between the remaining lease payments due less the estimate of net sublease income and expenses. This represents the Company's best estimate of the fair value of the liability as determined under FAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." Subsequent changes in the liability due to accretion, or changes in estimates of sublease assumptions, etc. will be recognized as adjustments to restructuring charges in future periods.

The Company records payments of rent related to the Bothell facility as a reduction in the amount of the accrued restructuring liability. Accretion expense, which is also reflected as a restructuring charge, is recognized due to the passage of time. Based on current projections of estimated sublease income, the Company expects to record additional accretion expense of approximately \$0.4 million over the remaining term of the lease.



Sales tax assessment

In connection with the abandonment of the leasehold improvements in the Seattle and Bothell facilities and the sale of assets in late 2005 the Company has been subjected to a state sales tax audit by the Department of Revenue of the State of Washington. The total tax liability assessed by the State of Washington equals approximately \$1 million. The Company has appealed the assessment and is awaiting the outcome of the appeal. Based on an evaluation of the underlying asset dispositions and State tax law, management believes that the potential loss from the ultimate settlement of the assessment ranges from \$270,000 to \$1 million. Based on this evaluation the Company continues to accrue \$270,000 plus related

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estimated interest costs of \$49,000 as a State tax assessment in 2007 and such amounts are included in the accompanying balance sheet as a component of accrued liabilities.

### 15 Pension Plans

The Company operates a defined contribution group personal pension plan for all of its U.K. based employees. Company contributions to the plan totaled \$0.2 million, \$0.2 million and \$0.2 million in the years ended December 31, 2005 and 2006 and 2007, respectively.

#### 401(k) Plan

The 401(k) Plan provides for matching contributions by the Company in an amount equal to the lesser of 100% of the employee's deferral or 6% of the U.S. employee's qualifying compensation. The 401(k) Plan is intended to qualify under Section 401(k) of the Internal Revenue Code, so that contributions to the 401(k) Plan by employees or by the Company, and the investment earnings thereon, are not taxable to the employees until withdrawn. If the 401(k) Plan qualifies under Section 401(k) of the Internal Revenue Code, the contributions will be tax deductible by the Company when made. Company employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit of \$15,500 if under 50 years old and \$20,500 if over 50 years old in 2008 and to have those funds contributed to the 401(k) Plan. In 2006 and 2007, the Company made contributions of approximately \$9,000 and approximately \$0.1 million, respectively, to the 401(k) Plan.

### 16 Taxes

In the accompanying Consolidated Statements of Operations, "Loss before taxes" includes the following components for the years ended December 31, 2005, 2006 and 2007:

	Year ended										
December 31, 2005	Year ended										
December 31, 2006	Year ended										
December 31, 2007	\$000	\$000	\$000	Domestic	—	(1,919 )	(5,448 )	Foreign	(19,948 )	(29,584 )	(20,646 )
Total loss before taxes				(19,948 )	(31,503 )	(26,094 )					
The benefit for income taxes consists of the following:											

											Year ended												
December 31,																							
2005												Year ended											
December 31,																							
2006												Year ended											
December 31,																							
2007												\$000	\$000	\$000	Current – domestic	—	—	(2)	Current – foreign	1,900	2,245	2,043	Current –

total 1,900 2,245 2,041

The Company has made a taxable loss in each of the operating periods since incorporation. The income tax credits of \$1.9 million, \$2.2 million and \$2.0 million for the years ended December 31, 2005, 2006 and 2007 respectively, represent U.K. research and development tax credits receivable against such expenditures in the United Kingdom.

