

Cyclacel Pharmaceuticals, Inc.

Form 10-K

March 29, 2010

**Table of Contents**

**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 FISCAL YEAR ENDED DECEMBER 31, 2009**

**OR**

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

**Commission file number 00-50626  
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,  
New Jersey

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:

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

Securities registered pursuant to Section 12(g) of the Act: None.

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to

submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act:

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting  
company

[Do not check if a smaller  
reporting company]

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), as of June 30, 2009 (based upon the closing sale price of \$1.13 of such shares on The NASDAQ Global Market on June 30, 2009) was \$19,164,232.

As of March 26, 2010, there were 35,411,325 shares of the registrant's common stock outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

The following documents (or parts thereof) are incorporated by reference into the following parts of this Annual Report on Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the registrant's Proxy Statement relating to the 2010 Annual Meeting of Stockholders, to be held on May 25, 2010, which we will file with the Securities and Exchange Commission within 120 days after our December 31, 2009 fiscal year end.

## TABLE OF CONTENTS

### PART I

<u>Item 1. Business</u>	3
<u>Item 1A. Risk Factors</u>	26
<u>Item 1B. Unresolved Staff Comments</u>	49
<u>Item 2. Properties</u>	49
<u>Item 3. Legal Proceedings</u>	49
<u>Item 4. (Removed and Reserved)</u>	49

### PART II

<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	50
<u>Item 6. Selected Financial Data</u>	52
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	55
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	71
<u>Item 8. Financial Statements and Supplementary Data</u>	74
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	118
<u>Item 9T. Controls and Procedures</u>	118
<u>Item 9B. Other Information</u>	120

### PART III

<u>Item 10. Directors; Executive Officers and Corporate Governance</u>	121
<u>Item 11. Executive Compensation</u>	121
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	121
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	121
<u>Item 14. Principal Accountant Fees and Services</u>	121

### PART IV

Item 15. Exhibits and Financial Statement Schedules

122

- Exhibit 21
- Exhibit 23.1
- Exhibit 31.1
- Exhibit 31.2
- Exhibit 32.1
- Exhibit 32.2

**Table of Contents**

**PART I**

**Item 1. Business**

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

**General**

Cyclacel Pharmaceuticals, Inc. was incorporated in the state of Delaware in 1996 and is headquartered in Berkeley Heights, New Jersey, with a research facility located in Dundee, Scotland. 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 to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates. 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**

On January 27, 2010, we announced that The NASDAQ Global Market, or NASDAQ, had notified us that we regained compliance with the minimum \$50 million market value of listed securities requirement and that we currently comply with all other applicable standards for continued listing on NASDAQ.

On January 25, 2010, we completed the sale of 2,350,000 units in a registered direct offering at a purchase price of \$2.50 per unit to certain institutional investors of the Company for gross proceeds of approximately \$5.9 million. Each unit consisted of one share of our common stock and one warrant to purchase 0.30 of one share of our common stock. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance and will be exercisable at an exercise price of \$2.85 per share of common stock.

On January 13, 2010, we completed the sale of 2,850,000 units in a registered direct offering to certain institutional investors. Each unit was sold at a purchase price of \$2.51 per unit and consists of one share of our common stock and one warrant to purchase 0.25 of one share of our common stock for gross proceeds of approximately \$7.2 million. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance and will be exercisable at an exercise price of \$3.26 per share of common stock.

On January 7, 2010, our Board decided not to declare the quarterly cash dividend on the Company's 6% Convertible Exchangeable Preferred Stock, or Preferred Stock, with respect to the fourth quarter of 2009 that would have otherwise been payable on February 1, 2010. As previously disclosed, the Board also did not declare the quarterly cash dividend with respect to the first, second and third quarters of 2009. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are accrued. This is the fourth quarterly dividend the Company decided not to declare and if we fail to pay dividends for at least six quarters (whether or not consecutive) on the Preferred Stock, the size of our Board of Directors could be increased by two members and the holders of the Preferred Stock, voting separately as a class, will have the right to vote to fill the two vacancies created thereby until all accrued but unpaid dividends have been paid in full, at which time such right is terminated.

Through March 25, 2010, we issued 2,618,266 shares of our common stock for gross proceeds of approximately \$2.6 million through the exercise of warrants. In addition, we completed draw downs from our Committed Equity financing Facility, or CEFF, under which we issued 1,563,208 shares for proceeds of approximately \$3.1 million. During March 2010, we issued 239,396 shares of our common stock to a stockholder in exchange for the stockholder's delivery to us of 123,400 shares of our outstanding Preferred Stock.

**Table of Contents**

**Corporate information**

Our corporate headquarters are located at 200 Connell Drive, Suite 1500, Berkeley Heights, New Jersey, 07922, and our telephone number is 908-517-7330. This is also where our medical and regulatory functions are located. Our research facility is located in Dundee, Scotland which is also the center of our translational work and development programs.

**Overview**

We are a biopharmaceutical business dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat cancer and other serious disorders. We are focused on delivering leading edge therapeutic management of cancer patients based on a clinical development pipeline of novel drug candidates. Our core area of expertise, and a foundation of the Company since our inception, is in cell cycle biology; the processes by which cells divide and multiply. We focus primarily on the 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.

Our clinical development priorities are focused on sapacitabine in the following indications:

- Acute myeloid leukemia, or AML, in the elderly;
- Myelodysplastic syndromes, or MDS; and
- Non-small cell lung cancer, or NSCLC.

We have additional clinical programs which are currently pending availability of clinical data. Once data become available and are reviewed, we will determine the feasibility of pursuing further development and/or partnering these assets including sapacitabine in combination with seliciclib, seliciclib in NSCLC and nasopharyngeal cancer, or NPC, and CYC116. In addition, we market directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia.

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 agents by regulating 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.

Although our resources are primarily directed towards advancing our anticancer drug candidate sapacitabine through in-house development activities we are also progressing, but with lower levels of investment than in previous years, our other novel drug series 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. As a consequence of our focus on sapacitabine clinical development and related cost reduction program, research and development expenditures for the year ended December 31, 2009 were reduced by \$9.1 million, or 48%, to \$9.8 million compared to \$18.9 million for the year ended December 31, 2008.

**Table of Contents**

We have executed our strategy through the following activities:

***Advancing our research and development programs***

Submitted a Special Protocol Agreement, or SPA, to the U.S. Food and Drug Administration, or FDA, for a randomized Phase 3 study design for sapacitabine in elderly AML following a Type A meeting with the FDA in December 2009;

Cyclacel's cyclin dependent kinase, or CDK, inhibitors' mechanism of action, target profile and selectivity elucidated in recent publications which reported activity in highly transformed and/or resistant cancers and potential in other proliferative diseases;

Sapacitabine Phase 2 elderly AML trial 1-year survival data announced at the 2009 American Society of Hematology (ASH) annual meeting;

Sapacitabine Phase 2 trial of patients with MDS interim results announced at the 2009 ASH annual meeting;

Sapacitabine and seliciclib combination trial initiated Phase 1 trial for solid tumors; and

Seliciclib Phase 2 trial of NPC initial results reported at the 2009 American Society of Clinical Operations, or ASCO, meeting.

***Managing our resources***

Ended 2009 with approximately \$11.5 million of cash and cash equivalents and short-term investments. Raised an additional \$15.6 million in gross proceeds through two registered direct offerings in January 2010 and the exercise of warrants;

In November 2009, we amended the Kingsbridge Capital Limited Committed Equity Financing Facility and raised approximately \$1.0 million;

In July 2009, we raised \$3.4 million in gross proceeds through a registered direct offering; and

Followed our operating plan with the focus on sapacitabine clinical development and further lowered operating costs through a reduction in workforce in the second and third quarters of 2009; since announcing our revised operating plan in September 2008, we have reduced our workforce by fifty one (51) people, or 63% of our workforce and closed our Cambridge research facility.

**Table of Contents****Research and Development Pipeline**

The following table summarizes our clinical and preclinical programs.

<b>Program</b>	<b>Indication</b>	<b>Development Status</b>	<b>Target</b>	<b>Cell Cycle Mechanism</b>
<i>Oncology</i>				
Sapacitabine, CYC682	Elderly AML	Phase 2 randomized trial completed	DNA polymerase	G2 and S phase
Sapacitabine, CYC682	MDS	Phase 2 randomized trial on-going	DNA polymerase	G2 and S phase
Sapacitabine, CYC682	CTCL	Phase 2 randomized trial stopped. Not a company priority	DNA polymerase	G2 and S phase
Sapacitabine, CYC682	NSCLC	Phase 2 trial on-going	DNA polymerase	G2 and S phase
Sapacitabine + Seliciclib	Cancer	Phase 1 trial on-going		
Seliciclib, CYC202	NSCLC	Phase 2b randomized trial closed to accrual	CDK2/A, 2/E, 7, 9	G1/S checkpoint and others
Seliciclib, CYC202	NPC	Phase 2 randomized trial. Lead-in phase only on-going	CDK2/A, 2/E, 7, 9	G1/S checkpoint and others
CYC116	Cancer	Phase 1 trial completed	Aurora kinase & VEGFR2	Mitosis
CDK Inhibitors, Second Generation	Cancer	Preclinical	CDK	G1/S checkpoint and others
Plk1 Inhibitors	Cancer	Preclinical	Plk	G2/M checkpoint
Hdm2 Inhibitors	Cancer	On hold, Not a company priority	Hdm2	G1/2 phase
Cyclin Binding Groove Inhibitors	Cancer	On hold. Not a company priority	Cyclin binding groove	S phase
<i>Other therapeutic areas</i>				
Cell Cycle Inhibitors	Autoimmune & Inflammatory Diseases	Phase 1 trial completed On hold. Not a company priority	CDK	G1/S checkpoint and others
Cell Cycle Inhibitors	HIV/AIDS	On hold. Not a company priority	CDK	Other
GSK-3 Inhibitors	Type 2 Diabetes	On hold. Not a company priority	GSK-3	Other

**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 of cancer 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 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 13,000 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.

**Table of Contents**

There are approximately 11,000 new cases of myelodysplastic syndromes diagnosed annually in the United States with incidence rates between 16,000 and 20,000. Patients currently receive hypomethylating agents as first-line treatment and while survival rates exceed one year, there is no established therapy for second-line treatment.

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 NSCLC type. According to the American Cancer Society, an estimated 215,000 patients are diagnosed annually with NSCLC in the United States. An estimated 380,000 new cases are diagnosed annually in the European Union. NSCLC is a deadly disease with an estimated 162,000 deaths annually in the United States.

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, once the disease recurs after initial chemotherapy and radiotherapy, 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.

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.

***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 Growth Factor Receptor 2, or AK/VEGFR2 inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitor, 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, and seliciclib is the only orally available CDK inhibitor currently in Phase 2 trials.

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 has relied 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. By devoting resources initially to this process, we were able to focus our efforts on targets that have a higher probability of yielding successful drug candidates through the utilization of an integrated suite of sophisticated discovery and design technologies by highly skilled personnel. However, as a result of the reduction in our workforce in 2008 and 2009 our ability to identify, optimize and develop new targets is significantly curtailed.

**Table of Contents**

***Sapacitabine***

Our lead 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 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 and repair by causing single-strand DNA breaks and induces arrest of the cell division cycle at G2/M checkpoint. A number of nucleoside drugs, such as gemcitabine, or Gemzar<sup>®</sup>, from Eli Lilly, and cytarabine, also known as Ara-C, a generic drug, 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 and 5-FU, two widely used nucleoside analogs, in delaying the onset and growth of liver metastasis. We have retained worldwide rights to commercialize sapacitabine, except for Japan, for which Daiichi-Sankyo Co., Ltd, or Daiichi-Sankyo, has a right of first negotiation.

We are currently exploring sapacitabine in both hematological cancers and solid tumors. To date, sapacitabine has been evaluated in approximately 400 patients in several Phase 1 and 2 studies and has shown signs of anti-cancer activity.

***Hematological Cancers***

***Phase 1 clinical trial in patients with advanced leukemias and myelodysplastic syndromes***

In December 2007, at the ASH annual meeting, we reported interim results from a Phase 1 clinical trial of oral sapacitabine in patients with advanced leukemias and MDS. The data demonstrated that sapacitabine had a favorable safety profile and promising anti-leukemic activity in patients with relapsed and refractory 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 was conducted at The University of Texas M. D. Anderson Cancer Center and is led by Hagop Kantarjian, M.D., 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.

**Table of Contents***Phase 2 randomized clinical trial in elderly patients with AML previously untreated or in first relapse*

In December 2007, we initiated an open-label, multicenter, randomized Phase 2 clinical trial of oral sapacitabine in 60 elderly patients with AML aged 70 or older who are previously untreated or in first relapse. The Phase 2 study, led by Dr. Kantarjian, has a primary endpoint of 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 CR or CRp, partial remission, or PR, duration of CR or CRp, or major hematological improvement and their corresponding durations, 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 arms, A. 200 mg twice daily for seven days every 3-4 weeks, B. 300 mg twice daily for seven days every 3-4 weeks, and C. 400 mg twice daily for three days per week for two weeks every 3-4 weeks, which produces a better 1-year survival rate in the event that all three dosing schedules are active. Each arm enrolled and treated 20 patients. Approximately 55% of patients had AML de novo and the rest had AML preceded by antecedent hematological disorder, or AHD, such as MDS, or myeloproliferative disease. Eighty percent of the patients were untreated and 20% in first relapse. We completed enrollment of 60 AML patients in this study in October 2008. In December 2009, at the 51<sup>st</sup> Annual Meeting of ASH we reported 1-year survival data. The primary endpoint of 1-year survival was 35% on Arm A, 30% on Arm C and 10% on Arm B. The median overall survival was 212 days on Arm C (range of 13 to over 654 days), 197 days on Arm A (range of 26 to over 610 days) and 100 days on Arm B (range of 6 to over 646 days). Overall response rate, or ORR, a secondary endpoint, was 45% on Arm A, 35% on Arm C and 25% on Arm B with CR rate of 25% on Arm C and 10% on Arms A and B. Thirty-day mortality was 10% on Arm C and Arm A and 20% on Arm B. Approximately 30% of all patients received sapacitabine for at least 6 cycles. Fifteen patients who survived one year or more received an average of 12 treatment cycles.

Exploratory subgroup analysis suggests that (i) Arm C may be more effective for de novo AML and (ii) Arm A may be more effective for AML preceded by AHD, such as MDS.

The 3-day dosing schedule in Arm C was selected for further clinical development in elderly patients with de novo AML based on a 1-year survival rate of 30%, ORR of 35% with durable CRs. The 7-day dosing schedule in Arm A was selected for further clinical development in elderly patients with AML preceded by AHD based on a 1-year survival rate of 35%, ORR of 45% with durable hematological improvement.

*Randomized Phase 2 clinical trial in older patients with MDS as a second-line treatment*

In September 2008, we advanced sapacitabine into Phase 2 development as a second-line treatment in patients aged 60 or older with MDS who are previously treated with hypomethylating agents. The MDS stratum of the study is designed as a protocol amendment expanding the ongoing Phase 2 trial of sapacitabine in AML described above, to include a cohort of patients with MDS. Patients with MDS often progress to AML. The primary objective of the MDS stratum is to evaluate the 1-year survival rate of three dosing schedules of sapacitabine. Secondary objectives are to assess the number of patients who have achieved CR or CRp, PR, hematological improvement and their corresponding durations, transfusion requirements, number of hospitalization days and safety. The study uses a selection design with the objective of identifying a dosing schedule which produces a better 1-year survival rate for each stratum in the event that all three dosing schedules are active.

In December 2009, at the 51<sup>st</sup> ASH Annual Meeting, we reported interim response data for the ongoing Phase 2 clinical trial of sapacitabine in older patients with MDS. The study has recently completed enrollment of 60 patients aged 60 or older with MDS who were previously treated with azacitidine and/or decitabine. Each arm enrolled 20 patients randomized across the same three dosing schedules of sapacitabine (Arms A, B and C) tested in the AML stratum of the study. Forty-nine of the patients enrolled have been followed-up for more than 30 days. Approximately 46% of the 49 patients had baseline bone marrow blast counts above 10%. Based on interim data, the highest number of responses was observed on Arm B, the 7-day high dose schedule. Thirty-day mortality from all-causes is 8.2%. Approximately 30% of the patients received 4 or more cycles of sapacitabine.

**Table of Contents**

*Pivotal trial plan for sapacitabine for the treatment of hematological malignancies*

In December 2009, we announced that we held a Type A meeting with the FDA to discuss a randomized Phase 3 study design for our oral sapacitabine capsules in AML and separately in MDS. Based on the FDA's confirmation that the proposed study design would be acceptable for a SPA, we submitted a SPA request during the first quarter of 2010. Should the SPA be granted we would plan to start such a study during 2010. The SPA process allows for official FDA evaluation of clinical protocols of a Phase 3 clinical trial intended to form the primary basis for an efficacy claim. A SPA provides trial sponsors with an FDA agreement that the design and analysis of the trial adequately address objectives in support of a submission for a marketing application if the trial is performed according to the SPA. The SPA may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. However, a SPA does not provide any assurance that a marketing application would be approved by the FDA. Furthermore, Phase 3 clinical trials are time-consuming and expensive, and because we have limited resources, we may be required to collaborate with a third party or raise additional funds. However, there is no assurance that we will be able to do so.

***Solid Tumors***

*Phase 1 clinical trials in patients with refractory solid tumors or lymphomas*

Two Phase 1 studies of sapacitabine were completed by Daiichi-Sankyo, from which we in-licensed sapacitabine, evaluating 87 patients in refractory solid tumors. In addition, we conducted a Phase 1b dose escalation clinical trial in patients with refractory solid tumors or lymphomas. Preliminary results of the Phase 1b study were reported at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics meeting 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 stromal tumor, and parotid acinar carcinoma.

*Phase 2 clinical trial in patients with non-small cell lung cancer*

In January 2009, we began treating patients in a Phase 2, open label, single arm, multicenter clinical trial in patients with NSCLC who have had one prior chemotherapy. This study builds on the observation of prolonged stable disease of four months or longer experienced by heavily pretreated NSCLC patients involved in two Phase 1 studies of sapacitabine. The multicenter Phase 2 trial is led by Philip D. Bonomi, M.D., at Rush University Medical Center, Chicago. The primary objective of the study is to evaluate the rate of response and stable disease in patients with previously treated NSCLC. Secondary objectives are to assess progression-free survival, duration of response, duration of stable disease, 1-year survival, overall survival and safety. The study will enroll approximately 40 patients and has a lead-in phase for dose escalation with the objective of defining a recommended dose followed by a second stage in which patients will be treated at the recommended dose.

*Phase 2 clinical trial in patients with cutaneous T-cell lymphoma, or CTCL*

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 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. Non-hematological toxicities were mostly mild to moderate. The best response by investigator assessment was partial response in 3 patients out of 16 enrolled. We stopped the trial in order to re-direct our resources to sapacitabine clinical trials with a higher priority.



**Table of Contents**

*EU Orphan Designation*

During May 2008, we received designation from the European Medicines Evaluation Agency, or EMEA, for sapacitabine as an orphan medicine in two separate indications: AML and MDS. The EMEA's Committee for Orphan Medicinal Products, or COMP, adopted a positive opinion on the Company's application to designate sapacitabine as an orphan medicinal product for the indications of AML and MDS. The objective of European orphan medicines legislation is to stimulate research and development of medicinal products for rare diseases by providing incentives to industry. An orphan designation in the European Union confers a range of benefits to sponsor companies including market exclusivity for a period of 10 years, EMEA scientific advice on protocol development, direct access to the centralized procedure for review of marketing authorizations, EMEA fee reductions and eligibility for grant support from European agencies.

***Seliciclib***

Our second drug candidate, seliciclib, is a novel, first-in-class, orally available, CDK inhibitor. The compound selectively inhibits a spectrum of enzyme targets -CDK2/E, CDK2/A, CDK7 and CDK9- that are central to the process of cell division and cell cycle control. The target profile of seliciclib is differentiated from the published target profile of other CDK inhibitors. Its selectivity is differentiated by recent publications by independent investigators which showed that seliciclib (i) is more active against NSCLC cells with K-Ras or N-Ras mutations than those with wild type Ras and (ii) overcomes resistance to letrozole (Femara®) in breast cancer cells caused by a particular form of cyclin E in complex with CDK2. Preclinical studies have shown that the drug works by inducing cell apoptosis, or cell suicide, in multiple phases of the cell cycle. To date, seliciclib has been evaluated in approximately 450 patients in several Phase 1 and 2 studies and has shown signs of anti-cancer activity. We have retained worldwide rights to commercialize seliciclib.

*Phase 1 clinical trials in patients with refractory solid tumors*

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 seliciclib given alone as monotherapy in patients with solid tumors who failed multiple previous treatments, several of these patients appeared to have benefited from seliciclib treatment.

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

*Phase 2 clinical trials in patients with NSCLC or breast cancer*

Four Phase 2 trials have been conducted in cancer patients to evaluate the tolerability and antitumor activities of seliciclib 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 52 patients with NSCLC, suggest that seliciclib 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 a standard dose of Capecitabine (Xeloda®) was not well tolerated in patients with advanced breast cancer.

**Table of Contents**

Selaciclib is currently being investigated in the Phase 2b APPRAISE study as a treatment for patients with advanced NSCLC. APPRAISE is a double-blinded, randomized study of single agent selaciclib 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. The study's main objective is to learn the anti-tumor activity of selaciclib as a single agent in refractory NSCLC and help determine further development strategies. The study design is randomized discontinuation. All patients receive selaciclib 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 selaciclib 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 selaciclib. The primary efficacy endpoint of APPRAISE is doubling progression free survival, or PFS, measured in the randomized portion of the study.

In August 2008, we announced that an independent data review committee, or IDRC, completed a review of the first interim analysis data from the study. The IDRC assessed the safety profile of selaciclib and recommended that the study continue after reviewing data from 173 patients with previously-treated NSCLC, of whom 45 proceeded into the blinded portion of the study and were randomized to receive either selaciclib or best supportive care. Based on the interim data, the IDRC reached the following main conclusions: there were no safety concerns that would warrant stopping the study; there was no trend favoring the selaciclib treatment arm; and as a definitive conclusion could not be reached because of the low number of events, it was recommended that the study be continued. Based on our cost versus benefit analysis, we decided not to enroll additional patients. The APPRAISE trial continues with the 191 patients already enrolled until the last enrolled patient has completed follow-up. In accordance with the protocol, we remain blinded to the study data.

*Phase 2 clinical trials in patients with NPC*

In November 2007, we commenced a Phase 2 multicenter, international, blinded randomized study of oral selaciclib as a single agent in patients with NPC. The primary objective is to evaluate 6-month progression free survival, or PFS, of two dosing schedules of selaciclib 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 selaciclib. 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 selaciclib and a placebo group in terms of 6-month PFS in approximately 51 patients. The start of the second part of the study is dependent on clinical data from the lead-in phase and available resources.

In May 2009, at the ASCO annual meeting, we reported interim data from the lead-in portion of the Phase 2 study which demonstrated that oral selaciclib could be safely administered in two dosing schedules which were well tolerated and met the criteria for proceeding to the randomized stage of the study. Selaciclib treatment resulted in prolonged stable disease in 70% of previously-treated NPC patients, including 3 with stable disease lasting longer than 8 months, suggesting selaciclib inhibits tumor growth in NPC. The data support further clinical development of oral selaciclib in NPC.

**Table of Contents**

***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, now completed, 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 pharmacokinetic and pharmacodynamic effects of the drug and document anti-tumor activity. Aurora kinases, or AK, are a family of serine/threonine protein kinases discovered by Professor David Glover, our Chief Scientist, 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. 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. Further work on CYC116 will be undertaken when appropriate levels of resource are available to direct to the program.

***Other programs***

We have allocated limited resources to other programs allowing us to maintain and build on our core competency in cell cycle biology and related drug discovery. In our second generation CDK inhibitor program, we have discovered several series of CDK inhibitors that we believe may prove to be more potent anticancer agents than seliciclib based on preclinical observations. Our polo-like kinase or Plk inhibitor program targets the mitotic phase of the cell cycle with the objective of identifying potent and selective small molecule inhibitors of Plk1, a kinase active during mitosis. Plk was discovered by Professor David Glover, our Chief Scientist. The Company has a number of earlier stage programs for which limited or no resources will be allocated. For example, extensive preclinical data published by independent investigators evidence activity by our CDK inhibitors, including seliciclib, in various autoimmune and inflammatory diseases of aberrant cell proliferation including glaucoma, lupus nephritis, idiopathic pulmonary fibrosis, polycystic kidney disease, and rheumatoid arthritis. In our GSK-3 inhibitor program we have demonstrated evidence of activity in preclinical models of Type 2 Diabetes.

Where appropriate we intend to progress such programs through collaboration with groups that specialize in the particular mechanism of action or disease area until such times that these programs can be partnered and/or progressed should funding become available. Where appropriate, the same approach will be used to progress unfunded programs described below.

***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 various methods, such as by blocking the ATP site, as is the case with seliciclib, or by inhibiting the substrate binding site on the associated cyclin protein. Preventing cyclin A from binding to its substrates results in cell cycle arrest and induces apoptosis in cancer cells. This 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.

**Table of Contents**

**Non-oncology Programs**

***Cell Cycle Inhibitors in Autoimmune & Inflammatory Diseases***

Preclinical results from several independent investigators suggest that cell cycle inhibitors such as seliciclib and its backup molecules arrest the progress of the cell cycle and may have therapeutic benefit in the treatment of patients with autoimmune and inflammatory diseases and in particular diseases characterized by uncontrolled cell proliferation. Published data indicate potential benefit in asthma, idiopathic pulmonary fibrosis, glomerulonephritis, lupus nephritis, polycystic kidney disease and rheumatoid arthritis.

***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 in infected host cells and may inhibit their replication 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 rely on 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 with antiviral potency equivalent to some 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 healthy 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. 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 relevant research 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.

**Commercial Products**

We have exclusive rights to sell and distribute three products in the United States and Canada used primarily to manage the effects of radiation or chemotherapy in cancer 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.

***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.

## **Table of Contents**

### ***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 with increasing effect 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.

### **Business Strategy**

In September 2008, we announced a revision of our operating plan to concentrate our resources on the advancement of our lead drug sapacitabine. Consistent with the revised operating plan, during the second and third quarters of 2009, we further reduced our workforce across all locations by twenty six (26) people making a total reduction of fifty one (51) people, or 63% of our workforce, since September 2008. With these reductions and our cost-containment efforts, we currently anticipate that our cash and cash equivalents of approximately \$11.5 million at December 31, 2009 together with the funds raised following the year-end totaling approximately \$18.8 million in gross proceeds, are sufficient to meet our anticipated short-term working capital needs and fund our current operations, including on-going sapacitabine clinical trials, for at least the next twelve months. However, we cannot be certain that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in clinical development, should they succeed.

### ***Focus on the cell cycle and cancer***

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 for the following reasons:

The novel, 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.

We believe that our sapacitabine is the only orally available nucleoside analogue presently being tested in Phase 2 trials in AML and MDS and seliciclib is the only orally available CDK inhibitor currently in Phase 2 trials. We believe that we are well positioned to realize some of the market potential of such drugs.

### ***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.

## **Table of Contents**

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

We currently retain virtually all marketing rights to the compounds associated with our current clinical-stage drug programs. To optimize our commercial return, we intend to enter into selected partnering arrangements, and to leverage our sales and marketing capability by retaining co-promotion rights as appropriate. Historically, we have planned to develop 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;

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

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

Invention assignment agreements with our employees and consultants;

Non-compete agreements with our key employees and consultants;

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

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

Freedom to use studies from patent counsel;

Material transfer agreements; and

Trademark protection.

In addition to our 27 United States patents, we own 11 patents that were granted by the European Patent Office, or EPO, for designated European countries, and 27 issued patents in other countries. The European granted patents expire between 2015 and 2022. In addition to the licenses we hold under the 6 patents issued in the United States, we hold licenses under 53 issued patents worldwide, seven granted by the EPO for designated European countries and 46 issued in other countries. The licensed European granted patents expire between 2012 and 2022. Our patent strategy is to file patents on compounds and 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 solid state forms, polymorphic and crystalline forms, 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 15 patent applications pending in the United States, 15 before the EPO, four

pending PCT applications still in the international application phase, and over 40 pending patent applications in other countries, including applications first filed 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. In addition to the pending patent applications referred to above that we own, there are 27 pending patent applications worldwide to which we have a license or an option to take a license.

**Table of Contents**

Our patent filings for the second-generation CDK inhibitor research program exemplify our patent strategy. Out of several series of discovered in this program we have filed patent applications seeking substance of matter protection that may be roughly grouped into 12 patent families. As we have progressed with our research, we have reviewed our patent portfolio and have focused active patent prosecution on 8 patent families covering substance of matter protection. 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. The first patent application from this family has resulted in the issuance of two United States patents with substance of matter claims covering a specific genus of compounds showing activity in preclinical and discovery 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.

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 develop or obtain alternative technology. We are aware of several published patent applications, and understand that others may exist, that could support claims that, if granted, would cover various aspects of our developmental programs, including in some cases particular uses of our lead drug candidates, sapacitabine, seliciclib, 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 and patents 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 the pending 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 European patent relating to human aurora kinase and the patent has been finally revoked (no appeal was filed). We are also aware of a corresponding United States 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. 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 United States 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.

## **Table of Contents**

### **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. Daiichi-Sankyo filed patent applications claiming sapacitabine and certain crystalline forms of sapacitabine and methods for its preparation and use which encompass our chosen commercial development form as well as related know-how and materials. The Daiichi-Sankyo agreement commenced on September 10, 2003. The issued patents for the sapacitabine compound cover the United States, EPO, Japan and 19 other countries. These patents expire between 2012 and 2014. The issued patents for the crystalline forms cover the United States, EPO, Japan and ten other countries, with patents pending in a further four countries. These patents expire in 2022. It may be possible to extend the term of a patent in the United States, Europe or Japan for up to five years to the extent it covers the sapacitabine compound or its crystalline form upon regulatory approval of that compound in the United States, Europe or Japan, 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 to CNDAC, both a precursor compound and initial metabolite of sapacitabine.

We are under an obligation to use reasonable endeavors to develop a product and obtain regulatory approval to sell 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 reimbursements 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, 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. In addition, pursuant to the Daiichi-Sankyo license, we are required 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, unless we are prevented from doing so by virtue of an exceptional cause, which generally constitutes a scientific or other technical cause outside of our control or arising from the activities of third parties, difficulties outside of our reasonable control in patient recruitment into trials or any significant, unexpected change in the regulatory requirements in a country affecting the development of our drug candidate. If regulatory approval is not obtained by September 2011, and there has been no exceptional cause responsible for the delay, the agreement provides that Daiichi-Sankyo may terminate the license. 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 payable on the first commercialization of a product that consists of a new chemical entity that is covered by one of the licensed patents.

**Table of Contents**

We will be obligated to 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, Australia and Korea. 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 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.

***Sinclair Pharma plc***

Through the acquisition of ALIGN we acquired from Sinclair Pharma plc, or Sinclair, United States and Canadian licensing rights to the three commercial products marketed by ALIGN Xclair<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges. Each of the agreements covering the three license rights 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.

## **Table of Contents**

### **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<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges. If any of Sinclair's third party manufacturers or 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 small pharmaceutical commercial sales organization marketing our ALIGN products, including two managers and three sales representatives. 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 NDA to the FDA;

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

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

- Regulation of commercial marketing and sale of drugs.



**Table of Contents**

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 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 trials are 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

**Table of Contents**

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 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 suggest or in any way guarantee that 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 the 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 the 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.



**Table of Contents**

When appropriate, we and our collaborators may attempt 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.

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, or 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 PMN 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.

**Table of Contents**

**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 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.

A large number of drug candidates are in development for the treatment of leukemia, lung cancer, lymphomas and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs or other products on the market or in clinical trials which may be competitive to sapacitabine in both hematological and oncology indications. These include Celgene, Cephalon, Eisai, Johnson & Johnson, Eli Lilly, Genzyme, GlaxoSmithKline, Hospira, Pfizer, Seattle Genetics, Sunesis and Vion. We believe that we are currently the only company that has an orally available CDK-specific agent in Phase 2 clinical trials but that there are a number of companies, including AstraZeneca, Eisai, Pfizer, Piramal Life Sciences, Roche, Merck and Bayer-Schering that 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, or CTEP, is continuing to enroll patients in a CTEP sponsored trial 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, Entremed, Merck, jointly with Vertex, Nerviano Medical Sciences, Pfizer, Rigel, Sunesis and Takeda-Millennium have commenced Phase 1 or Phase 2 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, Onconova and Nerviano Medical Sciences have commenced Phase 1 or Phase 2 clinical trials with Plk inhibitor candidates for oncology indications. For our ALIGN products, we believe that Beiersdorf, Daiichi-Sankyo, Eisai, Johnson & Johnson, MPM Medical and other companies market products for radiation dermatitis and xerostomia.

**Table of Contents**

**Employees**

As of March 19, 2010, we had 24 full-time employees, comprised of 11 employees in research and development and 13 employees in sales, 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. In September 2008, we announced a revision of our operating plan to concentrate our resources on the advancement of our lead drug sapacitabine. Consistent with the revised operating plan, during the second and third quarters of 2009, we further reduced our workforce across all locations by twenty six (26) people making a total reduction of fifty one (51) people, or 63% of the workforce, since September 2008.

**Available information**

We have filed reports, proxy statements and other information with the Securities and Exchange Commission, or 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 Room, 100 F Street, N.E., Washington D.C. 20549. The public may obtain information on the operation of the SEC's Public Reference Room 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 current reports on Forms 8-K, annual report on Form 10-K, quarterly reports on Form 10-Q and proxy statements, and all amendments to those reports at no charge through our website at [www.cyclacel.com](http://www.cyclacel.com) as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. Copies are also available, without charge, from Cyclacel Pharmaceuticals, Inc., 200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922.

**Table of Contents**

**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 company.*

***We believe regulatory agencies will not accept registration pathways based on Phase 2 data and, therefore, we will need to conduct randomized Phase 3 studies, which are time-consuming and expensive.***

Regulatory agencies, including, but not limited to, the FDA, have in certain instances accepted Phase 2 data from uncontrolled studies as sufficient for approval in indications where an unmet medical need exists or in exceptional circumstances. Recently, however, the Oncologic Drugs Advisory Committee (ODAC), which is the cancer drug advisory panel of the FDA, voted in favor of completion of a randomized trial prior to regulatory approval with respect to drugs submitted for approval as treatments for patients with AML and likely in respect of drugs submitted for approval as treatments for patients with other forms of cancer. Therefore, we believe that to gain regulatory approval from the FDA, we will need to conduct a randomized Phase 3 trial. Randomized Phase 3 studies are time-consuming and expensive, and because we have limited resources any such requirements may adversely impact our operating results and financial condition and delay or block our ability to commercialize our lead drug candidates. Even if we believe that the data collected from clinical trials of our drug candidates are promising with respect to safety and efficacy, such data may not be deemed sufficient by regulatory authorities to warrant product approval. Clinical data can be interpreted in different ways. Regulatory officials could interpret such data in different ways than we do which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our lead drug candidates, or in receiving regulatory approval for the commercialization of our lead drug candidates, may adversely affect our business.

***The current economic conditions and financial market turmoil could adversely affect our business and results of operations.***

Economic conditions remain difficult with the continuing uncertainty in the global credit markets, the financial services industry and the United States capital markets and with the United States economy as a whole experiencing a period of substantial turmoil and uncertainty characterized by unprecedented intervention by the United States federal government and the failure, bankruptcy, or sale of various financial and other institutions. We believe the current economic conditions and financial market turmoil could adversely affect our operations, business and prospects, as well as our ability to obtain funds and manage our liquidity. If these circumstances persist or continue to worsen, our future operating results could be adversely affected, particularly relative to our current expectations.

***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 have earned 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



**Table of Contents**

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. A combination trial of sapacitabine and seliciclib and CYC116 are currently in a Phase 1 clinical trial. 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, 2009, our accumulated deficit was \$222.3 million. Our net loss for the years ended December 31, 2008 and 2009 was \$40.4 million and \$19.6 million, respectively. Our net loss attributable to common shareholders from inception through December 31, 2009 was \$260.4 million. Our drug candidates are in the mid-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 drug candidates, seek regulatory approvals, commercialize any approved drugs and market and promote the ALIGN products: Xclair<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges. If our 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, particularly in light of the current economic conditions, you could lose all or part of your investment.

***Capital markets are currently experiencing a period of disruption and instability, which has had and could continue to have a negative impact on the availability and cost of capital.***

The general disruption in the United States capital markets has impacted the broader worldwide financial and credit markets and reduced the availability of debt and equity capital for the market as a whole. These global conditions could persist for a prolonged period of time or worsen in the future. Our ability to access the capital markets may be restricted at a time when we would like, or need, to access those markets, which could have an impact on our flexibility to react to changing economic and business conditions. The resulting lack of available credit, lack of confidence in the financial sector, increased volatility in the financial markets could materially and adversely affect the cost of debt financing and the proceeds of equity financing may be materially adversely impacted by these market conditions.

***If we fail to comply with the continued listing requirements of the NASDAQ Global Market our common stock price may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.***

Our common stock is currently listed for trading on the NASDAQ Global Market. We must satisfy NASDAQ's continued listing requirements, including among other things, a minimum stockholders' equity of \$10.0 million and a minimum bid price for our common stock of \$1.00 per share, or risk delisting, which would have a material adverse affect on our business. A delisting of our common stock from the NASDAQ Global Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. During 2009, Cyclacel received notification from the NASDAQ Stock Market that the Company was not in compliance with the minimum \$10 million stockholders' equity requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(b)(1)(A). On January 27, 2010, NASDAQ notified the Company that it regained compliance with the minimum \$50 million market value of listed securities requirement and that it currently complies with all other applicable standards for continued listing on The NASDAQ Global Market.

Accordingly, the Company's shares of common and preferred stock will continue to trade on The NASDAQ Global Market.

**Table of Contents**

***Raising additional capital in the future may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing stockholders would experience further dilution. If we fail to obtain additional funding, we may be unable to complete the development and commercialization of our lead drug candidate, sapacitabine, or continue to fund 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, licensing revenue, government grants, research and development tax credits and product revenue. 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 of focusing on the advancement of sapacitabine, we expect our existing resources to be sufficient to fund our planned operations for at least the next twelve months. To meet our long-term financing requirements, we may raise funds through public or private equity offerings, debt financings or strategic alliances. Raising additional funds by issuing equity or convertible debt securities may cause our stockholders 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, particularly in light of the current economic conditions. If we are unable to obtain additional funds, we may be forced to delay or terminate our current clinical trials and the development and marketing of our drug candidates including sapacitabine.

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

On December 10, 2007 and as amended on November 24, 2009, 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 from us the lesser of 4,084,590 shares of our common stock or \$60 million of our common stock, 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, among other things, a minimum price for our common stock of \$0.40 per share, effectiveness of the registration statement covering the shares subject to the CEFF and the continued listing of our stock on The NASDAQ Global Market.

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. In such a case, we would be unable to access any capital through the CEFF.

We are entitled, in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement which became effective in December 2007, and prohibit Kingsbridge from selling shares. 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 CEFF, 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 to be made by us could be significant.

**Table of Contents**

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 20% 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. During December 2009 and January 2010, we sold an aggregate of 1,583,626 shares of our common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of \$1.3 million in funds drawn down from the CEFF by us. During March 2010, we sold another 1,234,606 shares of our common stock to Kingsbridge in consideration of an aggregate of \$2.8 million in funds drawn down from the CEFF by us. However, because we have not declared dividends on our preferred stock for several quarters during the fiscal year 2009, we will not be able to use our Registration Statement on Form S-3, which covers the shares subject to the CEFF and therefore, we may not be able to access the CEFF until such time as an effective registration statement covering such shares be in place. This may limit our ability to access capital markets on short notice or make the cost of capital more expensive.

***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, including our anticipated Phase 3 clinical trials for sapacitabine. 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;
- the costs associated with establishing sales and marketing capabilities;

**Table of Contents**

the costs of acquiring or investing in businesses, products and technologies;  
the effect of competing technological and market developments; and  
the payment, other terms and timing of any strategic alliance, licensing or other arrangements that we may establish.

If we are not able to secure additional funding when needed, especially in light of the current economic conditions and financial market turmoil, 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.

***If we do not realize the expected benefits from the restructuring plans we announced in September 2008 and June 2009, our operating results and financial conditions could be negatively impacted.***

In September 2008 and June 2009, we announced a strategic restructuring designed to focus our resources on our lead drug, sapacitabine, while maintaining the Company's core competency in drug discovery and cell cycle biology. We cannot guarantee that we will not have to undertake additional restructuring activities, that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our restructuring. If we are unable to realize the expected operational efficiencies from our restructuring activities, our operating results and financial condition could be adversely affected.

***Any future workforce and expense reductions may have an adverse impact on our internal programs, strategic plans, and our ability to hire and retain key personnel, and may also be distracting to our management.***

Further workforce and expense reductions in addition to those carried out in September 2008 and June 2009 could result in significant delays in implementing our strategic plans. In addition, employees, whether or not directly affected by such reduction, may seek future employment with our business partners or competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidential nature of certain proprietary information may not be maintained in the course of any such future employment. In addition, any additional workforce reductions or restructurings would be expected to involve significant expense as a result of contractual terms in certain of our existing agreements, including potential severance obligations as well as any payments that may, under certain circumstances, be required under our agreement with the Scottish Enterprise. Further, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled personnel. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce and expense reductions. Finally, the implementation of expense reduction programs may result in the diversion of the time and attention of our executive management team and other key employees, which could adversely affect our business.

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

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

**Table of Contents**

***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.

***We are exposed to risks related to foreign currency exchange rates.***

Some of our costs and expenses are denominated in foreign currencies. Most of our foreign expenses are associated with our research and development operations of our United Kingdom-based wholly-owned subsidiary. When the United States dollar weakens against the British pound, the United States dollar value of the foreign currency denominated expense increases, and when the United States dollar strengthens against the British pound, the United States dollar value of the foreign currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations.

***We are exposed to risk related to the marketable securities we may purchase.***

We may invest cash not required to meet short term obligations in short term marketable securities. We may purchase securities in United States government, government-sponsored agencies and highly rated corporate and asset-backed securities subject to an approved investment policy. Historically, investment in these securities has been highly liquid and has experienced only very limited defaults. However, recent volatility in the financial markets has created additional uncertainty regarding the liquidity and safety of these investments. Although we believe our marketable securities investments are safe and highly liquid, we cannot guarantee that our investment portfolio will not be negatively impacted by recent or future market volatility or credit restrictions.

***Clinical trials are expensive, time consuming, subject to delay and may be required to continue beyond our available funding.***

Clinical trials are expensive, complex can take many years to conduct and may have uncertain outcomes. We estimate that clinical trials of our most advanced drug candidates may be required to continue beyond our available funding and may take several years more to complete. The designs used in some of our trials have not been used widely 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 because of competition for patients from other trials or other reasons;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;

**Table of Contents**

uncertain dosing issues may or may not be related to suboptimal pharmacokinetic and pharmacodynamic behaviors;  
approval and 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;  
inability or unwillingness of medical investigators to follow our clinical protocols; and  
unavailability of clinical trial supplies.

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 serious adverse events as defined in trial protocols have been noted in preclinical and clinical trials involving certain of our drug candidates. For example, neutropenia and gastro-intestinal toxicity were observed in patients receiving sapacitabine and elevations of liver enzymes and decrease in potassium levels have been observed in patients receiving seliciclib.

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

***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.***

Our development of small molecule inhibitors of CDK and AK is based on our understanding of the mechanisms of action of CDK and AK inhibitors and their interaction with other cellular mechanisms. One of our drug candidates, seliciclib, is a CDK inhibitor, and CYC116 is an AK and VEGFR2 inhibitor. 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. If our understanding of the role played by CDK or AK inhibitors in regulating the cell cycle is incorrect, seliciclib and/or CYC116 may fail to produce therapeutically relevant results hindering our ability to pursue our clinical and regulatory strategy.

**Table of Contents**

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

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

Although we are not currently party to any collaboration arrangement or strategic alliance that is material to our business, in the future we expect to be dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our drug candidates particularly after the Phase 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;

**Table of Contents**

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 currently marketed ALIGN products. We currently lack the resources or the capacity to manufacture any of our products on a clinical or commercial scale. We depend upon a third party, Sinclair, to manufacture the commercial products sold by our ALIGN subsidiary and we can not rely upon Sinclair to continue to supply the products. 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 and will be required to secure alternative third-party suppliers to our current suppliers. 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 our current or future 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 or are unable to secure alternative third-party suppliers to our current suppliers, the drug development, regulatory approval or commercial launch of any related drugs may be delayed or blocked 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, control and regulatory capabilities and develop financial, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Our ability to manage our operations and any growth will require us to make appropriate changes and upgrades, as necessary, to our operational, financial and management controls, reporting systems and procedures wherever we may operate. Any inability to manage growth could delay the execution of our business plan or disrupt our operations.

**Table of Contents**

***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. The success of the commercialization of the ALIGN products depends, in large part, on our continued ability to develop and maintain important relationships with 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 Investigational New Drug, or 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 pivotal or suitable for registration late Phase 2 or 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 the FDA and other applicable foreign and U.S. regulatory requirements may subject us 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.