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A reconciliation of the (benefit) provision for income taxes with the amount computed by applying the statutory federal tax rate to loss before income taxes is as follows:

									Year ended
December 31,									
2005	Year ended								
December 31,									
2006	Year ended								
December 31,									
2007	\$000	\$000	\$000	Loss before income taxes	(19,948 )	(31,503 )	(26,094 )	Income tax expense	
				computed at statutory federal tax rate	(5,984 )	(10,710 )	(8,872 )	State income tax (net of federal benefit)	
				1 Disallowed expenses and non-taxable income	2,629	4,655	(3,005 )	Tax losses	3,355
4,863	4,349			Research and development tax relief	(2,375 )	(2,796 )	(2,551 )	Valuation allowance	
				7,272 Change in state tax rate	(268 )			Research and development tax credit rate difference	475
559	510			Foreign tax rate differential	—	1,184	523	(1,900 )	(2,245 ) (2,041 )

Significant components of the Company's deferred tax assets are shown below:

						2006	2007	\$000	\$000	Net	
operating loss carryforwards	30,072	36,256	Depreciation, amortization and impairment of property and equipment	390	(447 )	Lease restructuring charges	797	1,203	Tax Credits	61	Stock Options
322	Accrued Expenses	1,450	Other	140	Deferred Tax Assets	31,259	38,985	Valuation allowance for deferred tax assets	(31,259 )	(38,985 )	Net deferred taxes
						—	—				

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting and tax purposes. A valuation allowance has been established, as realization of such assets is uncertain.

In certain circumstances, as specified in the Tax Reform Act of 1986, due to ownership changes, the Company's ability to utilize its net operating loss carryforwards may be limited. However, the Company's overseas subsidiary has, subject to agreement with the United Kingdom's H.M. Revenue & Customs, the following tax losses and accumulated tax losses available for carry forward against future operations, which under U.K. tax laws do not expire:

tax losses	97,980	110,128							

As of December 31, 2007 and 2006 we had federal NOLs of \$8.4 and \$2.9 million, state NOLs of \$5.6 and \$0 million and foreign NOLs of \$110.1 and \$97 million, respectively and federal research and development credit carryforwards of approximately \$0.1 million and \$0.1 million, respectively, which will

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expire starting in 2022. We have federal net operating losses that will start expiring in 2027 and state net operating losses that will start expiring in 2023.

As required by FAS No. 109, our management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, and has determined that it is not more likely than not that we will recognize the benefits of the deferred tax assets. Accordingly, a valuation allowance of approximately \$39.0 million has been established at December 31, 2007. The benefit of deductions from the exercise of stock options is included in the NOL carryforwards. The benefit from these deductions will be recorded as a credit to additional paid-in capital if and when realized through a reduction of cash taxes.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. We have not currently completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our formation, due to the significant complexity and related cost associated with such study. There also could be additional ownership changes in the future which may result in additional limitations in the utilization of the carryforward NOLs and credits.

In June 2006, the FASB issued FIN48. This statement clarifies the criteria that an individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company's financial statements. The Company adopted FIN48 on January 1, 2007. The implementation of FIN48 did not have a material impact on the Company's consolidated financial statements, results of operations or cash flows. At the adoption date of January 1, 2007, and also at December 31, 2007, the Company had no unrecognized tax benefits. The Company has not, as yet, conducted a study of its research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under FIN48. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

The tax years 1996 through 2006 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the United Kingdom and the United States, as carryforward attributes generated in years past may still be adjusted upon examination by the United Kingdom's H.M. Revenue & Customs, the Internal Revenue Service (IRS) or state tax authorities if they have or will be used in a future period. The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company recognizes both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company has not recorded any interest and penalties on any unrecognized tax benefits since its inception.

## 17 Segment and Geographic Information

The Company has one reportable segment. The Company maintains development operations in the United States and United Kingdom.



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Geographic information for the years ended December 31, 2005, 2006 and 2007 are as follows:

										2005	2006	2007	
\$000	\$000	\$000	Revenue	United States	—	—	—	United Kingdom	356	387	129	356	387
129	Net loss			United States	—	(1,142)	(1,783)	United Kingdom		(18,048)		(28,116)	
(22,270)		(18,048)	(29,258)	(24,053)	Total Assets				United States	—	17,636		
66,947	United Kingdom	19,071	45,640	8,965	19,071	63,276	75,912	Long Lived Assets, net					
	United States	—	453	532	United Kingdom	2,045	1,668	2,484	2,045	2,121			

3,016

## 18 Selected Quarterly Information (unaudited)

The following unaudited quarterly financial information includes, in management's opinion, all the normal and recurring adjustments necessary to fairly state the results of operations and related information for the periods presented.