**Table of Contents**

Despite the substantial time and expense invested in preparation and submission of an NDA or equivalents in other jurisdictions, regulatory approval is never guaranteed. The FDA and other regulatory authorities in the United States, the European Union and elsewhere exercise substantial discretion in the drug approval process. The number, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the drug candidate, the disease or condition for which the drug candidate is intended to be used and the regulations and guidance documents applicable to any particular drug candidate. The FDA or other regulators can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to:

- those discussed in the risk factor which immediately follows;
- the fact that the 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 adoption of 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 the rights to 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 which was licensed from Daiichi-Sankyo. 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.***

A large number of drug candidates are in development for the treatment of leukemia, lung cancer, lymphomas and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs or other products on the market or in clinical trials which may be competitive to sapacitabine in both hematological and oncology indications. These include Celgene, Cephalon, Eisai, Johnson & Johnson, Eli Lilly, Genzyme, GlaxoSmithKline, Hospira, Pfizer, Seattle Genetics, Sunesis and Vion. We believe that we are currently the only company that has an orally available CDK-specific agent in Phase 2 clinical trials but that there are a number of companies, including AstraZeneca, Eisai, Pfizer, Piramal Life Sciences, Roche, Merck and Bayer-Schering that are

developing CDK inhibitors in early stage clinical trials in cancer patients. Although Aventis,

**Table of Contents**

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, or CTEP, is continuing to enroll patients in a CTEP sponsored trial 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, Entremed, Merck, jointly with Vertex, Nerviano Medical Sciences, Pfizer, Rigol, Sunesis and Takeda-Millennium have commenced Phase 1 or Phase 2 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, Onconova and Nerviano Medical Sciences have commenced Phase 1 or Phase 2 clinical trials with Plk inhibitor candidates for oncology indications. For our ALIGN products, 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;
- conducting preclinical and clinical trials;
- obtaining regulatory approvals; and
- commercializing product candidates.

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

***The commercial success of 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 Xclafit<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges achieve and maintain market acceptance. If our drug candidates are approved by the FDA or by another regulatory authority, the resulting drugs, if any, may not gain market acceptance among physicians, healthcare providers and payors, patients and the medical community. The degree of market acceptance of any of our approved drugs or devices will depend on a variety of factors, including:

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

**Table of Contents**

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 our 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.

## **Table of Contents**

As we market commercialized products through our ALIGN subsidiary we are exposed to additional risks of product liability claims. These risks exist even with respect to 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 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



**Table of Contents**

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, sapacitabine is covered in granted, composition of matter patents that expire in 2014 in the US and 2012 outside the US. Sapacitabine is further protected by additional granted, composition of matter patents claiming certain, stable crystalline forms of sapacitabine and their pharmaceutical compositions and therapeutic uses that expire in 2022. In early development, amorphous sapacitabine was used. We have used one of the stable, crystalline forms of sapacitabine in nearly all our Phase 1 and in all of our Phase 2 clinical studies. We have also chosen this form for commercialization. Additional patents claim certain medical uses and formulations of sapacitabine which have emerged in our clinical trials. Seliciclib is protected by granted, composition of matter patents that expire in 2016. Additional patents claim certain medical uses which have emerged from our research programs.

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.

**Table of Contents**

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 sapacitabine, seliciclib 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 and patents 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 and the patent has been finally revoked (no appeal was filed). We are also aware of a corresponding U.S. patent containing method of treatment claims for specific cancers using aurora kinase modulators which, if held valid, could potentially restrict the use of our aurora kinase inhibitors once clinical trials are completed.

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

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder;
- decide to move some of our screening work outside Europe;

**Table of Contents**

be required to pay substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a competitor's patent or other proprietary rights; or

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

***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. Both of these license agreements impose payment and other material obligations on us. 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, unless we have in-licensed certain patent rights in connection with the development programs for each of our two lead drug candidates. Under both of the license agreements relating to these drug candidates 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.

Pursuant to the Daiichi-Sankyo license under which we license sapacitabine, we are obligated to pay license fees, milestone payments and royalties, provide regular progress reports and use commercially reasonable efforts to commercialize products based on the licensed rights and obtain regulatory approval to sell the products in at least one country by September 2011, unless we are prevented from doing so by virtue of certain causes outside of our reasonable control, including but not limited to difficulties in patient recruitment into trials or significant, unexpected change in regulatory requirements affecting the development of our drug. Pursuant to the CNRS and Institut Curie license under which we license seliciclib, we are obligated to pay license fees, milestone payments and royalties and provide regular progress reports.

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 may be entitled to terminate the licenses. This would restrict or delay or eliminate our ability to develop and commercialize these drug candidates, which could adversely affect our business. With respect to seliciclib we hold a license from CNRS and Institut Curie under which we are obligated to pay license fees, milestone payments and royalties. We are 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 could attempt to terminate the licenses and there can be no assurance as to what would constitute exceptional cause. This would restrict or delay or eliminate our ability to develop and commercialize these drug candidates, which could adversely affect our business.

***We incur increased costs and management resources as a result of being a public company, and we still may fail to comply with public company obligations.***

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 would 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 resulted in a significant initial cost to us as well as an ongoing 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, 2009, our internal control over financial reporting was 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.

**Table of Contents**

***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. In addition, the stock market as a whole and biotechnology and other life science stocks in particular have experienced significant recent volatility. Like our common stock, these stocks have experienced significant price and volume fluctuations for reasons unrelated to the operating performance of the individual companies. In addition, due to our existing stock price, we may not continue to qualify for continued listing on the NASDAQ Global Market. To maintain listing, we are required to maintain a minimum closing bid price of \$1.00 per share and, among other requirements, to maintain a minimum stockholders equity value of \$10 million. Factors giving rise to this volatility may include:

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

***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.

***If securities or industry analysts do not publish research or reports about us, if they change their recommendations regarding our stock adversely or if our operating results do not meet their expectations, our stock price and trading volume could decline.***

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock or if our operating results do not meet their expectations, our stock price could 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.



**Table of Contents**

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.

***Certain severance-related agreements in our executive employment agreements may make an acquisition more difficult and could result in the entrenchment of management.***

In March 2008 (as amended in December 2008 with respect to our President and Chief Executive Officer), we entered into employment agreements with our President and Chief Executive Officer and our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, which contain severance arrangements in the event that such executive's employment is terminated without cause or as a result of a change of control (as each such term is defined in each agreement). The financial obligations triggered by 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.

***In the event of an acquisition of our common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time.***

We may not effect a consolidation or merger with another entity without the vote or consent of the holders of at least a majority of the shares of our preferred stock (in addition to the approval of our common stockholders), unless the preferred stock that remains outstanding and its rights, privileges and preferences are unaffected or are converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our convertible preferred stock.

In addition, in the event a third party seeks to acquire our company or acquire control of our company by way of a merger, but the terms of such offer do not provide for our preferred stock to remain outstanding or be converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our preferred stock, the terms of the Certificate of Designation of our preferred stock provide for an adjustment to the conversion ratio of our preferred stock such that, depending on the terms of any such transaction, preferred stockholders may be entitled, by their terms, to receive up to \$10.00 per share in common stock, causing our common stockholders not to receive as favorable a price as the price at which such shares may be trading at the time of any such transaction. As of March 25, 2010, there were 1,923,413 shares of our preferred stock issued and outstanding. If the transaction were one in which proceeds were received by the Company for distribution to shareholders, and the terms of the Certificate of Designation governing the preferred stock were strictly complied with, approximately \$19,250,000 would be paid to the preferred holders before any distribution to the common stockholders, although the form of transaction could affect how the holders of preferred stock are treated. In such an event, although such a transaction would be subject to the approval of our holders of common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time. Thus, the terms of our preferred stock might hamper a third party's acquisition of our company.



**Table of Contents**

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

Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change in our Board of Directors and management teams. Some of these provisions:

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

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of large stockholders to complete a business combination with, or acquisition of, us. These provisions may prevent a business combination or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our stock. These provisions also make it more difficult for our stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team. Additionally, these provisions may prevent an acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our common stock.

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

Delaware law may limit our ability to pay cash dividends on the convertible preferred stock. Under Delaware law, cash dividends on our 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 not to declare the dividends. If that was to happen, holders of preferred stock would be granted certain additional rights until such dividends were paid.

***If we continue not to declare the quarterly dividends on our 6% Convertible Exchangeable Preferred Stock for a total of six quarterly dividend periods, we will have to grant additional rights to our holders of Preferred Stock with respect to the management of the Company.***

On April 6, 2009, September 22, 2009, October 19, 2009 and January 7, 2010, our Board of Directors decided not to declare payment of the quarterly cash dividend on the Company's 6% Convertible Exchangeable Preferred Stock, or the Preferred Stock, scheduled for May 1, 2009, August 1, 2009, November 1, 2009 and February 1, 2010, respectively. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are accumulated. However, we did not declare dividends on the Preferred Stock for four quarterly dividend periods and if we fail to declare dividends on the Preferred Stock for six quarterly dividend periods (whether or not consecutive), the size of our Board of Directors will be increased by two and the holders of the Preferred Stock will have the right to vote to fill the two vacancies created thereby until we pay all accumulated and unpaid dividends. Although our Board of Directors will continue to evaluate the payment of a quarterly cash dividend on a quarterly basis, we cannot assure you that we will be able to continue to pay the dividends and that holders of our Preferred Stock will not be granted additional rights with respect to our management.

**Table of Contents**

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

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

- additions to or departures of our key personnel;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements concerning our competitors or the biotechnology industry in general;
- new regulatory pronouncements and changes in regulatory guidelines;
- general and industry-specific economic conditions;
- changes in financial estimates or recommendations by securities analysts;
- variations in our quarterly results;
- announcements about our collaborators or licensors; and
- changes in accounting principles.

The market prices of the securities of biotechnology companies, particularly companies like us without product revenues and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the performance of particular companies. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Moreover, market prices for stocks of biotechnology-related and technology companies frequently reach levels that bear no relationship to the performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our financial condition and results of operations. In addition, due to our stock price from time to time, we may not continue to qualify for continued listing on the NASDAQ Global Market. Please see Risk Factor: *Our common stock may have a volatile public trading price.*

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

If our common or preferred stockholders sell substantial amounts of our stock in the public market, or the market perceives that such sales may occur, the market price of our common and preferred stock could fall. For example, we were approached by a preferred stockholder that elected to convert 123,400 of its shares of preferred stock, which shares were converted into 239,396 shares of common stock effective March 16, 2010. Thus if additional holders of preferred stock elect to convert their shares to shares of common stock at renegotiated prices, such conversion as well as the sale of substantial amounts of our common or preferred stock, could cause dilution to existing holders of our common stock, thereby also negatively affecting the price of our common stock.

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

An exchange of convertible preferred stock for debentures, as well as any dividend make-whole or interest make-whole payments paid in our common stock, will be taxable events for United States 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 the holders of the securities to pay these potential tax liabilities.

**Table of Contents**

***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. 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.

***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.

**Table of Contents**

***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 Current Good Manufacturing Practice or 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<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges and to recognize revenues on a timely basis is substantially dependent on our ability to maintain commercially reasonable agreements with each of these wholesale distributors and the extent to which these distributors, over whom we have no control, comply with such agreements. Our agreements with wholesaler distributors may contain terms that are not favorable, given our relative lack of market leverage as a company with only three approved products or other factors, which could adversely affect our commercialization of Xclair<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> 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.

***We may be unable to accurately estimate demand and monitor wholesaler inventory of Xclair<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid or Numoisyn<sup>®</sup> Lozenges. Although we attempt to monitor wholesaler inventory of Xclair<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid or Numoisyn<sup>®</sup> Lozenges, we also rely on third party information, which is inherently uncertain and may not be accurate, to assist us in monitoring estimated inventory levels and prescription trends. Inaccurate estimates of the demand and inventory levels of the product may cause our revenues to fluctuate significantly from quarter to quarter and may cause our operating results for a particular quarter to be below expectations.***

Inventory levels of Xclair<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid or Numoisyn<sup>®</sup> Lozenges held by wholesalers can also cause our operating results to fluctuate unexpectedly. For the years ended December 31, 2008 and 2009, approximately 85% and 86%, respectively, of our product sales in the United States were to three wholesalers, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen. Inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to wholesalers do not match end user demand. We have entered into inventory management agreements with these U.S. wholesalers under which they provide us with data regarding inventory levels at these wholesalers. However, these wholesalers may not be completely effective in matching inventory levels to end user demand, as they make estimates to determine end user demand. In addition, inventory is held at retail pharmacies and other non-wholesaler locations, for which we have no inventory management agreements and have no control in respect to their buying patterns. Also, the non-retail sector in the United States, which includes

government institutions and large health maintenance organizations, tends to be less consistent in terms of buying patterns, and often causes quarter-over-quarter fluctuations in inventory and ordering patterns. We attempt to monitor inventory of Xclair<sup>®</sup>, Numoisyn<sup>®</sup> Liquid or Numoisyn<sup>®</sup> Lozenges in the United States through the use of internal sales forecasts and the expiration dates of product shipped, among other factors.

**Table of Contents**

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

Our successful commercialization of Xclair<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> 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 small 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<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> 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.

**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. 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 in December 2010. Activities have been discontinued at the Bothell facility since the third quarter of 2005 and we do not plan to renew the lease.

We believe that our existing facilities are 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, 2009, we were not a party to any material legal proceedings that we believe will have a material impact on our financial position or results of operations.

**Item 4. (Removed and Reserved)**

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****Market Information**

Our common stock is traded on The NASDAQ Global Market, or NASDAQ, under the symbol "CYCC". Our preferred stock currently trades on NASDAQ under the symbol "CYCCP". The following table summarizes, for the periods indicated, the high and low sales prices for the common stock as reported by NASDAQ:

	<b>High</b>	<b>Low</b>
<b>2009</b>		
Quarter ended March 31, 2009	\$ 0.54	\$ 0.26
Quarter ended June 30, 2009	\$ 1.66	\$ 0.30
Quarter ended September 30, 2009	\$ 1.24	\$ 0.79
Quarter ended December 31, 2009	\$ 1.69	\$ 0.75
<b>2008</b>		
Quarter ended March 31, 2008	\$ 5.51	\$ 2.40
Quarter ended June 30, 2008	\$ 3.67	\$ 1.66
Quarter ended September 30, 2008	\$ 2.00	\$ 0.84
Quarter ended December 31, 2008	\$ 1.16	\$ 0.23

**Holders of Common Stock**

On March 22, 2010, we had approximately 55 registered holders of record of our common stock. On March 26, 2010, the closing sale price of our common stock as reported by NASDAQ was \$2.36 per share.

**Table of Contents****Performance Graph**

The following graph and table compare the cumulative total return of our common stock, The NASDAQ Composite Index and NASDAQ Biotechnology Index, as described below, for the period beginning March 27, 2006 (the date we became a public company) and ending December 31, 2009, assuming an initial investment of \$100 and the reinvestment of any dividends. We obtained the information reflected in the graph and table from independent sources we believe to be reliable, but we have not independently verified the information.

**COMPARISON OF 45 MONTH CUMULATIVE TOTAL RETURN\***

Among Cyclacel Pharmaceuticals, Inc., The NASDAQ Composite 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	December 31, 2008	December 31, 2009
Cyclacel	100.00	85.86	68.59	5.26	13.02
Nasdaq Composite	100.00	107.56	117.24	68.71	101.05
NASDAQ Biotechnology	100.00	93.30	94.18	88.44	100.49

Performance Graph and related information shall not be deemed soliciting material or 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.

**Table of Contents****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 foreseeable future. We are, however, required to make or accrue quarterly dividend payments on our Preferred Stock. Except for dividends paid on the 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, since inception through February 1, 2009, we paid these dividends when they have fallen due. However, as part of our program to reduce expenditure, on April 6, 2009, June 22, 2009, October 19, 2009 and January 7, 2010, our Board of Directors decided not to declare the quarterly cash dividend. The Board of Directors will continue to evaluate the payment of a cash dividend on a quarterly basis. Any dividends must be declared by our board of directors and must come from funds that are legally available for dividend payments.

**Unregistered Sales of Securities**

During the fiscal year ended December 31, 2009, we sold an aggregate of 1,255,024 shares of our common stock to Kingsbridge under the terms of our CEFF, in consideration of an aggregate of \$1.03 million in funds drawn down from the CEFF. Following the fiscal year-end, we sold an additional aggregate of 1,563,208 shares of our common stock to Kingsbridge under the CEFF, in consideration of an aggregate proceeds of \$3.1 million. We relied on the exemption from registration contained in Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder, in connection with the sale of the shares of common stock under the CEFF.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table provides certain aggregate information with respect to all of our equity compensation plans in effect as of December 31, 2009:

<b>Plan Category</b>	<b>(a)</b>	<b>(b)</b>	<b>(c)</b>
	<b>No. of securities to be issued upon exercise of outstanding options, warrants and rights</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</b>
Total equity compensation plans approved by security holders (1)	3,441,021	\$ 4.11	1,703,766
Equity compensation plans not approved by security holders			

(1) Consists of our Amended and Restated 2006 Stock Option

Plan (the 2006 Plan ). The 2006 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, and performance units. The number of shares available for issuance, as of March 30, 2010, under the 2006 Plan is 5,200,000.

**Item 6. Selected Financial Data**

This section presents our historical financial data. The consolidated statement of operations data for the years ended December 31, 2007, 2008, 2009 and for the period from August 13, 1996 (inception) to December 31, 2009 and the consolidated balance sheet data as of December 31, 2008 and 2009 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended 2005 and 2006 and the balance sheet data as of December 31, 2005, 2006 and 2007 have been derived from our audited financial statements that are not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results.

**Table of Contents**

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 Annual Report on Form 10-K.

	Years Ended December 31,					Period
	2005	2006	2007	2008	2009	from
						August 13,
						1996
						(inception)
						to
						December
						31,
						2009
	(in thousands)					
<b>Consolidated Statements of Operations:</b>						
<b>Revenues:</b>						
Collaboration and research and development income	\$ 245	\$ 231	\$ 10	\$	\$	\$ 3,000
Product revenue				838	910	1,748
Grant income	111	156	119	39	1	3,636
	356	387	129	877	911	8,384
<b>Operating expenses:</b>						
Cost of goods sold				429	545	974
Research and development	15,841	21,205	19,569	18,869	9,766	170,179
Selling, general and administrative	5,290	12,598	12,033	15,354	8,538	71,846
Goodwill and intangibles impairment				7,934		7,934
Other restructuring costs		225	1,554	489	366	2,634
<b>Total operating expenses</b>	21,131	34,028	33,156	43,075	19,215	253,567
<b>Operating loss</b>	(20,775)	(33,641)	(33,027)	(42,198)	(18,304)	(245,183)
Total other income (expense)	801	2,138	6,933	63	(2,214)	5,676
<b>Loss before taxes</b>	(19,948)	(31,503)	(26,094)	(42,135)	(20,518)	(239,507)
Income tax benefit	1,900	2,245	2,041	1,749	948	17,222
<b>Net loss</b>	(18,048)	(29,258)	(24,053)	(40,386)	(19,570)	(222,285)

Dividends on preferred shares	(11,876)	(2,827)				(38,123)
<b>Net loss applicable to common shareholders</b>	\$ (29,924)	\$ (32,085)	\$ (24,053)	\$ (40,386)	\$ (19,570)	\$ (260,408)
<b>Net loss per share basic and diluted</b>	\$ (4.50)	\$ (2.40)	\$ (1.21)	\$ (1.98)	\$ (0.88)	
Shares used in computing basic and diluted net loss per share	6,656,732	13,390,933	19,873,911	20,433,129	22,196,840	

**Table of Contents**

	2005	2006	As of December 31, 2007 (in thousands)	2008	2009
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 3,117	\$ 44,238	\$ 30,987	\$ 24,220	\$ 11,493
Short-term investments	10,690	9,764	27,766	1,502	
Working capital	2,152	50,244	49,065	20,387	3,547
Total assets	19,071	63,276	75,912	30,957	14,466
Long-term liabilities, net of current portion	(78)	(1,436)	(3,231)	(1,688)	
Total stockholders' equity	4,119	53,919	57,969	20,642	4,644

In connection with the stock purchase agreement entered into 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 Annual Report on Form 10-K reflect those of Cyclacel Limited prior to the reverse acquisition.

**Table of Contents**

**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 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, 2009 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 diversified biopharmaceutical business dedicated to the discovery, development and commercialization of novel, mechanism- targeted drugs to treat cancer and other serious disorders. We are focused on delivering leading edge therapeutic management of cancer patients based on a clinical development pipeline of novel drug candidates. Our core area of expertise, and a foundation of the Company since our inception, is in cell cycle biology; 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.

Our clinical development priorities are focused on sapacitabine in the following indications:

- Acute myeloid leukemia, or AML in the elderly;
- Myelodysplastic syndromes, or MDS; and
- Non-small cell lung cancer or NSCLC.

We have ongoing clinical programs in development which are currently pending availability of data. Once data become available and are reviewed, we will determine the feasibility of pursuing further development and/or partnering these assets, including sapacitabine in combination with seliciclib, seliciclib in NSCLC and nasopharyngeal cancer, or NPC, and CYC116. In addition, we market directly in the United States Xclair<sup>®</sup> Cream for radiation dermatitis and Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges for xerostomia.

Our core area of expertise is in cell cycle biology and we focus primarily on the 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 and MDS and seliciclib is the only orally available CDK inhibitor currently in Phase 2 trials. Although our resources are primarily directed towards advancing our anticancer drug candidate sapacitabine through in-house development activities we are also progressing, but with lower levels of investment than in previous years, our other novel drug series which are at earlier stages. As a consequence of our focus on sapacitabine clinical development and related cost reduction program, research and development expenditures for the year ended December 31, 2009 were reduced by \$9.1 million, or 48%, to \$9.8 million compared to \$18.9 million for the year ended December 31, 2008.



**Table of Contents**

We have worldwide rights to commercialize sapacitabine, seliciclib and CYC116 and our business strategy is to enter into selective partnership arrangements with these programs. 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, with a research facility located in Scotland. From our inception in 1996 through December 31, 2009, 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, 2009, our accumulated deficit during the development stage was approximately \$222.3 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and pre-clinical drug candidates. Our operating expenses comprise research and development expenses and selling and general and administrative expenses.

To date, we have not generated significant product revenue but have financed our operations and internal growth through private placements, registered direct financings, licensing revenue, interest on investments, government grants and research and development tax credits. Prior to October 2007, our revenue consisted of collaboration and grant revenue. We did not start recognizing sales from our commercial products until 2008. We have recognized revenues from inception through December 31, 2009 totaling approximately \$8.4 million of which approximately \$3.0 million is derived from fees under collaborative agreements, approximately \$3.6 million of grant revenue from various United Kingdom government grant awards and approximately \$1.8 million from product sales. We have also recognized amounts receivable from the United Kingdom's tax authority, H.M. Revenue & Customs of \$17.2 million for research and development tax credits since inception.

**Recent Events**

On January 27, 2010, we announced that The NASDAQ Global Market, or NASDAQ, had notified us that we regained compliance with the minimum \$50 million market value of listed securities requirement and that we currently comply with all other applicable standards for continued listing on NASDAQ.

On January 25, 2010, we completed the sale of 2,350,000 units in a registered direct offering at a purchase price of \$2.50 per unit to certain existing institutional investors of the Company for approximately \$5.9 million in gross proceeds. Each unit consisted of one share of our common stock and one warrant to purchase 0.30 of one share of our common stock. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance and will be exercisable at an exercise price of \$2.85 per share of common stock.

On January 13, 2010, we completed the sale of 2,850,000 units in a registered direct offering to certain institutional investors. Each unit was sold at a purchase price of \$2.51 per unit and consists of one share of our common stock and one warrant to purchase 0.25 of one share of our common stock totaling approximately \$7.2 million in gross proceeds. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance and will be exercisable at an exercise price of \$3.26 per share of common stock.

**Table of Contents**

On January 7, 2010, the Board of Directors of Cyclacel decided not to declare the quarterly cash dividend on the Company's 6% Convertible Exchangeable Preferred Stock, or Preferred Stock, with respect to the fourth quarter of 2009 that would have otherwise been payable on February 1, 2010. As previously disclosed, the Board also did not declare the quarterly cash dividend with respect to the first, second and third quarters of 2009. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are accrued. This is the fourth quarterly dividend that we have not declared and if we fail to pay dividends for at least six quarters (whether or not consecutive) on the Preferred Stock, the size of our Board of Directors could be increased by two members and the holders of the Preferred Stock, voting separately as a class, will have the right to vote to fill the two vacancies created thereby until all accrued but unpaid dividends have been paid in full, at which time such right is terminated.

During January and February 2010, we issued 2,618,266 shares of our common stock for gross proceeds of approximately \$2.6 million through the exercise of warrants. In addition, we completed a draw down from our CEFF under which we issued 1,563,208 shares for proceeds of approximately \$3.1 million.

During March 2010, we issued 239,396 shares of our common stock to a stockholder in exchange for the stockholder's delivery to us of 123,400 shares of our outstanding Preferred Stock.

**Results of Operations**

In connection with the stock purchase agreement entered into with 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 Annual Report on Form 10-K reflect those of Cyclacel Limited prior to the reverse acquisition.

In connection with the asset purchase agreement with ALIGN, Cyclacel recorded the assets and liabilities of ALIGN at fair value on October 5, 2007. The results of operations and balance sheet data for 2007 reflect the results of the combined companies from October 5, 2007 through December 31, 2007.

*Years ended December 31, 2008 and 2009 compared to years ended December 31, 2007 and 2008, respectively.*

**Revenues**

The following table summarizes the components of our revenues for the years ended December 31, 2007, 2008 and 2009:

	Years ended			\$ Differences		% Differences	
	2007	2008	2009	2007 to 2008	2008 to 2009	2007 to 2008	2008 to 2009
	(in thousands)						
Collaboration and research and development revenue	\$ 10	\$	\$	\$ (10)	\$	(100)%	%
Product Revenue		838	910	838	72	100%	9%
Grant revenue	119	39	1	(80)	(38)	(67)%	(97)%
Total revenue	\$ 129	\$ 877	\$ 911	\$ 748	\$ 34	580%	4%

Collaboration and research and development revenue is derived from several agreements under which the Company provides compounds for evaluation for an agreed consideration. No revenue was recognized under collaborative agreements during 2008 and 2009.

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges following the ALIGN asset acquisition on October 5, 2007. During the years ended December 31, 2008 and 2009, we recognized

approximately \$0.8 million and \$0.9 million, respectively in accordance with our revenue recognition policy.

**Table of Contents**

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. Grant revenue decreased by 97% from \$39,000 for the year ended December 31, 2008 to approximately \$1,000 for the year ended December 31, 2009. This was as a result of finalization of a three year European Union grant which concluded in 2009.

**The future**

This was the second full year of ALIGN product sales since we acquired ALIGN in October 2007. We expect to continue to grow the sales of ALIGN products in 2010 through the support of a small sales force infrastructure and marketing efforts. We expect that grant revenue will decrease as we focus our expenditure on the advancement of sapacitabine, which is currently waiting to advance into a Phase 3 clinical trial, and away from grant qualifying research expenditure.

**Cost of goods sold**

	Years ended			\$ Differences		% Differences	
	2007	2008	2009	2007 to 2008	2008 to 2009	2007 to 2008	2008 to 2009
	(in thousands)						
Cost of goods sold	\$	\$ 429	\$ 545	\$ 429	\$ 116	100%	27%

Total cost of sales represented 51% and 60%, respectively, of product revenue for the years ended December 31, 2008 and 2009. During 2009, we included an inventory provision of approximately \$0.1 million based upon current inventory levels, expiration dates, and future sales. Excluding the inventory provision, the cost of sales for the year ended December 31, 2009 represented 45% of product revenues and in the future we expect to maintain a similar margin level as we incurred in 2009.

**Research and development expenses**

To date, we have focused on drug discovery and development programs, with particular emphasis on orally available anticancer agents and our research and development expenses have represented costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for sapacitabine, seliciclib, sapacitabine in combination with seliciclib and CYC116. We have also incurred costs in the advancement of product candidates toward clinical and pre-clinical trials and the development of in-house research to advance our biomarker program and technology platforms. However, during 2008 and 2009, in response to changing market conditions, we extensively reduced or stopped expenditure on development and preclinical activities outside of our core focus on sapacitabine. The benefit of these cost reductions was realized in 2009 and will be also be realized in 2010. We expense all research and development costs as they are incurred. Research and development expenses primarily include:

- clinical trial and regulatory-related costs;
- payroll and personnel-related expenses, including consultants and contract research;
- preclinical studies and laboratory supplies and materials;
- technology license costs; and
- rent and facility expenses for our laboratories.

**Table of Contents**

The following table provides information with respect to our research and development expenditure for the years ended December 31, 2007, 2008 and 2009:

	Years ended			\$ Differences		% Differences	
	2007	2008	2009	2007 to 2008	2008 to 2009	2007 to 2008	2008 to 2009
	(in thousands)						
Sapacitabine	\$ 3,326	\$ 6,601	\$ 7,001	\$ 3,275	\$ 400	98%	6%
Seliciclib	3,270	2,906	(84)	(364)	(2,990)	(11)%	(103)%
CYC116	2,626	1,695	162	(931)	(1,533)	(35)%	(90)%
Other costs related to research and development programs, management and exploratory research	10,347	7,667	2,687	(2,680)	(4,980)	(26)%	(65)%
Total research and development expenses	\$ 19,569	\$ 18,869	\$ 9,766	\$ (700)	\$ (9,103)	(4)%	\$ (9,103)

Research and development expenses represented 59%, 44% and 51% of our operating expenses for the years ended December 31, 2007, 2008 and 2009, respectively. Included in research and development expenses is stock-based compensation of approximately \$0.8 million, \$0.7 million and \$0.3 million for the years ended December 31, 2007, 2008 and 2009, respectively.

*Fiscal 2009 as compared to fiscal 2008.* Research and development costs decreased by 51%, or approximately \$9.1 million, from approximately \$18.9 million for the year ended December 31, 2008 to approximately \$9.8 million for the year ended December 31, 2009. Starting in September 2008 with our announced cost containment efforts, we reduced or eliminated costs of all programs other than the sapacitabine clinical trials, and as of result, the research and development costs were reduced by approximately \$9.5 million in 2009 from 2008. The sapacitabine program increased by approximately \$0.2 million due to the increase in clinical trial costs of running the AML and MDS programs.

*Fiscal 2008 as compared to fiscal 2007.* Research and development costs decreased by 4%, or approximately \$0.7 million, from approximately \$19.6 million for the year ended December 31, 2007 to approximately \$18.9 million for the year ended December 31, 2008. The sapacitabine program increased by approximately \$3.3 million relating to the increased clinical trial activities, in particular the commencement of the Phase 2 trial in elderly AML in December 2007, the expansion of the trial to explore myelodysplastic syndromes, as well as additional pre-clinical efforts and product scale-up. This has been offset by cost reductions in other programs and cost savings from the workforce reduction in September 2008 to allow us to concentrate on the advancement of sapacitabine. The increase in strength of the U.S. dollar against the British Pound has also contributed to lower research and development expenses being recognized on the consolidated statement of operations for the year ended December 31, 2008 as compared to the year ended December 31, 2007.

*The future*

Following our reduction of expenditure in 2008 and 2009 in our non-core research and development programs, we have concentrated our resources on the development of sapacitabine in three indications. We anticipate that overall research and development expenditures in 2010 will be similar to 2009 levels.

**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, 2007, 2008 and 2009:



**Table of Contents**

Total selling, general and administrative expenses represented 36%, 36% and 44 % of our operating expenses for the years ended December 31, 2007, 2008 and 2009, respectively.

*Fiscal 2009 as compared to fiscal 2008.* Selling, general and administrative expenditure decreased by 44%, or \$6.8 million, from approximately \$15.4 million for the year ended December 31, 2008 to approximately \$8.5 million for the year ended December 31, 2009. This was as a result of cost saving measures first established in September 2008 and then during the second and third quarters of 2009. The cost savings resulted from reductions in employment related costs of \$2.6 million, intellectual property expenditures of \$1.3 million, stock-based compensation expenses of \$0.5 million, professional fees of \$0.5 million, investor relations of \$0.2 million, information technology costs of \$0.2 million and travel costs of \$0.1 million. Additionally, sales and marketing costs related to ALIGN in 2009 were reduced by \$0.1 million compared to 2008, which included one-time business launch costs not repeated in 2009. During 2008, a charge for amortization of intangibles of \$0.7 million with no corresponding charge in 2009 was recognized as the intangible assets were impaired during the third quarter of 2008.

*Fiscal 2008 as compared to fiscal 2007.* Selling, general and administrative expenditure increased 28% or \$3.3 million to approximately \$15.3 million for the year ended December 31, 2008 from approximately \$12.0 million for the year ended December 31, 2007, primarily attributable to the sales operations of ALIGN. Included within the expense of \$15.3 million for the year ended December 31, 2008 are approximately \$2.3 million of costs in respect of the support and development of ALIGN's commercial operations and sales and marketing, reflecting the fact that 2008 is the first full year of reporting for the ALIGN business following its acquisition in October 2007. In addition, \$0.7 million of intangible asset amortization charges were recognized prior to the intangible asset impairment. Included in selling, general and administrative expenses is stock compensation of approximately \$0.9 million and \$1.0 million for the years ended December 31, 2007 and 2008, respectively.

*The future*

Following our reduction in expenditure in 2008 and 2009, we expect our selling, general and administrative expenditures in 2010 to remain at the same levels as in 2009 or be lower.

Goodwill and intangible asset impairment

The following table summarizes the goodwill and intangibles impairment charges for the years ended December 31, 2007, 2008 and 2009:

	Years ended			\$ Differences		% Differences	
	2007	2008	2009	2007 to 2008	2008 to 2009	2007 to 2008	2008 to 2009
	(in thousands)						
Goodwill and intangibles impairment	\$	\$ 7,934	\$	\$ 7,934	\$ (7,934)	100%	(100)%

In September 2008, the goodwill acquired in the Xcyte transaction was written down in full and we recorded an impairment charge of approximately \$2.7 million in accordance with Accounting Standard Codification, or ASC, 350 Intangibles Goodwill and Other, or ASC 350. This impairment charge was identified through our annual impairment review process and was triggered primarily by a decline in our stock price that reduced our market capitalization below book value of the net assets of the Xcyte reporting unit. Our reduced market capitalization reflected the general decline in the economic environment.

Intangible assets acquired in the ALIGN transaction were also fully written down in September 2008, in accordance with Accounting Standard Codification, Codification Topic 360, entitled Property, Plant and Equipment, or ASC 360. An impairment charge of approximately \$3.6 million was identified through our annual impairment review process and was recognized on the consolidated statement of operations. This one-time non-cash charge was triggered by a downwards revision of our projected net cash flows from product sales, required due to budgetary constraints experienced by health care providers and restrictions of the cost reimbursement regime. As a result, the sum of the expected undiscounted cash flows was less than the carrying amount of the intangible assets on September 30, 2008.



**Table of Contents**

In December 2008, goodwill allocated to our ALIGN reporting unit following the ALIGN acquisition was fully written down in accordance with ASC 350, resulting in an impairment charge of approximately \$1.6 million being recognized on the consolidated statement of operations. A further decline in our stock price during the fourth quarter of 2008 caused us to perform an impairment analysis during December 2008. In determining the impairment charge, we considered the negative impact the current economic situation might have on sales growth expectations of the ALIGN products resulting in a downward revisions of projected net cash flows from product sales. These factors caused the discounted cash flows for the reporting unit to be less than its carrying value on December 31, 2008.

*The future*

Previously recognized goodwill and intangible assets acquired have been fully impaired as of December 31, 2008.

**Restructuring charge**

The following table summarizes the restructuring charges for years ended December 31, 2007, 2008 and 2009:

	Years ended			\$ Differences		% Differences	
	2007	2008	2009	2007 to 2008	2008 to 2009	2007 to 2008	2008 to 2009
	(in thousands)						
Total restructuring charge	\$ 1,554	\$ 546	\$ 366	\$ (1,008)	\$ (180)	(65)%	(33)%

*Fiscal 2009 as compared to fiscal 2008.* The restructuring charge decreased by 33% or \$0.1 million from approximately \$0.5 million for the year ended December 31, 2008 to \$0.4 million for the year ended December 31, 2009.

In September 2008, we announced a revision of our operating plan that concentrates our resources on the advancement of our lead drug, sapacitabine, while maintaining a core competency in drug discovery and cell cycle biology. The plan initially reduced our workforce across all locations by 25 people. We recorded and paid approximately \$0.4 million of severance costs and \$0.1 million of accelerated depreciation for assets that will no longer be utilized. In addition we have accrued a charge of \$0.1 million in respect of costs of exiting the lease of our redundant Cambridge research facility. During the second and third quarters of 2009, we further reduced our workforce across all locations by an additional twenty six (26) people, making a total reduction of fifty one (51) people, or 63% of our workforce, since September 2008, totaling approximately \$0.4 million.

*Fiscal 2008 as compared to fiscal 2007.* The restructuring charge decreased by 65% or \$1.0 million from approximately \$1.5 million for the year ended December 31, 2007 to \$0.5 million for the year ended December 31, 2008.

In September 2008, we announced a revision of our operating plan that concentrates our resources on the advancement of our lead drug, sapacitabine, while maintaining a core competency in drug discovery and cell cycle biology. The plan initially reduced the workforce across all locations by 25 people. We recorded and paid approximately \$0.4 million of severance costs and \$0.1 million of accelerated depreciation for assets that will no longer be utilized. In addition we have accrued a charge of \$0.1 million in respect of costs of exiting the lease of our redundant Cambridge research facility.

During the year ended December 31, 2008, there were no changes to the assumption and estimates underlying the restructuring liability associated with exiting the Bothell facility. In 2007, we recognized a charge of \$1.7 million in respect of the lease. As of December 31, 2009, the fair value of the remaining lease payments, net of estimated sub-lease income was approximately \$1.1 million.

**Table of Contents***The future*

As of December 31, 2009, the restructuring liability associated with exiting the Bothell facility was approximately \$1.1 million representing the present 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 adjust the accrual if necessary. These changes may be material.

As a result of the workforce reduction in September 2008, and during the second and third quarters of 2009, we vacated our laboratory facility in Cambridge, England. Further revisions to our operating plan, if any, will be assessed as circumstances dictate.

Other income / (expense)

The following table summarizes the other income for years ended December 31, 2007, 2008 and 2009:

	Years ended			\$ Differences		% Differences	
	2007	2008	2009	2007 to 2008	2008 to 2009	2007 to 2008	2008 to 2009
	(in thousands)						
Payment under guarantee	\$	\$	\$ (1,652)	\$	\$ (1,652)		(100)%
Change in valuation of derivative	(93)			93		100%	0%
Change in valuation of warrants liability	3,205	3,502	(299)	\$ 297	(3,801)	9%	(109)%
Change in valuation of warrant			(44)		(44)		(100)%
Foreign Exchange gain/(loss)	490	(4,501)	(144)	(4,991)	4,357	(1019)%	97%
Interest income	3,554	1,380	102	(2,174)	(1,278)	(61)%	(93)%
Interest expense	(223)	(318)	(177)	(95)	141	(42)%	44%
Total other income (expense), net	\$ 6,933	\$ 63	\$ (2,214)	\$ (6,870)	\$ (2,277)	(99)%	3,614%

*Fiscal 2009 as compared to fiscal 2008.* Total other income (expense), net, reduced by approximately \$2.3 million from a gain \$0.1 million in 2008 to an expense of \$2.2 million in 2009 due to the reduction in interest income of \$1.3 million arising from lower yields available on lower average interest bearing cash and cash equivalents, an increase of \$3.8 million in the valuation of warrants liability and \$1.6 million in respect of a payment under guarantee related to our arrangement with Scottish Enterprise. This increase in expense was offset by a reduction in foreign exchange losses of \$4.4 million in 2009 compared to 2008. The differences related to these items are explained further below.

*Change in valuation of derivative*

On November 3, 2007, the embedded derivative associated with the dividend make-whole payment expired reducing the liability to \$0 and thus no further marked to market adjustments will be made with regard to this embedded derivative.

**Table of Contents***Change in value of warrants*

The change in valuation of warrants relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007. The warrants issued to the investors meet the requirements of and are being accounted for as a liability in accordance with ASC 840 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. ( ASC 840 ). 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, 2008, we recorded a gain of approximately \$3.5 million in the change in the value of warrants. For the year ended December 31, 2009, we recognized an expense of approximately \$0.3 million as the change in the value of warrants.

*Foreign Exchange gain / (loss)*

In conjunction with the operational review conducted by the Company in September 2008, the nature of intercompany funding was considered. It was concluded that as repayment of intercompany loans is not expected in the foreseeable future, the nature of the funding advanced was of a long-term investment nature and that the terms of the loans should be amended to reflect this. Effective October 1, 2008, intercompany loans ceased to be repayable on demand and have no fixed repayment date. As a result of the change in repayment terms, from October 1, 2008, all unrealized foreign exchange gains or losses arising on the intercompany loans will be recognized in other comprehensive income on the consolidated statement of stockholders' equity until repayment of the intercompany loan becomes foreseeable. For the year ended December 31, 2009 unfavorable unrealized foreign exchange movements recorded in other comprehensive income totaled \$5.7 million compared to \$12.3 million in 2008.

As a result of this change only foreign exchange gains/losses unrelated to the intercompany loans are recorded in income (expense) in the year ended December 31, 2009 which totaled \$0.1 million expense compared to a \$4.5 million of expense in 2008 of which \$4.8 million related to unrealized foreign exchange gains or losses arising on the intercompany loans charged to this category before the October 1, 2008 change offset by a realized gain of \$0.3 million on transactions in the year in respect of underlying operations.

*Interest Income*

Interest income decreased by approximately \$1.3 million from \$1.4 million for the year ended December 31, 2008 to \$0.1 million for the year ended December 31, 2009. During 2008, maturing short-term investments were reinvested in cash and cash equivalents, being a more secure form of investment and providing greater liquidity. As a result, these assets attracted a lower rate of interest. This was compounded by a reduction in the average balance of cash and cash equivalents and short-term investments during 2008 as compared to 2009.

*Interest Expense*

Interest expense decreased by \$0.1 million from \$0.3 million for year ended December 31, 2008 to \$0.2 million for the year ended December 31, 2009. For each of the years ended December 31, 2007 and 2008, we recorded accretion expense associated with the Bothell restructuring lease of \$0.2 million and \$0.1 million in 2009 on the consolidated statement of operations as interest expense. A further \$0.1 million of accretion expense will be recognized over the remaining life of the lease to December 2010.

*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, interest rates and the remaining term of the instrument and may fluctuate significantly, which may have a significant impact on our statement of operations.

As the nature of funding advanced through inter-company loans is that of a long-term investment in nature, future unrealized foreign exchange gains and losses on such funding will be recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable. This will minimize the future impact of unrealized foreign exchange fluctuations on earnings.

A further accretion expense of approximately \$0.1 million associated with the Bothell lease restructuring charge will be recognized over the remaining life of the lease through December 2010.



**Table of Contents****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, 2007, 2008 and 2009:

	Years ended			\$ Differences		% Differences	
	2007	2008	2009	2007 to 2008	2008 to 2009	2007 to 2008	2008 to 2009
	(in thousands)						
Total income tax benefit	\$ 2,041	\$ 1,749	\$ 948	\$ (292)	\$ (801)	(14)%	(46)%

*Fiscal 2009 as compared to fiscal 2008.* Research and development tax credits recoverable decreased by 46%, or approximately \$0.8 million, from approximately \$1.7 million for the year ended 2008 to approximately \$0.9 million for the year ended December 31, 2009. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year but restricted to payroll taxes paid by us in the United Kingdom in that same year. The decrease was a reflection of decreased income taxes available for recovery as a consequence of the lower eligible research and development payroll expenses in the United Kingdom following the workforce reductions commenced in September 2008 and continued in the second and third quarters of 2009.

*Fiscal 2008 as compared to fiscal 2007.* Research and development tax credits recoverable decreased by 14%, or approximately \$0.3 million, from approximately \$2.0 million for the year ended 2007 to approximately \$1.7 million for the year ended December 31, 2008. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year but restricted to payroll taxes paid by us in the United Kingdom in that same year. The decrease was a reflection of decreased income taxes available for recovery as a consequence of the lower eligible research and development payroll expenses in the United Kingdom in 2008 following the workforce reductions announced in September 2008.

*The future*

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so, however as a result of our revised operating plan announced in September 2008 and the subsequent reduction in workforce in the second and third quarters of 2009 the amount of payroll taxes payable in future periods will be lower than in previous periods, restricting available income tax credits to that lower amount.

**Liquidity and Capital Resources**

The following is a summary of our key liquidity measures as at December 31, 2008 and 2009:

	December 31, 2008	December 31, 2009	\$ Difference	% Difference
	(in thousands)			
Cash and cash equivalents	\$ 24,220	\$ 11,493	\$ (12,727)	(53)%
Short-term investments, available for sale	1,502		(1,502)	(100)%
Total cash and cash equivalents and short-term investments	\$ 25,722	\$ 11,493	\$ (14,229)	(55)%



**Table of Contents**

At December 31, 2009, we had cash and cash equivalents and short-term investments of \$11.5 million as compared with \$25.7 million at December 31, 2008. The lower balance at December 31, 2009 was primarily due to funding ongoing clinical trials, research and development, and to a lesser extent, sales and marketing activities.