For the three months ended	March 31,											
2007	June 30,											
2007	September 30,											
2007	December 31,											
2007	\$000, except per share amounts	Revenues	52	31	33	13	Loss before taxes	(5,442)	(4,158)			
)	(4,647)	(11,847)	Net loss applicable to common shareholders	(4,890)	(3,595)	(4,214)						
(11,354)	Net loss per share – basic and diluted(1)	\$ (0.27)	\$ (0.18)	\$ (0.21)	\$ (0.57)							

For the three months ended	March 31,											
2006	June 30,											
2006	September 30,											
2006	December 31,											
2006	\$000, except per share amounts	Revenues	151	36	83	117	Loss before taxes	(11,709)				
(7,638)	(6,035)	(6,121)	Net loss applicable to common shareholders	(14,176)	(6,942)	(5,432)						
(5,535)	Net loss per share – basic and diluted(1)	\$ (2.09)	\$ (0.48)	\$ (0.34)	\$ (0.34)							

(1) The addition of loss per common share by quarter may not equal the total loss per common share for the year or year to date due to rounding.

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None

Item 9A. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures:

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act 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 Chief Operating Officer, 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 in reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of December 31, 2007, the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Operating Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief Operating Officer concluded that our disclosure controls and procedures were effective.

(b) Management's Annual Report on Internal Control Over Financial Reporting:

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Operating Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- (1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- (2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- (3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Align Pharmaceuticals LLC or ALIGN, which we acquired on October 5, 2007. ALIGN is included in the 2007 consolidated financial statements of Cyclacel Pharmaceuticals, Inc and constituted \$6.6 million and \$3.3 million of total assets and net assets, respectively, as of December 31, 2007 and \$0 and \$0.7 million of revenues and net losses, respectively, for the year then ended. ALIGN was excluded as it was acquired



during the last quarter of 2007 and as permitted by the Securities and Exchange Commission we have excluded ALIGN from our assessment in 2007.

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Operating Officer, we conducted an evaluation of the effectiveness of our internal control over

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financial reporting as of December 31, 2007 based on the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2007.

The attestation report of the Company's independent registered public accounting firm on internal control over financial reporting is set forth below:

### (c) Attestation Report of the Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

The Board of Directors and Stockholders of Cyclacel Pharmaceuticals, Inc.

We have audited Cyclacel Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Cyclacel Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying "Management's Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As indicated in the accompanying "Management's Report on Internal Control over Financial Reporting", management's assessment of and conclusion on the effectiveness of internal controls over financial reporting did not include the internal controls of Align Pharmaceuticals LLC which is included in the 2007 consolidated financial statements of

Cyclacel Pharmaceuticals, Inc and constituted \$6.6 million and \$3.3 million of total and net assets, respectively, as of December 31, 2007 and \$0 and \$0.7 million of revenues and net losses, respectively, for the year then ended. Our audit of internal controls over financial reporting of Cyclacel Pharmaceuticals, Inc also did not include an evaluation of the internal controls over the financial reporting of Align Pharmaceuticals, LLC.

In our opinion, Cyclacel Pharmaceuticals Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

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We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cyclacel Pharmaceuticals, Inc. as of December 31, 2007 and December 31, 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2007 and for the period from August 13, 1996 (inception) to December 31, 2007, and our report dated March 13, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

London, England  
March 13, 2008

Item 9B.

Other information

None.

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PART III

The information required by Part III is omitted from this report because the Company will file a definitive proxy statement with the SEC within 120 days after the end of the fiscal year pursuant to Regulation 14A for its annual meeting of stockholders to be held on May 14, 2008, and the information to be included in the proxy statement is incorporated herein by reference.

Item 10.

Directors and Executive Officers and Corporate Governance

The information required by Item 10 is incorporated herein by reference from the Company's definitive proxy statement which will be filed with the SEC within 120 days after the end of the Company's 2007 fiscal year pursuant to Regulation 14A for its annual meeting to be held on May 14, 2008.