Current liabilities increased by 14%, or \$1.2 million, to \$9.8 million at December 31, 2009 from \$8.6 million at December 31, 2008. Of the \$1.2 million increase, \$0.8 million relates to the amount payable under guarantee to Scottish Enterprise as part of the amendment in July 2009 to the March 2006 Agreement. In addition, the accounts payable balance increased by \$1.0 million primarily related to the manufacture of clinical trial supplies. This was offset by a \$0.6 million reduction in accrued compensation.

Since our inception, we have not generated any significant product 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 research and development tax credits. We have incurred significant losses since our inception. As of December 31, 2009, we had an accumulated deficit of \$222.3 million.

We believe that existing funds together with cash generated from operations and recent financing activities are sufficient to satisfy our planned working capital, capital expenditures, debt service and other financial commitments for at least the next twelve months. Current business and capital market risks could have a detrimental affect on the availability of sources of funding and our ability to access them in the future which may delay or impede our progress of advancing our drugs currently in the clinic to approval by the FDA for commercialization.

**Cash provided by (used in) operating, investing and financing activities**

Cash provided by (used in) operating, investing and financing activities for the years ended December 31, 2007, 2008 and 2009 is summarized as follows:

	<b>Year ended December 31,</b>		
	<b>2007</b>	<b>2008</b>	<b>2009</b>
	<b>(in thousands)</b>		
Net cash used in operating activities	\$ (23,140)	\$ (29,905)	\$ (15,193)
Net cash provided by (used by) investing activities	\$ (22,693)	\$ 27,342	\$ 1,559
Net cash provided by (used by) financing activities	\$ 32,208	\$ (1,238)	\$ 3,852

***Fiscal 2009 as compared to fiscal 2008.******Operating activities***

Net cash used in operating activities decreased by \$14.7 million, from \$29.9 million in 2008 to \$15.2 million in 2009. Our net cash used in operating activities significantly decreased primarily as a result of our cost reduction plan first implemented in September 2008 and then again during June of 2009 and the focus to advancing sapacitabine into a pivotal Phase 3 trial. Net cash used in operating activities during the year ended December 31, 2009 of \$15.2 million resulted from our net operating loss of \$19.6 million, adjusted for material non-cash activities comprising amortization of investment premiums (discounts), change in valuation of liability-classified warrants, depreciation and amortization, unrealized foreign exchange losses and non-cash stock based compensation expense, amounting to \$2.1 million and a net reduction in working capital of \$2.1 million due to a decrease in prepaid expenses combined with a net increase in accounts payable and other current liabilities.

**Table of Contents**

Net cash used in operating activities increased by \$6.8 million, to \$29.9 million in 2008 from \$23.1 million in 2007. Net cash used in operating activities during the year ended December 31, 2008 of \$29.9 million resulted from our net operating loss of \$40.4 million, adjusted for material non-cash activities comprising amortization of investment premiums (discounts), change in valuation of liability-classified warrants, depreciation and amortization, goodwill and intangibles impairment, unrealized foreign exchange losses and non-cash stock based compensation expense, amounting to \$11.4 million and a net reduction in working capital of \$0.9 million due to a decrease in prepaid expenses combined with a net decrease in accounts payable and other current liabilities. The decrease of \$14.7 million in net cash used in operations was mainly due to downsizing of operations and the year on year change in working capital.

*Investing activities*

Net cash provided by investing activities in the year ended December 31, 2008 amounted to \$27.3 million. During the year ended December 31, 2009, cash provided by investing activities amounted to \$1.6 million. During the year ended December 31, 2007, we purchased short-term investments totalling \$153.6 million which was offset by maturities of \$136.4 million in short term investments and incurred cash expenditures of \$3.8 million for the acquisition of ALIGN on October 5, 2007. During 2008, the proceeds from maturing short-term investments were reinvested in cash and cash equivalents to reduce our risk profile. In addition, the net proceeds from \$27.7 million of maturing short-term investments were used to fund our operating activities.

Capital expenditure was reduced to \$15,000 for the year ended December 31, 2009 compared to expenditures of \$0.4 million for the year ended December 31, 2008.

*Financing activities*

Net cash provided by financing activities increased by \$5.1 million, from a use of \$1.2 million for the year ended December 31, 2008 to a source of \$3.9 million for the year ended December 31, 2009.

For year ended December 31, 2009, the net cash provided by financing activities related primarily to net proceeds received from the registered direct financing of \$2.9 million in July 2009. On December 10, 2007, we entered into a CEFF with Kingsbridge, which was subsequently amended on November 24, 2009, in which Kingsbridge committed to purchase the lesser of 4,084,590 shares of common stock or \$60 million of common stock from us over a three years-year period. 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 as described below, with each tranche being 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.

Pursuant to the amendment to the CEFF, we may, subject to certain conditions require Kingsbridge to purchase shares of common stock at a price that is between 80% and 94% of the volume weighted average price for each trading day during an eight-day pricing period. Additionally, we may access capital under the CEFF in maximum draw downs of (i) 4.0% of our market capitalization at the time of the draw down, with respect to the first draw down, (ii) 3.0% of our market capitalization at the time of the draw down with respect to one draw down per calendar quarter beginning on February 1, 2010, and (iii) 2.0% of our market capitalization at the time of the draw down with respect to all other draw downs. Finally, the interest rate applicable to any outstanding Make Whole Amount (as defined in the amendment) that may arise out of the our failure to deliver draw down shares on time was changed from five percent (5%) per annum to a rate equal to the greater of (i) the prime rate of interest then in effect as published by the Wall Street Journal plus three percent (3%) and (ii) ten percent (10%).

During December 2009 and subsequent to the year end, we sold an aggregate of 2,818,232 shares of our common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of \$4.1 million, of which \$1.0 million was received in 2009 and \$3.1 million in 2010. Because we did not declare the payment of dividends on our preferred stock for several quarters during the fiscal year 2009, we will not be able to use our Registration Statement on Form S-3, which covers the shares subject to the CEFF and therefore, we may not be able to access the CEFF until such time as an effective registration statement covering such shares be in place.

In July 2009, we sold our securities to select institutional investors consisting of 4,000,000 units in a registered direct offering at a purchase price of \$0.85 per unit for approximately \$3.4 million in gross proceeds.

**Table of Contents**

For the year ended December 31, 2008, the net cash outflow for financing activities primarily related to the payment of our preferred stock dividend of \$1.2 million.

During 2007 the net cash provided by financing activities related primarily to gross proceeds received from the registered direct financing which raised \$36.0 million in gross proceeds, before deducting placement agent fees and offering expenses of \$2.6 million.

In February 2007, 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 in a registered direct offering. 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. We issued 4,249,668 shares of common stock and warrants to purchase 1,062,412 shares of common stock.

For the years ended December 31, 2008 and 2009, the net cash outflow for financing activities primarily related to the payment of our preferred stock dividend of \$1.2 million and \$0.3 million, respectively.

***Operating Capital and Capital Expenditure Requirements***

We expect to continue to incur substantial operating losses in the future. While we have generated modest product revenues from ALIGN product sales for the years ended December 31, 2008 and 2009, we can not guarantee that we will generate any significant 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 and short-term investments, together with funds raised in January and February 2010, will be sufficient to fund our operations for at least the next 12 months. We can not 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. Although we are not reliant on institutional credit finance and therefore not subject to debt covenant compliance requirements or potential withdrawal of credit by banks, the current economic climate has also impacted the availability of funds and activity in equity markets. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or make changes to our operating plan similar to the revision made in September 2008. 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.

**Table of Contents**

**Off-Balance Sheet Arrangements**

As of December 31, 2009, we had no off-balance sheet arrangements.

**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. Our significant accounting policies are described in Note 2 of the consolidated financial statements. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. We believe the judgments and estimates required by the following accounting policies to be critical in the preparation of our consolidated financial statements.

***Revenue Recognition***

***Product sales***

We have adopted the following revenue recognition policy related to the sales of Xclair<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> 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 ASC 605, and ASC 605 10. 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, 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. To estimate product sold through to end users, we rely on third-party information, including information obtained from significant distributors with respect to their inventory levels and sell-through to customers.

***Stock-based Compensation***

The Company grants stock options, restricted stock units and restricted stock to officers, employees, directors and consultants under the Company's 2006 Amended and Restated 2006 Equity Incentive Plan, which was amended and restated as of April 14, 2008. We also have outstanding options under various stock-based compensation plans for employees and directors.

ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of our common stock on the date of grant. The determination of grant-date fair value for stock option awards 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.

**Table of Contents**

Such value is recognized as an expense over the requisite service period, net of estimated forfeitures, using the straight-line attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. During the quarter ended March 31, 2009, we revised the forfeiture rates because actual forfeiture rates were higher than that previously estimated primarily due to the lapsing of stock option grants on the termination of employees. The revision to past forfeiture estimates for the three months ended March 31, 2009 resulted in a reversal of stock-based compensation cost recognized in prior years with a consequent net gain of approximately \$0.2 million on the consolidated statement of operations. During the second and third quarters of 2009, we reduced the scale of our operations, including a workforce reduction across all locations. As a result, we recorded an expense of approximately \$0.4 million.

***Warrants Liability******February 2007 Financing***

ASC 840 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 ASC 840, 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 ASC 840, since we are unable to control all the events or actions necessary to settle the warrants in registered shares the warrants have been recorded as a current liability at fair value. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the consolidated statements of operations. For the year ended December 31, 2009, we recorded a charge of \$0.3 million. For the year ended December 31, 2008, we recorded a gain of \$3.5 million. Fair value is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrants liability.

***Goodwill and Intangible Assets***

We recorded goodwill in March 2006 with respect to the merger with Xcyte and in October 2007 with respect to the acquisition of ALIGN. In accordance with ASC 350, we are required to test for impairment of goodwill, and intangible assets with indefinite lives which are not amortized, on an annual basis and at any other time if events occur or circumstances indicate that the carrying amount of goodwill and intangible assets may not be recoverable. Circumstances that could indicate impairment and require us to perform impairment tests more frequently than annually include significant adverse changes in market and economic conditions; adverse regulatory action; unanticipated competition or significant adverse change in perceived revenue potential.

We are organized as a single operating segment with two reporting units; ALIGN and Xcyte, to which goodwill was assigned along with relevant identifiable assets and liabilities. To test for impairment, we compared the fair value of each reporting unit to their respective carrying values, including assigned goodwill. To the extent the carrying amount of the reporting units exceeds its fair value; we compare the implied fair value of the reporting unit's goodwill with its carrying amount. 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 ASC 805, *Business Combinations* (ASC 805). The residual fair value after this allocation represents the implied fair value of the goodwill. To the extent the implied fair value of goodwill is less than its carrying amount we are required to recognize an impairment loss.

## **Table of Contents**

The fair value of our Xcyte reporting unit is determined by the market value of our outstanding common stock. However, the fair value of our ALIGN reporting unit is determined by using the income based valuation approach with respect to projected product sales. The income-based valuation measures the current value of the reporting unit by calculating the present value of its future cash flows using appropriate discount factors with regard to cost of capital experienced by entities of the same size and condition as us.

In September 2008, the goodwill acquired in the Xcyte transaction was written down in full and we recorded an impairment charge of approximately \$2.7 million in accordance with ASC 350. This impairment charge was identified through our annual impairment review process and was triggered primarily by a decline in our stock price that reduced our market capitalization below book value of the net assets of the Xcyte reporting unit. Our reduced market capitalization reflected the general decline in the economic environment.

In December 2008, goodwill allocated to our ALIGN reporting unit following the ALIGN acquisition was fully written down in accordance with ASC 350, resulting in an impairment charge of approximately \$1.6 million being recognized on the consolidated statement of operations. In determining the impairment charge, we considered the negative impact the current economic situation might have on sales growth expectations of the ALIGN products resulting in a downward revision of projected net cash flows from product sales. These factors caused the discounted cash flows for the reporting unit to be less than its carrying value on December 31, 2008.

### ***Impairment of Long-Lived Assets***

In accordance with ASC 360, when indicators of impairment exist, we assess the recoverability of the potentially affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the estimated fair value of the related asset, which is generally determined based on the present value of the expected future cash flows.

Measurement of fair value is determined using the income-based valuation methodology. The income based valuation approach measures the current value of an asset (or asset group) by calculating the present value of the future expected cash flows to be derived from that asset, from the perspective of a market participant. Such cash flows are discounted using a rate of return that incorporates the risk-free rate for the use of funds, the expected rate of inflation and risks associated with using the asset. If the carrying amount of a long-lived asset exceeds its fair value, an impairment loss is recognized immediately and cannot be relieved at a later date.

Intangible assets acquired in the ALIGN transaction were also fully written down in September 2008, in accordance with ASC 360. An impairment charge of approximately \$3.6 million was identified through our annual impairment review process and was recognized in the consolidated statement of operations. This one-time, non-cash charge was triggered by a downwards revision of projected net cash flows from product sales, required due to budgetary constraints experienced by health care providers and restrictions of the cost reimbursement regime. As a result the sum of the expected undiscounted cash flows was less than the carrying amount of the intangible assets on September 30, 2008.

### **Recent Accounting Pronouncements**

For information about recently issued accounting pronouncements please see Note 2 of our consolidated financial statements.

**Table of Contents**

In May 2009, the FASB issued ASC 855, *Subsequent Events* ( ASC 855 ), which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855 also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. ASC 855 is effective for interim and annual periods ending after June 15, 2009 and will be effective for the Company beginning with its interim period June 30, 2009. On February 24, 2010, The FASB issued Accounting Standards Update ( ASU ) 2010-09 to amend ASC 855. As a result of the ASU, SEC Registrants will not disclose the date through which management evaluated subsequent events in the financial statements. Since ASC 855 at most requires additional disclosures, the Company does not expect the adoption to have a material impact on its consolidated financial position, results of operations or cash flows.

In June 2009, the FASB issued FAS 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*, which establishes the FASB Accounting Standards Codification ( Codification ) as the source of authoritative US GAAP recognized by the FASB to be applied to nongovernmental entities. Codification does not change current U.S. GAAP but is intended to simplify user access to all authoritative US GAAP by providing all the authoritative literature related to a particular topic in one place. All existing accounting standard documents will be superseded and all other accounting literature not included in the Codification will be considered non-authoritative. Rules and interpretive releases of the SEC under authority of federal securities laws are also included in the Codification as sources of authoritative US GAAP for SEC registrants. FAS 168 and the Codification are effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification is effective for the Company during its interim period ending September 30, 2009 and did not have an impact on its financial condition or results of operations.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

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

**Investment and Interest Rate Risk**

Financial instruments which potentially subject us to interest rate risk consist principally of cash and cash equivalents and short-term investments. At December 31, 2009, our cash and cash equivalents of \$11.5 million are primarily invested in highly liquid money market accounts, and commercial paper, both of which have remaining maturities of 90 days or less.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. Pursuant to our investment guidelines, all investments in commercial paper and corporate bonds of financial institutions and corporations are rated A or better by both Moody's and Standard and Poor's, no one individual security shall have a maturity of greater than 18 months and investments in any one corporation is restricted to 5% of the total portfolio. To minimize our exposure to adverse shifts in interest rates, we invest in short-term instruments and at December 31, 2009 we held no investments with a maturity in excess of one year. Due to the short-term nature of our investments, portfolio diversification, and our investment policy we believe that our exposure to market interest rate fluctuations is minimal, liquidity is maintained and we do not have a material financial market risk exposure.

A hypothetical 10% change in short-term interest rates from those in effect at December 31, 2009 would not have a significant impact on our financial position or our expected results of operations, however we may continue to have risk exposure to our holdings in cash, money market accounts and cash equivalents, which may adversely impact the fair value of our holdings. As of December 31, 2009, there were no indicators of credit risk impact to the valuation of our cash, cash equivalents or short term investments. We do not currently hold any derivative financial instruments with interest rate risk.

**Table of Contents**

**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. Intercompany loans with this subsidiary are denominated in U.S. dollars and unrealized foreign exchange gains and losses arising on these loans have been recorded in the consolidated statement of operations within the separate line item foreign exchange gains/(losses) within other income (expense) up to September 30, 2008.

During the year ended December 31, 2008, there were unfavorable unrealized foreign exchange movements of approximately \$17.2 million on intercompany loans due to the increase in the strength of the United States dollar against the British pound. Of the \$17.2 million, \$4.8 million is recorded in the consolidated statement of operations within the separate line item foreign exchange gains/(losses), within other income (expense). This has been offset by a realized gain of \$0.3 million on transactions in the year in respect of underlying operations, resulting in a net foreign exchange loss of \$4.5 million.

In conjunction with the operational review conducted by us in September 2008, the nature of intercompany funding was considered. It was concluded that as repayment of intercompany loans is not expected in the foreseeable future, the nature of the funding advanced was of a long-term investment nature and that the terms of the loans should be amended to reflect this. Effective October 1, 2008, intercompany loans ceased to be repayable on demand and have no fixed repayment date. As a result of the change in repayment terms, from October 1, 2008 all unrealized foreign exchange gains or losses arising on intercompany loans are recognized in other comprehensive income. This has restricted the unfavorable unrealized foreign exchange movements recorded in other income to \$4.8 million, with \$12.3 million recognized in other comprehensive income for the three months from October 1, 2008 to December 31, 2008. Future unrealized foreign exchange gains or losses arising on the intercompany loans will be recognized in other comprehensive income on the consolidated statement of stockholders' equity until repayment of the intercompany loan becomes foreseeable.

We currently do not engage in foreign currency hedging. We enter into certain transactions denominated in foreign currencies in respect of underlying operations and, therefore, we are subject to currency exchange risks. During the years ended December 31, 2009 and 2008, we realized losses of \$0.1 million and gains of approximately \$0.3 million on such transactions, respectively. Other differences on foreign currency translation arising on consolidation of \$14.9 million are also recorded as a movement in other comprehensive income.

**Table of Contents**

**Common Stock Price Risk**

In February 2007, we issued common stock and warrants. Pursuant to ASC 840, we recorded the fair value of the warrants as a current liability. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the condensed consolidated statements of operations. The change in fair value recognized in the financial statements during the years to December 31, 2008 and 2009 was a \$3.5 million gain and a \$0.3 million loss, 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 and amended in November 2009, 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. We may access capital under the CEFF in tranches, with each tranche being issued and priced over an eight-day pricing period. Kingsbridge will purchase shares of common stock pursuant to the CEFF at discounts ranging from 10% to 20% 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 \$0.40 or 85% of our common stock closing price the day before the commencement of each draw down.

During December 2009 and subsequent to year-end, we sold an aggregate of 2,818,232 shares of our common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of \$4.1 million in funds received by us.

**Table of Contents**

**Item 8. Financial Statements and Supplementary Data**

**INDEX TO CYCLACEL PHARMACEUTICALS, INC. FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	75
<u>Consolidated Balance Sheets as of December 31, 2008 and 2009</u>	76
<u>Consolidated Statements of Operations for the years ended December 31, 2007, 2008 and 2009 and the period from August 13, 1996 (inception) to December 31, 2009</u>	77
<u>Consolidated Statements of Stockholders' Equity (Deficit) for the period from August 13, 1996 (inception) to December 31, 2009</u>	78
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2008 and 2009 and the period from August 13, 1996 (inception) to December 31, 2009</u>	85
<u>Notes to Consolidated Financial Statements</u>	88

**Table of Contents**

**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, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009 and the period from August 13, 1996 (inception) to December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 and for the period from August 13, 1996 (inception) to December 31, 2009, in conformity with U.S. generally accepted accounting principles.

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, 2009, 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 29, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

London, England

March 29, 2010

**Table of Contents**

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

	<b>December 31,</b>	
	<b>2008</b>	<b>2009</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	24,220	11,493
Short-term investments	1,502	
Inventory	508	145
Prepaid expenses and other current assets	2,784	1,731
Total current assets	29,014	13,369
Property, plant and equipment (net)	1,748	901
Deposits and other assets	195	196
Total assets	30,957	14,466
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	754	1,709
Accrued and other current liabilities	6,801	6,709
Warrant liability	43	342
Current portion of other accrued restructuring charges	1,029	1,062
Total current liabilities	8,627	9,822
Other accrued restructuring charges, net of current	1,062	
Other long term payables	626	
Total liabilities	10,315	9,822
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2008 and 2009, respectively; 2,046,813 shares issued and outstanding at December 31, 2008 and 2009, respectively. Aggregate preference in liquidation of \$20,673,000 at December 31, 2008 and December 31, 2009	2	2
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2008 and 2009, respectively; 20,433,129 and 25,743,363 shares issued and outstanding at December 31, 2008 and 2009, respectively	20	26
Additional paid-in capital	223,377	226,881
Accumulated other comprehensive (loss)/income	(42)	20
Deficit accumulated during the development stage	(202,715)	(222,285)
Total stockholders' equity	20,642	4,644

Total liabilities and stockholders' equity	30,957	14,466
--	--------	--------

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

Table of Contents

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

	Year ended December 31, 2007	Year ended December 31, 2008	Year ended December 31, 2009	Period from August 13, 1996 (inception) to December 31, 2009
<b>Revenues:</b>				
Collaboration and research and development revenue	10			3,000
Product Revenue		838	910	1,748
Grant revenue	119	39	1	3,636
	129	877	911	8,384
<b>Operating expenses:</b>				
Cost of goods sold		429	545	974
Research and development	19,569	18,869	9,766	170,179
Selling, general and administrative	12,033	15,354	8,538	71,846
Goodwill and intangibles impairment		7,934		7,934
Other restructuring costs	1,554	489	366	2,634
<b>Total operating expenses</b>	<b>33,156</b>	<b>43,075</b>	<b>19,215</b>	<b>253,567</b>
<b>Operating loss</b>	<b>(33,027)</b>	<b>(42,198)</b>	<b>(18,304)</b>	<b>(245,183)</b>
Other income (expense):				
Costs associated with aborted 2004 IPO				(3,550)
Payment under guarantee			(1,652)	(1,652)
Change in valuation of derivative	(93)			(308)
Change in valuation of warrants liability	3,205	3,502	(299)	6,408
Warrant re-pricing			(44)	(44)
Foreign exchange gains / (losses)	490	(4,501)	(144)	(4,187)
Interest income	3,554	1,380	102	13,643
Interest expense	(223)	(318)	(177)	(4,634)
Total other income, net	6,933	63	(2,214)	5,676
<b>Loss before taxes</b>	<b>(26,094)</b>	<b>(42,135)</b>	<b>(20,518)</b>	<b>(239,507)</b>
Income tax benefit	2,041	1,749	948	17,222
<b>Net loss</b>	<b>(24,053)</b>	<b>(40,386)</b>	<b>(19,570)</b>	<b>(222,285)</b>
Dividends on Preferred Ordinary shares				(38,123)

<b>Net loss applicable to common shareholders</b>		(24,053)	(40,386)	(19,570)	(260,408)
Net loss per share basic and diluted	\$	(1.21)	\$ (1.98)	\$ (0.88)	
Weighted average common shares outstanding		19,873,911	20,433,129	22,196,840	

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

**Table of Contents**

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

	Preferred Stock No.	Common Stock No.	Additional paid capital \$000	Accumulated other income/(loss) \$000	Deferred compensation \$000	Deficit accumulated during stage development \$000	Total \$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.



**Table of Contents**

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

	<b>Preferred Stock No.    \$000</b>	<b>Common Stock No.    \$000</b>	<b>Additional paid in capital \$000</b>	<b>Accumulated other income/(loss) \$000</b>	<b>Deferred compensation \$000</b>	<b>Deficit accumulated during stage development \$000</b>	<b>Total \$000</b>	
Issue of shares for cash, net of issuance costs		538,889	1	12,716			12,717	
Issue of shares on conversion of bridging loan		90,602		1,638			1,638	
Issue of shares in lieu of cash bonus		9,060		164			164	
Issue of shares for research & development agreement				409			409	
Exercise of share options		2,265		40			40	
Deferred stock-based compensation				167	(167)			
Amortization of deferred stock-based compensation					433		433	
Translation adjustment					(194)		(194)	
Loss for the year						(5,686)	(5,686)	
Comprehensive loss for the year							(5,880)	
Balance at March 31, 2000		907,594	1	21,616	(132)	(1,028)	(12,474)	7,983
Deferred stock-based compensation				294	(294)			
Amortization of deferred stock-based compensation					275		275	
Translation adjustment					(466)		(466)	
Loss for the year						(10,382)	(10,382)	
Comprehensive loss for the year							(10,848)	
Balance at March 31, 2001		907,594	1	21,910	(598)	(1,047)	(22,856)	(2,590)

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



**Table of Contents**

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

	Preferred Stock No.	Common Stock No.	Additional capital \$000	Accumulated other income/(loss) \$000	Deferred compensation \$000	Deficit accumulated during development stage \$000	Total \$000
Issue of shares for cash, net of issuance costs		5,451					
Exercise of share options for cash				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)		
Amortization of deferred stock-based compensation					672		672
Translation adjustment				191			191
Loss for the year						(14,853)	(14,853)
Comprehensive loss for the year							(14,662)
Balance at March 31, 2002		917,555	1	23,777	(407)	(738)	(37,709)
Exercise of share options for cash				12			12
Deferred stock-based compensation			(84)		84		
Amortization of deferred stock-based compensation					305		305
Translation adjustment				(1,846)			(1,846)
Loss for the year						(15,542)	(15,542)
Comprehensive loss for the year							(17,388)
Balance at March 31, 2003		917,555	1	23,705	(2,253)	(349)	(53,251)

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



**Table of Contents**

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

	<b>Preferred Stock No. \$000</b>	<b>Common Stock No. \$000</b>	<b>Additional capital \$000</b>	<b>Accumulated other income/(loss) \$000</b>	<b>Deferred compensation \$000</b>	<b>Deficit accumulated during stage \$000</b>	<b>Total \$000</b>
Issue of shares for cash, net of issuance costs		1,510,288	1	27,634			27,635
Exercise of share options for cash		6,549		115			115
Conversion of Preferred C Ordinary shares		3,769,139	4	58,144			58,148
Amortization of deferred stock-based compensation					217		217
Translation adjustment				(1,343)			(1,343)
Loss for the period						(14,977)	(14,977)
Comprehensive loss for the period							(16,320)
Balance at December 31, 2003		6,203,531	6	109,598	(3,596)	(132)	(68,228)
Issues of shares for cash, net of issuance costs		430,571	1	8,540			8,541
Exercise of warrants for cash		22,630					

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

**Table of Contents**

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (cont d)**

	<b>Preferred Stock No.</b>	<b>\$000</b>	<b>Common Stock No.</b>	<b>\$000</b>	<b>Additional paid-in capital</b>	<b>Accumulated other income/(loss)</b>	<b>Deferred compensation</b>	<b>Deficit accumulated during development stage</b>	<b>Total</b>
					<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>
Deferred stock-based compensation					(2,050)		132		(1,918)
Translation adjustment						2,424			2,424
Loss for the year								(22,742)	(22,742)
Comprehensive loss for the year									(20,318)
Balance at December 31, 2004			6,656,732	7	116,088	(1,172)		(90,970)	23,953
Translation adjustment						(1,786)			(1,786)
Loss for the year								(18,048)	(18,048)
Comprehensive loss for the year									(19,834)
Balance at December 31, 2005			6,656,732	7	116,088	(2,958)		(109,018)	4,119
Issue of shares to certain directors and officers			648,413	1	(1)				
Issue of shares on conversion of Loan Note Instrument			456,308						
Reverse Acquisition	2,046,813	2	1,967,928	2	16,251				16,255
Loan from Cyclacel Group plc waived					10,420				10,420
Issue of common stock and warrants for cash			6,428,572	6	42,356				42,362
Stock-based compensation					9,600				9,600
Change in unrealized loss on investment						5			5
Translation adjustment						416			416
Loss for the year								(29,258)	(29,258)

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

**Table of Contents**

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (cont'd)**

	<b>Preferred Stock No.</b>		<b>Common Stock No.</b>		<b>Additional paid-in capital</b>	<b>Accumulated other income/(loss)</b>	<b>Deferred compensation</b>	<b>Deficit accumulated during development stage</b>	<b>Total</b>
	<b>\$000</b>		<b>\$000</b>		<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>
Comprehensive loss for the year									(28,842)
Balance at December 31, 2006	2,046,813	2	16,157,953	16	194,714	(2,537)		(138,276)	53,919
Loss for the year								(24,053)	(24,053)
Translation adjustment						(93)			(93)
Comprehensive loss for the year									(24,146)
Stock-based compensation					1,733				1,733
Issue of common stock upon exercise of stock options			25,508		163				163
Issue of common stock for cash on registered direct offering, net of expenses			4,249,668	4	33,353				33,357
Preferred stock dividends declared					(307)				(307)
Issue of warrants in connection with registered direct offering					(6,750)				(6,750)
Balance at December 31, 2007	2,046,813	2	20,433,129	20	222,906	(2,630)		(162,329)	57,969
Loss for the year								(40,386)	(40,386)
Unrealized foreign exchange on intercompany loans						(12,330)			(12,330)
Translation adjustment						14,918			14,918
									(37,798)

Comprehensive loss  
for the year

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

**Table of Contents**

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (cont d)**

	<b>Preferred Stock</b>		<b>Common Stock</b>		<b>Additional paid-in capital</b>		<b>Accumulated other comprehensive income/(loss)</b>	<b>Deferred compensation stage</b>	<b>Deficit accumulated during development</b>	<b>Total</b>
	<b>No.</b>	<b>\$000</b>	<b>No.</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>
Stock-based compensation					1,698					1,698
Preferred stock dividends declared					(1,227)					(1,227)
Balance at December 31, 2008	2,046,813	2	20,433,129	20	223,377		(42)		(202,715)	20,642
Loss for the year									(19,570)	(19,570)
Unrealized foreign exchange on intercompany loans							5,651			5,651
Translation adjustment							(5,589)			(5,589)
Warrant re-pricing					44					44
Issue of common stock for cash on registered direct offering, net of expenses			4,000,000	4	2,843					2,847
Issue of common stock upon draw down of Committed Equity Finance Facility			1,255,024	2	1,028					1,030
Issue of common stock upon exercise of stock options, restricted stock units and restricted stock			55,210		7					7
Stock-based compensation					810					810
Preferred stock dividends declared					(1,228)					(1,228)
Balance at 31 December, 2009	2,046,813	2	25,743,363	26	226,881		20		(222,285)	4,644

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



**Table of Contents**

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

	Year ended December 31, 2007 \$000	Year ended December 31, 2008 \$000	Year ended December 31, 2009 \$000	Period from August 13, 1996 (inception) to December 31, 2009 \$000
<b>Operating activities:</b>				
Net loss	(24,053)	(40,386)	(19,570)	(222,285)
Adjustments to reconcile net loss to net cash used in operating activities:				
Accretion of guaranteed stock	10	(10)		
Amortization of interest payable on notes payable	19	79	2	100
Amortization of investment premiums, net	(844)	(1,444)	20	(2,297)
Change in valuation of derivative	93			308
Change in valuation of warrants	(3,205)	(3,502)	299	(6,408)
Warrant re-pricing			44	44
Depreciation	946	1,154	668	11,857
Amortization of intangible assets	178	708		886
Fixed asset impairment			221	221
Unrealized foreign exchange (gains) losses	(449)	4,831		7,747
Deferred revenue				(98)
Compensation for warrants issued to non employees				1,215
Shares issued for IP rights				446
Gain on disposal of property, plant and equipment		2	83	112
Goodwill and intangibles impairment		7,934		7,934
Stock-based compensation	1,733	1,698	810	16,395
Provision for restructuring	1,554			1,779
Amortization of issuance costs of Preferred Ordinary C shares				2,517
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(653)	1,732	1,716	(748)
Accounts payable and other current liabilities	1,531	(2,701)	514	(986)
Net cash used in operating activities	(23,140)	(29,905)	(15,193)	(181,261)

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



**Table of Contents**

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

	Year ended December 31, 2007 \$000	Year ended December 31, 2008 \$000	Year ended December 31, 2009 \$000	Period from August 13, 1996 (inception) to December 31, 2009 \$000
<b>Investing activities:</b>				
Purchase of ALIGN	(3,763)			(3,763)
Purchase of property, plant and equipment	(1,773)	(366)	(15)	(8,823)
Proceeds from sale of property, plant and equipment			91	117
Purchase of short-term investments on deposit, net of maturities	(153,597)	(3,057)		(156,657)
Cash proceeds from redemption of short term securities	136,440	30,765	1,483	162,729
Net cash provided by (used in) investing activities	(22,693)	27,342	1,559	(6,397)
<b>Financing activities:</b>				
Payments of capital lease obligations	(89)	(11)		(3,719)
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	33,357		3,845	79,828
Proceeds from the exercise of stock options and issue of warrants, net of issuance costs	163		7	170
Payment of preferred stock dividend	(1,223)	(1,227)		(3,372)
Repayment of government loan				(455)
Government loan received				414
Loan received from Cyclacel Group plc				9,103
Proceeds of committable loan notes issued from shareholders				8,883
Loans received from shareholders				1,645
Cash and cash equivalents assumed on stock purchase of Xcyte				17,915
Costs associated with stock purchase				(1,951)
Net cash provided by (used in) financing activities	32,208	(1,238)	3,852	199,319
	374	(2,966)	(2,945)	(168)

Effect of exchange rate changes on cash and cash equivalents

Net (decrease) increase in cash and cash equivalents	(13,251)	(6,767)	(12,727)	11,493
Cash and cash equivalents, beginning of period	44,238	30,987	24,220	
Cash and cash equivalents, end of period.	30,987	24,220	11,493	11,493

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

**Table of Contents**

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

	<b>Year ended December 31, 2007 \$000</b>	<b>Year ended December 31, 2008 \$000</b>	<b>Year ended December 31, 2009 \$000</b>	<b>Period from August 13, 1996 (inception) to December 31, 2009 \$000</b>
Supplemental cash flow information:				
Cash received during the period for:				
Interest	2,437	723	59	11,704
Taxes	2,045	2,033	1,523	16,440
Cash paid during the period for:				
Interest	(858)		(78)	(1,759)
Schedule of non-cash transactions				
Acquisitions of equipment purchased through capital leases				3,470
Issuance of common shares in connection with license agreements				592
Issuance of Ordinary shares on conversion of bridging loan				1,638
Issuance of Preferred Ordinary C shares on conversion of secured convertible loan notes and accrued interest				8,893
Issuance of Ordinary shares in lieu of cash bonus				164
Issuance of other long term on ALIGN acquisition	1,122			1,122

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

**Table of Contents**

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1 Organization of the Company**

Cyclacel Pharmaceuticals, Inc. (Cyclacel or the Company) is a development-stage biopharmaceutical company dedicated to the development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Our clinical development priorities are focused on sapacitabine in the following indications:

Acute myeloid leukemia, or AML in the elderly;

Myelodysplastic syndromes, or MDS; and

Non-small cell lung cancer or NSCLC.

The Company has additional clinical programs in development which are currently pending availability of clinical data. Once data become available and are reviewed, the Company will determine the feasibility of pursuing further development and/or partnering these assets, including sapacitabine in combination with seliciclib, seliciclib in NSCLC and nasopharyngeal cancer or NPC and CYC116. In addition, we market directly in the United States Xclair<sup>®</sup> Cream for radiation dermatitis and Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges for xerostomia.

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.

As disclosed in Note 19, subsequent to the year end the Company raised approximately \$18.8 million through the completion of two registered direct financings, drawdown of the Company's Committed Equity Financing Facility, or CEFF, and the exercise of warrants. Consequently the Company believes that it has sufficient resources to fund its operations for at least the next twelve months.

***Basis of Presentation***

The accompanying consolidated financial statements as of December 31, 2008 and 2009, and for each of the three years in the period ended December 31, 2009, 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.

**Table of Contents*****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. The Company invests its cash, cash equivalents and short-term investments in the United States and the United Kingdom in highly liquid money market accounts, federal agency obligations & municipal bonds and commercial paper & corporate bonds of financial institutions and corporations which are rated A or better by both Moody's and Standard and Poor's. Pursuant to the Company's investment guidelines, no one individual security shall have a maturity of greater than 18 months and investments in any one corporation is restricted to 5% of the total portfolio. At December 31, 2008 and 2009, the Company held no investments with a maturity in excess of one year. Due to the short-term nature of our investments, portfolio diversification, and the Company's investment policy we believe that concentration of credit risk is limited and liquidity is maintained.

The Company has significant customer concentration and the loss of any major customer could have a significant negative impact on the Company's revenue. During the years ended December 31, 2008 and 2009, approximately 85% and 86%, respectively, of our product sales in the United States were to three wholesalers: Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen. As of December 31, 2008 and 2009, these three wholesalers accounted for 83% and 98%, respectively, of the Company's trade accounts receivable. The loss of any of these major wholesalers or reduced demand for products by a major wholesaler could have a significant negative impact on the Company's revenue. It is likely that we will continue to have significant customer concentration in the future. 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.

***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 rate on the date of the transaction. 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. Translation adjustments arising on consolidation due to differences between average rates and balance sheet rates and unrealized foreign exchange gains or losses arising on translation of intercompany loans which are of a long-term-investment nature are shown as a movement in other comprehensive income. Other exchange rate differences are reported in the statements of operations for the year.

***Segments***

The Company has adopted Statement of ASC 280, *Segment Reporting* (ASC 280) 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.

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

The Company invests in certain marketable debt securities. Debt securities at December 31, 2008 and 2009 comprise investment-grade government and commercial securities purchased to generate a higher yield than cash equivalents. In accordance with ASC 320 Debt and Equity Securities (ASC 320) such investment securities are classified as available-for-sale and are carried at fair value. Under ASC 320, 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 and the financial condition of the issuer. 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.

***Trade Accounts Receivable and Allowance for Doubtful Accounts***

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

***Inventory***

Cyclacel values inventories at lower of cost or market value. The Company determines cost using the first-in, first-out method. As December 31, 2008 and 2009, all inventories were classified as finished goods. The Company analyzes its inventory levels quarterly and writes-down inventory that has become obsolete or that has a cost basis in excess of its expected net realizable value. 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 in future periods.

The Company analyzes its inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. The determination of whether or not inventory costs will be realizable requires estimates by the Company's management. A critical input in this determination is future expected inventory requirements, based on internal sales forecasts. The Company then compares these requirements to the expiry dates of inventory on hand. To the extent that inventory is expected to expire prior to being sold, the Company will write down the value of inventory. If actual results differ from those estimates, additional inventory write-offs may be required. During 2009, the Company determined and recorded a reserve of approximately \$0.1 million, based upon current inventory levels, expiration dates, and future sales. This amount was recorded within cost of sales on the condensed consolidated statement of operations. In the future, reduced demand, quality issues or excess supply may result in write-downs, which would be recorded as adjustments to cost of sales.

**Table of Contents*****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. During 2009, the Company sold fixed assets totaling \$0.1 million, as part of its previously announced closing of the Cambridge facility and the reduction of workforce.

***Goodwill and intangible assets***

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 ASC 350, *Intangibles Goodwill and Other* (ASC 350). To test for impairment, the Company compares the fair value of its reporting units to their respective carrying values, including assigned goodwill. The Company is organized as a single operating segment with two reporting units; ALIGN and Xcyte. To the extent the carrying amount of the reporting units exceeds its fair value, the Company would be required to perform the second step of the impairment analysis, as this is an indication that goodwill may be impaired. In this second step, the Company compares the implied fair value of the reporting units goodwill with its carrying amount. The implied fair value of goodwill is determined by allocating the fair value of the reporting units to all of the assets (recognized and unrecognized) and liabilities of the reporting units in a manner similar to a purchase price allocation, in accordance with ASC 805, *Business Combinations* (ASC 805). The residual fair value after this allocation represents the implied fair value of the goodwill. To the extent the implied fair value of goodwill is less than its carrying amount, the Company would be required to recognize an impairment loss.

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

In accordance with the provisions of ASC 360, *Property, Plant, and Equipment* (ASC 360), the Company reviews long-lived assets, including property, plant and equipment and intangible assets which are subject to amortization, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. We assess the recoverability of the potentially affected long-lived assets under ASC 360 by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows.

Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. If impairment is indicated, the Company measures the amount of such impairment by comparing the carrying value of the asset to the estimated fair value of the related asset, which is generally determined based on the present value of the expected future cash flows.

Measurement of fair value is determined using the income-based valuation methodology. The income-based valuation approach measures the current value of an asset (or asset group) by calculating the present value of the future expected cash flows to be derived from that asset, from the perspective of a market participant. Such cash flows are discounted using a rate of return that incorporates the risk-free rate for the use of funds, the expected rate of inflation and risks associated with using the asset. If the carrying amount of a long-lived asset exceeds its fair value, an impairment loss is recognized.

**Table of Contents*****Revenue Recognition******Product sales***

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

The Company offers a general right of return on these product sales, and has considered the guidance in ASC 605-15,

*Revenue Recognition -Products* ( ASC 605-15 ) and ASC 605 10 *Revenue Recognition Overall* ( ASC 605-10 ). Under these pronouncements, the Company accounts for all product sales using the sell-through method. Under the sell-through method, revenue is not recognized upon shipment of product to distributors. Instead, the Company records deferred revenue at gross invoice sales price and deferred cost of sales at the cost at which those goods were held in inventory. The Company recognizes revenue when such inventory is sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, the Company relies on third-party information, including information obtained from significant distributors with respect to their inventory levels and sell-through to customers.

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

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

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

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

***Clinical Trial Accounting***

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

***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.

**Table of Contents****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 the guidance related to accounting for uncertainty in income taxes, primarily codified in ASC 740 *Income taxes* ( ASC 740 ). ASC 740 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.

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 ASC 260 *Earnings Per Share* ( ASC 260 ). Basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. The Company's potentially dilutive shares, which include outstanding common stock options, restricted stock, restricted stock units, convertible preferred stock, 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.

	<b>Years ended December 31,</b>		
	<b>2007</b>	<b>2008</b>	<b>2009</b>
Stock options	2,592,246	3,674,899	3,349,876
Restricted Stock and Restricted Stock Units		141,700	91,145
Convertible preferred stock	870,980	870,980	870,980
Cyclacel stock to be issued on October 5, 2008	46,044		
Common stock issuable to Kingsbridge			328,602
Common stock warrants	3,809,703	3,809,272	7,044,363
Total shares excluded from calculation	7,318,973	8,496,851	11,684,966

**Table of Contents*****Derivative Instruments***

The Company issued warrants to purchase shares of common stock under the registered direct financing completed in February 2007. These warrants are being accounted for as a liability in accordance with ASC 815 *Derivatives and Hedging* ( ASC 815 ). 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 4.68%, expected volatility 85%, expected dividend yield 0%, and a remaining contractual life of 7 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, 2008, the fair value of the warrants was approximately \$43,000 (utilizing the following assumptions: risk free interest rate 1.47%, expected volatility 75%, expected dividend yield 0%, and a remaining contractual life of 5.13 years). At December 31, 2009, the fair value of the warrants was \$0.3 million (utilizing the following assumptions: risk free interest rate 2.13%, expected volatility 96%, expected dividend yield 0%, and a remaining contractual life of 4.13 years). During 2009, the Company recognized the change in the value of warrants of approximately \$0.3 million as a loss on the consolidated statement of operations. During 2008, the Company recognized the change in the value of warrants of approximately \$3.5 million as a gain on the consolidated statement of operations.

The terms of the Company's November 2004 convertible preferred stock offering included a make-whole dividend payment feature. If the Company elected to automatically convert, or the holder elected to voluntarily converted, some or all of the convertible preferred stock into shares of its common stock prior to November 3, 2007, the Company was required to make an additional payment on the convertible preferred stock equal to the aggregate amount of dividends that would have been payable on the convertible preferred stock through and including November 3, 2007, less any dividends already paid on the convertible preferred stock. This additional payment 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 make-whole dividend payment feature was considered to be an embedded derivative and was recorded on the balance sheet at fair value as a current liability. During the year ended December 31, 2007 the Company recognized other income (expense) in the consolidated statement of operations as the fair value of this derivative fluctuated from period to period. The conversion feature expired on November 3, 2007.

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 grants stock options, restricted stock units and restricted stock to officers, employees and directors under the 2006 Plans, which were approved on March 16, 2006. The Company has outstanding options under various stock-based compensation plans for employees and directors. These plans are described more fully in Note 14

Stock-Based Compensation Arrangements . The Company accounts for these plans under ASC 718 *Compensation Stock Compensation* ( ASC 718 ) which was adopted effective January 1, 2006 under the modified prospective transition method.

ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of our common stock on the date of grant. Such value is recognized as expense over the service period, net of estimated forfeitures, using the straight-line attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. Actual results and future estimates may differ substantially from our current estimates.



**Table of Contents**

***Comprehensive Income (Loss)***

In accordance with ASC 220, *Comprehensive Income* ( ASC 220 ) all components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized.

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 taxes were recorded on these items.

***Restructuring Expense***

The Company records costs and liabilities associated with exit and disposal activities, when certain criteria have been met in accordance with ASC 420 *Exit or Disposal Cost Obligation* ( ASC 420 ), at fair value in the period the liability is incurred. The Company's restructuring and integration plan is subject to continued future refinement as additional information becomes available.

On September 16, 2008, the Company announced a revision of its operating plan that concentrates its resources on the advancement of our lead drug, sapacitabine, while maintaining its core competency in drug discovery and cell cycle biology. The plan reduced its workforce across all locations by 25 people. During the year ended December 31, 2008, the Company recorded approximately \$0.4 million for severance payments and \$0.1 million of accelerated depreciation for assets that will no longer be utilized. All severance payments were paid as of December 31, 2008. The Company assigned the lease of its redundant Cambridge research facility back to the landlord and, in accordance with the terms of the lease, incurred a net charge, incorporating a surrender fee, of \$0.1 million. In June 2009, the Company further reduced its workforce across all locations by 26 people making a total reduction of 51 people (or 63% of the workforce) since September 2008. The Company recorded approximately \$0.4 million for severance payments all of which were paid as of December 31, 2009. An asset impairment amounting to \$0.2 million was also charged to the consolidated statement of operations as a result of assets being identified that were no longer being utilized.