Item 11.

Executive Compensation

The information required by Item 11 is incorporated herein by reference from the Company's definitive proxy statement which will be filed with the SEC within 120 days after the end of the Company's 2007 fiscal year pursuant to Regulation 14A for its annual meeting to be held on May 14, 2008.

Item 12.

Security Ownership of Certain Beneficial Owners and Management and Related Stockholders matters

The information required by Item 12 is incorporated herein by reference from the Company's definitive proxy statement which will be filed with the SEC within 120 days after the end of the Company's 2007 fiscal year pursuant to Regulation 14A for its annual meeting to be held on May 14, 2008.

Item 13.

Certain Relationships and Related Transactions, and Director Independence

The information required by Item 13 is incorporated herein by reference from the Company's definitive proxy statement which will be filed with the SEC within 120 days after the end of the Company's 2007 fiscal year pursuant to Regulation 14A for its annual meeting to be held on May 14, 2008.

Item 14.

Principal Accountant Fees and Services

The information required by Item 14 is incorporated herein by reference from the Company's definitive proxy statement which will be filed with the SEC within 120 days after the end of the Company's 2007 fiscal year pursuant to Regulation 14A for its annual meeting to be held on May 14, 2008.

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PART IV

Exhibits and Financial Statement Schedules	Item 15.
filed as part of this report are as follows:	(a) Documents
Statements and Report of Independent Registered Public Accounting Firm	(1) Financial
Statement Schedules	(2) Financial

None required.

Exhibits	(3)
	Exhibit
Number	Description
3 .1	Amended and Restated Certificate of Incorporation of Xcyte Therapies, Inc. (Previously filed as exhibit 3.1 to Registrant's registration statement on Form S-1, File No. 333-109653, originally filed with the Commission on October 10, 2003, as subsequently amended, and incorporated herein by reference.)
3 .1.1	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Xcyte Therapies, Inc. (previously filed as exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended March 31, 2006, originally filed with the Securities and Exchange Commission on May 16, 2006, and incorporated herein by reference.)
3 .2	Amended and Restated Bylaws of Xcyte Therapies, Inc. (Previously filed as exhibit 3.3 to Registrant's registration statement on Form S-1, File No. 333-109653, originally filed with the Commission on October 10, 2003, as subsequently amended, and incorporated herein by reference.)
3 .3	Preferred Stock Certificate of Designations (previously filed as exhibit 3.2 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on November 5, 2004, and incorporated herein by reference.)
4 .1	Specimen of Common Stock Certificate (previously filed as exhibit 4.1 to Registrant's registration statement on Form S-1, File No. 333-109653, originally filed with the Commission on October 10, 2003, as subsequently amended, and incorporated herein by reference.)
4 .2	Specimen of Preferred Stock Certificate of Designation (previously filed as exhibit 3.2 to Registrant's registration statement on Form S-1, File No. 333-19585, originally filed with the Commission on October 7, 2004, as subsequently amended, and incorporated herein by reference.)
4 .3	Form of warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as exhibit 99.3 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on April 28, 2006, and incorporated herein by reference.)
4 .4	Form of Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as exhibit 10.2 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on February 15, 2007, and incorporated herein by reference.)
4 .5	Warrant for the purchase of shares of common stock, dated December 10, 2007, issued by the Cyclacel Pharmaceuticals, Inc. to Kingsbridge Capital Limited (previously filed as exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on December 11, 2007, and incorporated herein by reference.)