***Recent Accounting Pronouncements***

**Table of Contents**

In May 2009, the FASB issued ASC 855, *Subsequent Events* ( ASC 855 ), which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855 also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. ASC 855 is effective for interim and annual periods ending after June 15, 2009 and was effective for the Company beginning with its interim period June 30, 2009. On February 24, 2010, The FASB issued Accounting Standards Update ( ASU ) 2010-09 to amend ASC 855. As a result of the ASU, SEC Registrants will not disclose the date through which management evaluated events in the financial statements. The adoption of ASC 855 did not to have a material impact on the Company s consolidated financial position, results of operations or cash flows as it mostly requires only additional disclosures.

**Table of Contents**

In June 2009, the FASB issued FAS 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*, primarily codified in ASC 105, which establishes the FASB Accounting Standards Codification (Codification) as the source of authoritative US GAAP recognized by the FASB to be applied to nongovernmental entities. Codification does not change current U.S. GAAP but is intended to simplify user access to all authoritative US GAAP by providing all the authoritative literature related to a particular topic in one place. All existing accounting standard documents will be superseded and all other accounting literature not included in the Codification will be considered non-authoritative. Rules and interpretive releases of the SEC under authority of federal securities laws are also included in the Codification as sources of authoritative US GAAP for SEC registrants. FAS 168 and the Codification are effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification was adopted on September 30, 2009 and it did not have a material impact on the Company's financial condition or results of operations.

**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 had commitments to make future payments totaling approximately \$1.3 million of which \$0.6 million was paid in 2009 and the remainder of \$0.7 million is due in 2010. Also, the Company has a minimum purchase obligation equivalent to the value of product purchased in the previous year. For the year ended December 31, 2010 this equates to \$0.1 million.

**4 Acquisition**

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 for a purchase price of approximately \$3.8 million. The Company also committed, as part of securing long term supply arrangements, to make future payments totaling approximately \$1.3 million of which \$0.6 million was paid in 2009 and the remainder of \$0.7 million will be paid in 2010. The present value of these commitments has been reported as other short term payables and other long term payables on the consolidated balance sheet as at December 31, 2008 and as short term payables as of December 31, 2009.

**Table of Contents****5 Cash and Cash Equivalents**

The following is a summary of cash and cash equivalents at December 31, 2008 and 2009:

	<b>December 31,</b>	
	<b>2008</b>	<b>2009</b>
	<b>\$000</b>	<b>\$000</b>
Cash	4,580	2,996
Deposits with original maturity of less than three months	19,640	8,497
	24,220	11,493

**6 Short-term Investments**

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

	<b>December 31, 2008</b>			
	<b>Amortized</b>	<b>Gross</b>	<b>Gross</b>	<b>Fair value</b>
	<b>cost</b>	<b>unrealized</b>	<b>unrealized</b>	<b>\$000</b>
	<b>\$000</b>	<b>gains</b>	<b>losses</b>	<b>\$000</b>
	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>
Corporate bonds & commercial paper	1,501	1		1,502

At December 31, 2009, the Company did not own any short-term investments. In 2008, the Company disposed of short-term securities prior to maturity, realizing a gain of approximately \$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.

At December 31, 2008, the Company had marketable securities at fair value with contractual maturities of greater than one year but less than 5 years of \$1.5 million. At December 31, 2009, the Company did not own any marketable securities.

**Fair value measurements**

The Company adopted ASC 820 *Fair Value Measurements and Disclosures* ( ASC 820 ) for its financial assets and liabilities on January 1, 2008, and for non-financial assets and non-financial liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis on January 1, 2009. The Company's adoption of ASC 820 did not materially affect the Company's financial position, results of operations or liquidity. As defined in ASC 820, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, ASC 820 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

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

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

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

**Table of Contents**

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

Financial assets and liabilities carried at fair value on a recurring basis as of December 31, 2009 are classified in the table below in one of the three categories described above:

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>
Warrants		342		342

**7 Prepaid Expenses and Other Current Assets**

The following is a summary of prepaid expenses and other current assets at December 31, 2008 and 2009:

	<b>December 31,</b>	
	<b>2008</b>	<b>2009</b>
	<b>\$000</b>	<b>\$000</b>
Research and development tax credit receivable	1,530	1,096
Prepayments	1,017	456
Other current assets	237	179
	2,784	1,731

**8 Property, Plant and Equipment**

Property, plant and equipment consisted of the following:

	<b>Useful lives in years from</b>	<b>December 31,</b>	
	<b>date of acquisition</b>	<b>2008</b>	<b>2009</b>
		<b>\$000</b>	<b>\$000</b>
Leasehold improvements	Life of lease (15 yrs)	811	860
Research and laboratory equipment	3 to 5 yrs	7,170	7,894
Office equipment and furniture	3 to 5 yrs	1,859	1,280
		9,840	10,034
Less: accumulated depreciation and amortization		(8,003)	(8,912)
Impairment		(89)	(221)
		1,748	901

The depreciation and amortization of property, plant and equipment amounted to \$1.0 million, \$1.1 million and \$0.7 million for each of the years ended December 31, 2007, 2008 and 2009, 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, 2009 was \$11.9 million. At December 31, 2008 and 2009 there were no assets held under capital lease.

As a result of the Company revising its operating plan in September 2008, the Company identified that certain research and development assets at its Cambridge, UK facility would no longer be utilized (see note 14 Restructuring). For the years ended December 31, 2008 and 2009, the Company recorded an asset impairment of \$0.1 million and \$0.2 million, respectively, in respect of these assets as accelerated depreciation in accordance with ASC 420 which are shown within research and development expense on the consolidated income statement. There were no impairments of

property, plant and equipment during the year ended December 31, 2007.

**Table of Contents****9 Intangible Assets and Goodwill**

Intangible assets consisted of the following:

	ALIGN					
	License agreements	Customer relationships	trade name	Non-compete agreements	Beneficial contract pricing arrangement	Total
<b>Intangible Assets</b>						
<b>Useful lives in years from date of acquisition</b>	<b>7 yrs</b>	<b>7 yrs</b>	<b>2 yrs</b>	<b>2 yrs</b>	<b>2 yrs</b>	
	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>
Balance as of December 31, 2007	2,945	516	88	343	413	4,305
Less: amortization	(295)	(51)	(38)	(147)	(177)	(708)
Less: impairment charge	(2,650)	(465)	(50)	(196)	(236)	(3,597)

Balance as of December 31, 2008

*Intangibles*

As part of the acquisition of ALIGN, the Company acquired rights to a license agreement with Sinclair as well as to various customer relationships. The license agreement allows Cyclacel to exclusively sell and distribute Xclair<sup>®</sup> Cream, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges in the United States. The Company has amortized the license agreement and customer relationship intangible assets over the remaining life of the contract of approximately seven years. The Company also assumed all rights to the ALIGN trade name, as well as non-compete agreements signed between ALIGN and its senior managers and a beneficial contract pricing arrangement. The Company has amortized the fair values of these assets 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 Company performed its annual impairment review of these assets as of September 2008. The fair values of these assets, when treated as an asset group in accordance with ASC 360, was established by using the income based valuation methodology, and an impairment charge of approximately \$3.6 million was recognized in the consolidated statement of operations. This one-time, non-cash charge was triggered by a downwards revision of projected net cash flows from product sales, required due to budgetary constraints experienced by health care providers and restrictions of the cost reimbursement regime. As a result the sum of the expected undiscounted cash flows was less than the carrying amount of the intangible assets on September 30, 2008.

*Goodwill*

The Company recognized goodwill arising on the Xcyte and ALIGN purchase transactions in 2006 and 2007 respectively in accordance with ASC 805, *Business Combinations* (ASC 805), The Company is organized as a single operating segment with two reporting units; ALIGN and Xcyte. The Company performed impairment analyses of goodwill for both Xcyte and ALIGN as at September 30, 2008 and of ALIGN as at December 31, 2008. The fair value of the Company's Xcyte reporting unit was determined by the fair market value of the Company's outstanding common stock and in the case of the ALIGN reporting unit by using the income based valuation approach with respect to projected product sales. The income-based valuation measures the current value of the reporting unit by calculating the present value of its future cash flows using appropriate discount factors with regard to cost of capital experienced by entities of the same size and condition as the Company.

To test for impairment, the Company compares the fair value of its reporting units to their respective carrying values, including assigned goodwill. To the extent the carrying amount of the reporting units exceeds its fair value; the Company is required to perform the second step of the impairment analysis, as this is an indication that goodwill may be impaired. In this second step, the Company compares the implied fair value of the reporting units goodwill with its carrying amount. The implied fair value of goodwill is determined by allocating the fair value of the reporting units to all of the assets (recognized and unrecognized) and liabilities of the reporting units in a manner similar to a purchase

price allocation, in accordance with ASC 805. The residual fair value after this allocation represents the implied fair value of the goodwill. To the extent the implied fair value of goodwill is less than its carrying amount the Company is required to recognize an impairment loss.

**Table of Contents**

In September 2008, the goodwill acquired in the Xcyte transaction was written down in full and we recorded an impairment charge of approximately \$2.7 million in accordance with ASC 350. This impairment charge was identified through our annual impairment review process and was triggered primarily by a decline in our stock price that reduced our market capitalization below book value of the net assets of the Xcyte reporting unit. Our reduced market capitalization reflected the general decline in the economic environment.

In December 2008, goodwill allocated to our ALIGN reporting unit following the ALIGN acquisition was fully written down in accordance with ASC 350, resulting in an impairment charge of approximately \$1.6 million being recognized on the consolidated statement of operations. In determining the impairment charge, we considered the negative impact the current economic situation might have on sales growth expectations of the ALIGN products resulting in a downward revisions of projected net cash flows from product sales. These factors caused the discounted cash flows for the reporting unit to be less than its carrying value on December 31, 2008.

**10 Accrued and Other Current Liabilities**

Accrued and other current liabilities consisted of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2009</b>
	<b>\$000</b>	<b>\$000</b>
Accrued research and development	3,653	2,654
Accrued IP / Patent costs	264	283
Accrued compensation	707	136
Amount payable under license agreement	594	651
Amount payable under guarantee		796
Proposed preference dividend	307	1,228
Other current liabilities	1,276	961
	<b>6,801</b>	<b>6,709</b>

**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.

**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, 2009:

	<b>Operating lease obligations \$ 000</b>
2010	1,606
2011	671
2012	415
2013	407
2014	407
Thereafter	4,396

**Table of Contents**

Rent expense, which includes lease payments related to the Company's research and development facilities and corporate headquarters and other rent related expenses, was, \$1.1 million, \$0.9 million and \$0.9 million for the years ended December 31, 2007, 2008 and 2009, respectively.

In October 2000, the Company entered into a 25-year lease for its research and development facility in Dundee, Scotland. 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.

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, 2009 the accrued restructuring liability was \$1.1 million. This represents the Company's best estimate of the fair value of the liability as determined under ASC 420. 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. (See Restructuring under Footnote 14).

The Company also leased a second research facility at the Babraham Research Campus, Cambridge, England with a lease expiration date of August 2010. Under the revised plan announced in September 2008, the Cambridge laboratory facility will no longer be used by the Company. In 2009, the Company assigned the lease of its redundant Cambridge research facility back to the landlord and, in accordance with the terms of the lease, incurred a net charge, incorporating a surrender fee, of \$0.1 million.

***Guarantee***

On July 28, 2005 and amended on March 27, 2006, Cyclacel Group plc (the Group) signed a convertible Loan Note Instrument constituting convertible unsecured loan notes (the Loan) and entered into a Facility Agreement (the Agreement) with Scottish Enterprise (SE), as lender, whereby SE subscribed for £5 million, or approximately \$9 million at the time, of the convertible loan notes. The loan was subsequently converted into 1,231,527 preferred D shares of the Group in satisfaction of all amounts owed by Group under the convertible loan notes. The number of preferred D shares that SE received was calculated by dividing the principal amount outstanding under the loan note by £4.06. The preferred D shares were exchanged for shares in Xcyte Therapies, Inc. on March 27, 2006 as part of the transaction between Xcyte and Cyclacel Limited. However, Scottish Enterprise retained the ability it had under the Agreement to receive a cash payment should the research operations in Scotland be significantly reduced. Cyclacel Limited guaranteed approximately £5 million, the amount potentially due to SE, 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 SE at the time of any significant reduction in research facilities.

**Table of Contents**

On June 22, 2009, the Company amended the March 2006 Agreement with SE, in order to allow the Company to implement a reduction of the Company's research operations located in Scotland in exchange for the parties' agreement to modify the payment terms of the Agreement in the principal amount of £5 million (approximately \$8.0 million at December 31, 2009), which SE had previously entered into with the Company. The original agreement dated March 27, 2006, provided for repayment of £5 million in the event the Company significantly reduced its Scottish research operations. Pursuant to the terms of the Amendment, in association with Cyclacel's material reduction in staff at its Scottish research facility, the parties agreed to a modified payment of £1 million (approximately \$1.7 million at June 22, 2009) payable in two equal tranches. On July 1, 2009 the first installment of £0.5 (approximately \$0.8 million) million was paid and the remaining amount of \$0.8 million was paid on January 6, 2010. In addition, should a further reduction below current minimum staff levels be effectuated before July 2014 without SE's prior consent, the Company will guarantee approximately £4 million, the amount potentially due to SE, which will be calculated as a maximum of £4 million less the market value of the shares held (or would have held in the event they dispose of any shares) by SE at the time of any further reduction in research facilities. This resulted in a charge to the income statement in the second quarter of 2009 of £1 million (\$1.7 million), with the outstanding liability being recorded under accrued liabilities on the condensed consolidated balance sheet as at December 31, 2009.

***Purchase Obligations***

At December 31, 2008 and December 31, 2009, the Company had obligations in relation to the purchase of manufactured products within the ALIGN business of \$0.4 million and \$0.1 million respectively.

***Preferred Dividends***

Pursuant to the terms of the Company's outstanding preferred stock, since inception through January 2009, the Company paid quarterly cash dividends when they have fallen due. However, as part of the program to reduce expenditure, on April 6, 2009, June 22, 2009, October 19, 2009 and January 7, 2010, the Board of Directors decided not to declare the quarterly cash dividend.

***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*****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 issuance 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. Since inception until April 6, 2009, the Company paid these dividends when due. However, as part of the Company's program to reduce expenditure, on April 6, 2009, June 22, 2009, October 19, 2009 and January 7, 2010, the Company's Board of Directors resolved to suspend payment of, but continue to accumulate, the cash dividend. The Board of Directors will continue to evaluate the payment of a quarterly cash dividend on a quarterly basis. 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. Each quarterly dividend distribution totals \$0.3 million.

**Table of Contents**

The Preferred Stock is convertible at the option of the holder at any time into the Company's common stock at a conversion rate of approximately 0.42553 shares of common stock for each share of Preferred Stock, based on a price of \$23.50 after giving effect to the one for ten reverse stock split of Xcyte's common stock pursuant to the Stock Purchase. In the year ended December 31, 2004, holders voluntarily converted 910,187 shares of Preferred Stock into 3,873,124 shares of common stock and in the year ended December 31, 2005, holders voluntarily converted 33,000 shares of preferred stock into 140,425 shares of common stock (before giving effect to the one for ten reverse stock split of Xcyte's common stock). During 2007, 2008 and 2009 no shares of Preferred Stock were converted into common stock. The Company has reserved 870,980 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at December 31, 2009.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded \$35.25, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion. To date, the Company has not elected to automatically convert the Preferred Stock in whole or part into common stock.

Prior to November 3, 2007, the Company was required to make 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, for each Preferred Stock converted to the Company's common stock, whether at the option of the holder or the Company, the "Make-Whole Dividend Payment". This additional payment was 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. The Company issued 81,927 shares of common stock (before giving effect to the one for ten reverse stock split of Xcyte's common stock) to converting holders in 2004 and 2005 in satisfaction of this additional payment.

In accordance with Statement of ASC 815, the Company was required to separate and account for, as an embedded derivative, the Make-Whole Dividend Payment feature of the Preferred Stock. As an embedded derivative instrument, the Make-Whole Dividend 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). Since this feature lapsed on November 3, 2007, the liability was reduced to \$0. During 2007, the Company recorded a charge of \$0.1 million on the consolidated statement of operations.

From November 6, 2007, the Company may, at its option, redeem the Preferred Stock in whole or in part, out of funds legally available at the redemption prices per share stated below, plus an amount equal to accrued and unpaid dividends up to the date of redemption:

Year from November 1, 2009 to October 31, 2010	\$ 10.30
Year from November 1, 2010 to October 31, 2011	\$ 10.24
Year from November 1, 2011 to October 31, 2012	\$ 10.18
Year from November 1, 2012 to October 31, 2013	\$ 10.12
Year from November 1, 2013 to October 31, 2014	\$ 10.06
November 1, 2014 and thereafter	\$ 10.00

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.

**Table of Contents*****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, 2009, 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 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. As of December 31, 2009, all of the warrants remain outstanding.

The warrants issued to the investors are being accounted for as a liability in accordance with ASC 840. 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, 2008 and 2009, the fair value of the warrants determined utilizing the Black-Scholes option pricing model was approximately \$43,000 and approximately \$0.3 million, respectively. The fair value at December 31, 2009 reflects the increase in the Company's common stock price, risk free rate of return and the remaining expected term of the warrants. During 2008, the Company recognized the change in the value of warrants of approximately \$3.5 million as a gain on the consolidated statement of operations. During 2009, the Company recorded the change in the value of warrants of \$0.3 million as a loss on the consolidated statement of operations.

***July 2009 Registered Direct Financing***

On July 29, 2009, the Company sold its securities to certain institutional investors consisting of 4,000,000 units in a registered direct offering (the Offering) at a purchase price of \$0.85 per unit (each, a Unit). Each Unit consisted of (i) one share of the Company's common stock, par value \$0.001 per share (the Common Stock), (ii) one warrant to purchase 0.625 of one share of Common Stock (a Series I Warrant) and (iii) one warrant to purchase 0.1838805 of one share of Common Stock (a Series II Warrant). The Series I Warrants have a seven-month term from the date of issuance, are exercisable beginning six months from the date of issuance and will be exercisable at an exercise price of \$1.00 per share of Common Stock. As of December 31, 2009, all of the Series I Warrants remain outstanding. The Series II Warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance and will be exercisable at an exercise price of \$1.00 per share of Common Stock. As of December 31, 2009, all of the Series II Warrants remain outstanding. The sale of the Units was made pursuant to Subscription Agreements, dated July 23, 2009, with each of the investors. The net proceeds to the Company from the sale of the Units, after deducting for the Placement Agent's fees and offering expenses, were approximately \$2.9 million.



**Table of Contents**

As of December 31, 2009, the warrants issued to the investors have been classified as equity in accordance with ASC 815. The transaction date fair value of the Series I Warrants of \$1.0 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 0.26%, expected volatility 125%, expected dividend yield 0%, and a remaining contractual life of 0.58 years. The transaction date fair value of the Series II Warrants of \$0.6 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 2.69%, expected volatility 90%, expected dividend yield 0%, and a remaining contractual life of 5.00 years.

*December 2007 Committed Equity Financing Facility (CEFF)*

On December 10, 2007 and amended on November 24, 2009, 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 of capital over a three-year period. 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 10% to 20% 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 \$0.40 or 90% of Cyclacel's common stock closing price the day before the commencement of each draw down.

During December 2009 and January 2010, the Company sold an aggregate of 1,583,626 shares of its common stock to Kingsbridge under the terms of the CEFF with Kingsbridge, dated as of December 10, 2007, as amended, in consideration of an aggregate of \$1.3 million, of which approximately \$1.0 million was received in 2009 with the balance of \$0.3 million in respect of common shares subscribed but unissued at December 31, 2009, received by the Company in January 2010.

In connection with the Amendment, the Company issued an amended and restated warrant to Kingsbridge to purchase 175,000 shares of its common stock at an exercise price of \$1.40 per share, (from an original exercise price of \$7.17) which represents 175% of the closing bid price of our common stock on the date prior to the date on which the Amendment was signed. The warrant amends and restates the original warrant issued by the Company to Kingsbridge in connection with the CEFF. No other changes were made to the original warrant. As a result of the change in exercise price, the Company recorded an expense of approximately \$44,000. 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 and 2008, the warrants issued to the investors have been classified as equity in accordance with ASC 840. The transaction date fair value of the warrants of \$0.6 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 3.605%, expected volatility 70%, expected dividend yield 0%, and a remaining contractual life of 5.5 years.

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

The following table summarizes information about warrants outstanding at December 31, 2009:

	<b>Expiration</b>	<b>Common Shares Issuable</b>	<b>Weighted Average Exercise Price</b>
<b>Issued in Connection With</b>	<b>Date</b>		
March 2006 stock issuance	2013	2,571,429	7.00
February 2007 stock issuance	2014	1,062,412	8.44
December 2007 CEFF	2012	175,000	1.40
July 2009 Series I stock issuance	2010	2,500,000	1.00
July 2009 Series II stock issuance	2014	735,522	1.00
Total		7,044,363	4.32

*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 2008. During 2009, 17,180 shares of common stock were issued from the exercise of stock options resulting in proceeds of approximately \$7,000.

**13 Stock-Based Compensation Arrangements**

The Company adopted ASC 718 on January 1, 2006 using the modified prospective method of transition as detailed in Note 2 Summary of significant accounting policies.

ASC 718 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), vest ratably over four years, with 1/4 of the award vesting one year from the date of grant and 1/48 of the award granted vesting each month thereafter. However, a large grant of awards issued in June 2006 vests (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 ASC 718 under the straight-line attribution method. ASC 718 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 is evaluated quarterly and the forfeiture rate adjusted as necessary. Ultimately, the actual expense recognized over the vesting period is based on only those shares that vest.

Stock based compensation has been reported within expense line items on the consolidated statement of operations for 2007, 2008 and 2009 as shown in the following table:

	<b>Year ended December 31, 2007</b>	<b>Year ended December 31, 2008</b>	<b>Year ended December 31, 2009</b>
		<b>(\$000s)</b>	
Research and development	837	736	271
Selling, general and administrative	896	962	539
Stock-based compensation costs before income taxes	\$ 1,733	\$ 1,698	\$ 810



**Table of Contents*****2006 Plans***

On March 16, 2006, Xcyte stockholders approved the adoption of the 2006 Plans, under which Cyclacel, may make equity incentive grants to its officers, employees, directors and consultants. On May 14, 2008, at the Company annual stockholders meeting the stockholders increased the number of shares reserved under the 2006 Plans to 5.2 million shares of common stock from 3.0 million shares of common stock.