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	Exhibit
Number Description	
4.6 Registration Rights Agreement, dated December 10, 2007, by and between the Cyclacel Pharmaceuticals, Inc. and Kingsbridge Capital Limited (previously filed as exhibit 4.2 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on December 11, 2007, and incorporated herein by reference.)	10.1
10.1 Stock Purchase Agreement, dated December 15, 2005, between Xcyte Therapies, Inc., and Cyclacel Group plc. (previously filed as exhibit 2.1 to the Registrant's current report on Form 8-K filed with the Commission on December 20, 2005, and incorporated herein by reference.)	10.2
10.2 Amendment No. 1 to the Stock Purchase Agreement, dated January 13, 2006, between Xcyte Therapies Inc., and Cyclacel Group (previously filed as exhibit 2.1 to the Registrant's current report on Form 8-K filed with the Commission on January 19, 2006, and incorporated herein by reference.)	10.3
10.3 Form of Securities Purchase Agreement, dated April 26, 2006 (previously filed as exhibit 99.2 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on April 28, 2006, and incorporated herein by reference.)	10.4
10.4 Form of Subscription Agreement, dated February 13, 2007, by and between Cyclacel Pharmaceutics, Inc. and certain purchasers (previously filed as exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on February 15, 2007, and incorporated herein by reference.)	10.5
10.5 Form of Placement Agent Agreement, dated February 13, 2007, by and between Cyclacel Pharmaceutics, Inc. and Lazard Capital Markets LLC, Needham & Company, LLC and ThinkEquity Partners LLC (previously filed as exhibit 10.3 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on February 15, 2007, and incorporated herein by reference.)	10.6†
10.6† Asset Purchase Agreement by and between ALIGN Pharmaceuticals, LLC, ALIGN Holdings, LLC and Achilles Acquisition, LLC, dated October 5, 2007 (previously filed as exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended September 30, 2007, originally filed with the Securities and Exchange Commission on February 15, 2007, and incorporated herein by reference.)	10.7
10.7 Common Stock Purchase Agreement, dated December 10, 2007, by and between the Cyclacel Pharmaceuticals, Inc. and Kingsbridge Capital Limited (previously filed as exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on December 11, 2007, and incorporated herein by reference.)	10.8
10.8 Employment Offer Letter by and between Achilles Acquisition, LLC and William C. Collins, dated October 3, 2007 (previously filed as exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended September 30, 2007, originally filed with the Securities and Exchange Commission on February 15, 2007, and incorporated herein by reference.)	10.9
10.9 Description of Dr. John Womelsdorf's compensatory arrangement (previously filed as exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended September 30, 2006, originally filed with the Securities and Exchange Commission on November 13, 2006, and incorporated herein by reference.)	10.10
10.10 Cyclacel Pharmaceuticals, Inc.'s 2006 Equity Incentive Plan (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on June 18, 2007, and incorporated herein by reference.)	21
21 Subsidiaries of Cyclacel Pharmaceuticals, Inc.	

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		Exhibit
Number	Description	
23 .1	Consent of Independent Registered Public Accounting Firm.	31 .1
	Certificate of Spiro Rombotis, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	31 .2
	Certificate of Paul McBarron, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	32 .1
	Certification of Spiro Rombotis, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code).	32 .2
	Certification of Paul McBarron, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code).	

†  
Confidential treatment has been requested as to certain portions of this agreement, which has been filed separately with the Securities and Exchange Commission



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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities 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 on the 13th of March, 2008.

Cyclacel Pharmaceuticals, Inc.

By: /s/ Paul McBarron

Paul McBarron

Chief Operating Officer &

Executive Vice President, Finance

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature

Title Date /s/ Spiro Rombotis President & Chief Executive Officer (Principal Executive Officer)

and Director March 13, 2008 Spiro Rombotis /s/ Paul McBarron Chief Operating Officer &

Executive Vice President, Finance

(Principal Financial and

Accounting Officer)

and Director March 13, 2008 Paul McBarron /s/ Dr. David U'Prichard Chairman March 13, 2008

Dr. David U'Prichard /s/ Dr. Christopher Henney Vice Chairman March 13, 2008 Dr. Christopher Henney /s/ Sir

John Banham Director March 13, 2008 Sir John Banham /s/ Pierre Legault Director March 13, 2008 Pierre Legault

/s/ Prof. Gordon McVie Director March 13, 2008 Prof. Gordon McVie /s/ Daniel Spiegelman Director March 13,

2008 Daniel Spiegelman

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