During 2006, the Company granted 829,079 stock options under the 2006 Plans, two-thirds of which 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.

The total fair value of all options granted in 2006 under the 2006 Plans was \$5.7 million, of which \$5.2 million has been recognized as of December 31, 2009. During 2007, the Company granted approximately 1.3 million options to employees and directors with a grant date fair value of \$3.3 million, of which \$2.2 million has been expensed. During 2008, the Company granted approximately 1.5 million options to employees and directors with a grant date fair value of \$0.7 million, of which \$0.4 million has been expensed. During 2009, the Company granted approximately 0.2 million options to employees and directors with a grant date fair value of \$0.1 million, of which approximately \$28,000 has been expensed. As of December 31, 2009, the total remaining unrecognized compensation cost related to the non-vested stock options amounted to approximately \$1.8 million, which will be amortized over the weighted-average remaining requisite service period of 3.25 years.

During 2008 and 2009, the Company did not settle any equity instruments with cash.

The Company received \$7,000 from the exercise of 17,180 stock options during 2009. The total intrinsic value of options exercised during 2009 was approximately \$11,000. No options were exercised in 2008. The weighted average grant-date fair value of options granted during 2008 and 2009 was \$0.67 and \$0.39, respectively.

***Acceleration of Options***

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.

***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 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

**Table of Contents**

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 options are granted under the 1997 Plan, 2000 Plan and Discretionary Plan.

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 were not subject to additional future vesting or service requirements, the stock-based compensation expense of \$5.2 million recorded during 2006 constituted the entire grant-date fair value of this award, and no subsequent period charges have been recorded. The stock was restricted only in that it could not be sold for a specified period of time. There were 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 was 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.

*Xcyte Plans*

Upon closing of the Stock Purchase, the vesting of 43,491 options of common stock granted pursuant to the 2003 Directors Plan, the 1996 Plan and the 2003 Plan were immediately accelerated and became fully vested.

Since March 16, 2006, no further options have been 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.

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 have been issued under such plans. However, such partial termination has not affected 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:

	<b>Number of options outstanding</b>	<b>Weighted average exercise price</b>	<b>Weighted average remaining contractual term (years)</b>	<b>Aggregate intrinsic value</b>
<b>Cyclacel Pharmaceuticals, Inc.</b>				
Balance as of December 31, 2007	2,592,346	\$ 6.39	9.14	
Granted	1,469,575	\$ 1.18		
Exercised				
Cancelled/forfeited	(387,022)	\$ 5.92		
Options outstanding at December 31, 2008	3,674,899	\$ 4.36	8.74	2
Granted	221,000	\$ 0.39		
Exercised	(17,180)	\$ 0.43		7
Cancelled/forfeited	(528,843)	\$ 3.76		
Options outstanding at December 31, 2009	3,349,876	\$ 4.21	7.76	698

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

Unvested at December 31, 2009	1,381,616	\$	2.62	8.43	484
Vested and exercisable at December 31, 2009	1,968,260	\$	5.34	7.79	

**Table of Contents**

The following table summarizes information about options outstanding at December 31, 2009:

<b>Exercise price</b>	<b>Number outstanding</b>	<b>Weighted Average remaining contractual life</b>	<b>Number exercisable</b>
\$ 0.31 1.98	1,176,146	8.92	365,676
2.15 4.95	223,667	8.04	107,134
5.26 5.81	619,030	7.79	324,738
6.30 8.30	1,309,033	6.71	1,148,712
15.00 45.30	22,000	5.12	22,000
	3,349,876		1,968,260

The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option-pricing model as prescribed by ASC 718 using the following assumptions:

	<b>Year ended December 31, 2007</b>	<b>Year ended December 31, 2008</b>	<b>Year ended December 31, 2009</b>
Expected term (years)	4.25 6.00	4.25 6.00	0.75 5 Yrs
Risk free interest rate	3.28 5.07%	1.54 3.76%	0.325 .84%
Volatility	65 80%	45 75%	65 169%
Dividends	0.00%	0.00%	0.00%
Resulting weighted average grant date fair value	\$3.68	\$0.68	\$0.39

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. Estimates of pre-vesting option forfeitures are based on the Company's experience. Currently the Company uses a forfeiture rate of 20-75% depending on when and to whom the options are granted. The Company adjusts its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and may impact the amount of compensation expense to be recognized in future periods. During both quarters ended September 30, 2009 and June 30, 2009 the Company revised the forfeiture rates because actual forfeiture rates were higher than that previously estimated primarily due to the lapsing of stock option grants on the termination of employees. During 2009, the Company recognized a net cumulative charge of approximately \$0.5 million with respect to the revised forfeiture rates.

**Table of Contents**

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.

The Company received approximately \$7,000 from the exercise of 17,180 options during 2009. There were no stock option exercises for the year ended December 31, 2008. The Company received \$0.2 million from the exercise of 25,508 options during 2007. No income tax benefits were recorded because ASC 718 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 and 2009, 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.

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

Related to the workforce reduction in the second and third quarters of 2009, the Company amended the exercise period to which the employees would be able to exercise their vested stock options from thirty days post termination date, per the option agreement terms, to nine months resulting in a charge to condensed consolidated statement of operations of approximately \$0.1 million. In addition, the Company allowed the individuals to continue to vest their stock options and restricted stock units until November 18, 2009 as if they were still employed in recognition of their past work provided to the Company.

*Restricted Stock*

In November 2008, the Company issued restricted common stock to an employee subject to certain forfeiture provisions. Specifically, one quarter of the award vests one year from the date of grant and 1/48 of the award effectively vests each month thereafter. This restricted stock grant is accounted for at fair value at the date of grant and an expense is recognized during the vesting term. Summarized information for restricted stock grants for the year ended December 31, 2009 is as follows:

	<b>Restricted Stock Units</b>	<b>Weighted Average Grant Date Value Per Share</b>	
Non-vested at December 31, 2007			
Granted	50,000	\$	0.44
Non-vested at December 31, 2008	50,000	\$	0.44
Granted			
Vested	(13,542)	\$	0.44
Cancelled			
Non-vested at December 31, 2009	36,458	\$	0.44



**Table of Contents***Restricted Stock Units*

Restricted stock units were issued to senior executives of the Company in November 2008, which entitle the holders to receive a specified number of shares of the Company's common stock over the four year vesting term. A restricted stock unit grant is accounted for at fair value at the date of grant which is equivalent to the market price of a share of the Company's common stock, and an expense is recognized during the vesting term. There were no restricted stock unit grants prior to November 2008. Summarized information for restricted stock grants for the year ended December 31, 2009 is as follows:

	<b>Restricted Stock Units</b>	<b>Weighted Average Grant Date Value Per Share</b>
Non-vested at December 31, 2007		
Granted	91,700	\$ 0.44
Non-vested at December 31, 2008	91,700	\$ 0.44
Granted		
Vested	(24,488)	\$ 0.44
Cancelled	(12,525)	\$ 0.44
Non-vested at December 31, 2009	54,687	\$ 0.44

**14 Restructuring**

On September 16, 2008, the Company announced a revision of its operating plan that concentrates the Company's resources on the advancement of its lead drug, sapacitabine, while maintaining the Company's core competency in drug discovery and cell cycle biology. The plan reduced the workforce across all locations by 25 people. The Company recorded approximately \$0.4 million for severance payments and \$0.1 million of accelerated depreciation for assets that will no longer be utilized. All severance payments were paid as of December 31, 2008. During 2009, the Company recorded approximately \$0.4 million for severance payments all of which were paid as of December 31, 2009. As part of the plan the Company vacated its laboratory facility in Cambridge, England. The Company assigned the lease of its redundant Cambridge research facility back to the landlord and, in accordance with the terms of the lease, incurred a net charge, incorporating a surrender fee, of \$0.1 million to effect this. In June 2009, the Company further reduced its workforce across all locations by 26 people making a total reduction of 51 people (or 63% of the workforce) since September 2008. An asset impairment amounting to \$0.2 million was also charged to the consolidated statement of operations as a result of assets being identified that were no longer being utilized.

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.

**Table of Contents**

The table below presents a summary of and reconciliation of those provisions for the years ended December 31, 2008 and 2009:

	<b>Lease restructuring charges \$000</b>	<b>Sales tax assessment \$000</b>	<b>Total \$000</b>
Balance at December 31, 2007	2,995	270	3,265
Cash payments	(1,106)		(1,106)
Adjustments for lease-related deferred expenses and liabilities	202		202
 Balance at December 31, 2008	 2,091	 270	 2,361
Cash payments	(1,156)	(372)	(1,528)
Adjustments for lease-related deferred expenses and liabilities	127		125
Adjustment for sales tax assessment		102	102
Balance at December 31, 2009	1,062		1,062
 Current	 1,062		 1,062

## Long term liabilities

*Lease restructuring charges*

Under the stock purchase agreement entered into with Xcyte Therapies, Cyclacel, assumed the accrued restructuring liability in relation to the Bothell manufacturing facility. The lease term on this space expires December 2010. 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 ASC 420. Subsequent changes in the liability due to accretion are recognized in interest expense, and changes in estimates of sublease assumptions, etc. are 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 and a discount rate of 7.8%, the Company expects to record additional accretion expense of approximately \$0.2 million over the remaining term of the lease. As of December 31, 2009, the Bothell accrued restructuring liability was \$1.1 million.

*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 was approximately \$1 million. During the fourth quarter of 2009, the Company paid \$0.5 million, including interest charges of \$0.1 million, to settle the claim and the assessment by the Department of Revenue of the State of Washington was dismissed. The Company had accrued \$0.4 million on its consolidated balance sheet and the difference of \$0.1 million was expensed within the selling, general and administrative line of the consolidated income statement.

The Company records costs and liabilities associated with exit and disposal activities, when certain criteria have been met in accordance with ASC 420, at fair value in the period the liability is incurred. The Company's restructuring and integration plan is subject to continued future refinement as additional information becomes available.

**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 approximately \$0.2 million in each of the years ended December 31, 2007

and 2008 and 2009, 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 \$16,500 if under 50 years old and \$22,000 if over 50 years old in 2010 and to have those funds contributed to the 401(k) Plan. For each of the years ended December 31, 2007, 2008 and 2009, the Company made contributions of approximately \$0.1 million to the 401(k) Plan.

**Table of Contents****16 Taxes**

In the accompanying Consolidated Statements of Operations, Loss before taxes includes the following components for the years ended December 31, 2007, 2008 and 2009:

	<b>Year ended December 31, 2007 \$000</b>	<b>Year ended December 31, 2008 \$000</b>	<b>Year ended December 31, 2009 \$000</b>
Domestic	(5,448)	(11,337)	(3,013)
Foreign	(20,646)	(30,798)	(17,505)
Total loss before taxes	(26,094)	(42,135)	(20,518)

The benefit for income taxes consists of the following:

	<b>Year ended December 31, 2007 \$000</b>	<b>Year ended December 31, 2008 \$000</b>	<b>Year ended December 31, 2009 \$000</b>
Current domestic	(2)	(4)	(12)
Current foreign	2,043	1,753	960
Current total	2,041	1,749	948

The Company has made a taxable loss in each of the operating periods since incorporation. The income tax credits of \$2.0 million, \$1.7 million and \$0.9 million for the years ended December 31, 2007, 2008 and 2009 respectively, represent U.K. research and development tax credits receivable against such expenditures in the United Kingdom. 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:

	<b>Year ended December 31, 2007 \$000</b>	<b>Year ended December 31, 2008 \$000</b>	<b>Year ended December 31, 2009 \$000</b>
Loss before income taxes	(26,094)	(42,135)	(20,518)
Income tax expense computed at statutory federal tax rate	(8,872)	(14,361)	(6,976)
State income tax (net of federal benefit)	1	3	8
Disallowed expenses and non-taxable income	(3,005)	(1,939)	(773)
Tax losses	4,349	3,584	2,322
Research and development tax relief	(2,551)	(2,191)	(1,185)
Valuation allowance	7,272	11,161	4,605
Change in state tax rate	(268)		
Research and development tax credit rate difference	510	438	237
Foreign tax rate differential	525	1,556	814

(2,039)

(1,749)

(948)

**Table of Contents**

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

	<b>2008</b>	<b>2009</b>
	<b>\$000</b>	<b>\$000</b>
Net operating loss carryforwards	35,140	42,534
Depreciation, amortization and impairment of property and equipment	2,178	1,996
Lease restructuring charges	817	399
Tax Credits	61	
Stock Options	582	775
Accrued Expenses	1,563	2,684
Other	110	67
Translation adjustment	(2,814)	(3,097)
Deferred Tax Assets	37,637	45,358
Valuation allowance for deferred tax assets	(37,637)	(45,358)

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:

	<b>2008</b>	<b>2009</b>
	<b>\$000</b>	<b>\$000</b>
Accumulated tax losses	110,478	131,685

As of December 31, 2009 and 2008, the Company had federal, state and foreign net operating losses or (NOLs) of \$185.2 million and \$124.8 million, respectively and federal research and development credit carryforwards of approximately \$0.1 million and \$0.1 million, respectively, which will expire starting in 2022. The Company has federal net operating losses that will start to expire in 2027 and state net operating losses that will start expiring in 2023.

As required by ASC 740, the Company's management 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 \$45.4 million has been established at December 31, 2009. 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.



**Table of Contents**

The Company adopted ASC 740 on January 1, 2007. The implementation of ASC 740 did not have a material impact on the Company's consolidated financial statements, results of operations or cash flows. Management has evaluated all significant tax positions at December 31, 2008 and 2009 concluding that there are no material uncertain tax positions. The tax year 2008 remains 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 IRS 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 determined its reportable segments in accordance with ASC 280 through consideration of the Company's business activities and geographic area. The Company has concluded that it has one operating segment, being the discovery, development and commercialization of novel, mechanism-targeted drugs to treat cancer and other serious disorders, with development operations in two geographic areas, namely the United States and the United Kingdom.

Geographic information for the years ended December 31, 2007, 2008 and 2009 are as follows:

	<b>2007</b>	<b>2008</b>	<b>2009</b>
	<b>\$000</b>	<b>\$000</b>	<b>\$000</b>
<b>Revenue</b>			
United States		838	910
United Kingdom	129	39	1
	129	877	911
<b>Net loss</b>			
United States	(1,783)	(11,341)	(3,007)
United Kingdom	(22,270)	(29,045)	(16,563)
	(24,053)	(40,386)	(19,570)
<b>Total Assets</b>			
United States	66,947	22,842	10,460
United Kingdom	8,965	8,115	4,006
	75,912	30,957	14,466
<b>Long Lived Assets, net</b>			
United States	532	516	330
United Kingdom	2,484	1,232	571
	3,016	1,748	901





In January, 2010, the Company completed the sale of 2,850,000 units in a registered direct offering to certain institutional investors for approximately \$7.2 million in gross proceeds. Each unit was sold at a purchase price of \$2.51 per unit and consists of one share of the Company's common stock and one warrant to purchase 0.25 of one share of the Company's common stock. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance and will be exercisable at an exercise price of \$3.26 per share of common stock.

In January, 2010, the Board of Directors of Cyclacel resolved to suspend the quarterly cash dividend on the Company's 6% Convertible Exchangeable Preferred Stock ( Preferred Stock ) with respect to the fourth quarter of 2009 that would have otherwise been payable on February 1, 2010.

During January and February 2010, the Company issued 2,618,266 shares of our common stock for gross proceeds of approximately \$2.6 million through the exercise of warrants.

During March 2010, the Company issued 239,396 shares of its common stock to a stockholder in exchange in exchange for the stockholder's delivery to the Company of 123,400 shares of the Company's outstanding Preferred Stock.

During March 2010, the Company issued 1,234,606 shares of its common stock to Kingsbridge for \$2.8 million.

**Table of Contents**

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

None.

**Item 9T. Controls and Procedures**

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

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 Financial 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.

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial 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.

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(e) and 15d-15(e). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2009 based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

As of December 31, 2009, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2009, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

**Table of Contents**

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

*(b) Report of the Independent Registered Public Accounting Firm:*

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, 2009 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 Annual 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.

**Table of Contents**

In our opinion, Cyclacel Pharmaceuticals Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

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, 2009 and December 31, 2008, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2009 and for the period from August 13, 1996 (inception) to December 31, 2009 of Cyclacel Pharmaceuticals, Inc, and our report dated March 29, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

London, England

March 29, 2010

*(c) Changes in Internal Control Over Financial Reporting:*

No changes were made in the Company's internal control over financial reporting during the fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other information**

*(a) Submission of matters to a vote of security holders.*

No matters were submitted to a vote of the shareholders during the fourth quarter of 2009.

**Table of Contents**

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by Item 10 is incorporated herein by reference from the Company's Proxy Statement which will be filed with the SEC within 120 days after the end of the Company's 2009 fiscal year pursuant to Regulation 14A for its 2010 Annual Meeting of Stockholders.

**Item 11. Executive Compensation**

The information required by Item 11 is incorporated herein by reference from the Company's Proxy Statement which will be filed with the SEC within 120 days after the end of the Company's 2009 fiscal year pursuant to Regulation 14A for its 2010 Annual Meeting of Stockholders.

**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 Proxy Statement which will be filed with the SEC within 120 days after the end of the Company's 2009 fiscal year pursuant to Regulation 14A for its 2010 Annual Meeting of Stockholders.

**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 Proxy Statement which will be filed with the SEC within 120 days after the end of the Company's 2009 fiscal year pursuant to Regulation 14A for its 2010 Annual Meeting of Stockholders.

**Item 14. Principal Accountant Fees and Services**

The information required by Item 14 is incorporated herein by reference from the Company's Proxy Statement which will be filed with the SEC within 120 days after the end of the Company's 2009 fiscal year pursuant to Regulation 14A for its 2010 Annual Meeting of Stockholders.

**Table of Contents**

## PART IV

**Item 15. Exhibits and Financial Statement Schedules**

(a) Documents filed as part of this report are as follows:

(1) Financial Statements and Report of Independent Registered Public Accounting Firm

(2) Financial Statement Schedules

None required.

(3) Exhibits: see below Item 15(b)

(b) Exhibits:

**EXHIBIT  
NUMBER****DESCRIPTION**

1.1	Placement Agent Agreement, dated July 23, 2009, by and between the Company and Lazard Capital Markets LLC (previously filed as Exhibit 1.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on July 24, 2009, and incorporated herein by reference).
1.2	Placement Agent Agreement, dated January 11, 2010, by and between the Company and ROTH Capital Partners, LLC (previously filed as Exhibit 1.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 11, 2010, and incorporated herein by reference).
1.3	Placement Agent Agreement, dated January 21, 2010, by and between the Company and ROTH Capital Partners, LLC (previously filed as Exhibit 1.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 21, 2010, and incorporated herein by reference).
3.1	Amended and Restated Certificate of Incorporation of Xcyte Therapies, Inc. (previously filed as Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, File No. 333-109653, originally filed with the SEC 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 3.3.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended March 31, 2006, originally filed with the SEC 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 SEC on October 10, 2003, as subsequently amended, and incorporated herein by reference).
3.2.1	Amendment No. 1 to the Amended and Restated Bylaws of Xcyte Therapies, Inc. (previously filed as Exhibit 3.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on September 8, 2008, 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 SEC 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 SEC 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. 333-119585, originally filed with the SEC on October 7, 2004, as subsequently amended, and incorporated herein by reference).
4.3	

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form 10-K

- 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 SEC 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 SEC on February 15, 2007, and incorporated herein by reference).
- 4.5 Form of Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock, dated December 10, 2007, issued to Kingsbridge Capital Limited (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 11, 2007, and incorporated herein by reference).
- 4.6 Registration Rights Agreement, dated December 10, 2007, by and between 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 SEC on December 11, 2007, and incorporated herein by reference).
- 4.7 Amended and Restated Warrant to purchase Common Stock, dated as of November 24, 2009, issued by the Company to Kingsbridge Capital Limited. (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on November 25, 2009, and incorporated herein by reference).
- 4.8 Form of Series I Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on July 24, 2009, and incorporated herein by reference).
- 4.9 Form of Series II Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on July 24, 2009, and incorporated herein by reference).
- 4.10 Form of Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 11, 2010, and incorporated herein by reference).
- 4.11 Form of Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 21, 2010, and incorporated herein by reference).
- 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, originally filed with the SEC on December 20, 2005, and incorporated herein by reference).

**Table of Contents**

<b>EXHIBIT NUMBER</b>	<b>DESCRIPTION</b>
10.2	Amendment No. 1 to the Stock Purchase Agreement, dated January 13, 2006, 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 January 19, 2006, and incorporated herein by reference).
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 SEC on April 28, 2006, and incorporated herein by reference).
10.4	Form of Subscription Agreement, dated February 13, 2007, by and between Cyclacel Pharmaceuticals, Inc. and certain purchasers (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on February 15, 2007, and incorporated herein by reference).
10.5	Form of Placement Agent Agreement, dated February 13, 2007, by and among Cyclacel Pharmaceuticals, Inc., 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 SEC on February 15, 2007, and incorporated herein by reference).
10.6	Asset Purchase Agreement by and among 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 SEC on November 7, 2007, and incorporated herein by reference).
10.7	Common Stock Purchase Agreement, dated December 10, 2007, by and between 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 SEC on December 11, 2007, and incorporated herein by reference).
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 SEC on November 7, 2007, and incorporated herein by reference).
10.9	Amended and Restated 2006 Equity Incentive Plan (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on June 19, 2007, and incorporated herein by reference).
10.10	Employment Agreement by and between Cyclacel Pharmaceuticals, Inc. and Spiro Rombotis, dated as of January 1, 2008 (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on March 24, 2008, and incorporated herein by reference).
10.11	Employment Agreement by and between Cyclacel Pharmaceuticals, Inc. and Paul McBarron, dated as of January 1, 2008 (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on April 2, 2008, and incorporated herein by reference).
10.12	Amendment No. 1, dated as of December 31, 2008, to Employment Agreement by and between Cyclacel Pharmaceuticals, Inc. and Spiro Rombotis, dated as of January 1, 2008 (previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended March 31, 2009, originally filed with the SEC on May 15, 2009, and incorporated herein by reference).
10.13	

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

- Amendment No. 1 to Common Stock Purchase Agreement, dated as of November 24, 2009, by and between the Company and Kingsbridge Capital Limited (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on November 25, 2009, and incorporated herein by reference).
- 10.14 Form of Subscription Agreement between the Company and certain investors (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on July 24, 2009, and incorporated herein by reference).
- 10.15 Form of Subscription Agreement between the Company and certain investors (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 11, 2010, and incorporated herein by reference).
- 10.16 Form of Subscription Agreement between the Company and certain investors (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 21, 2010, and incorporated herein by reference).
- 10.17 Agreement between the Company and Scottish Enterprise dated March 27, 2006 (previously filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2009, originally filed with the SEC on August 13, 2009, and incorporated herein by reference).
- 10.18 Addendum to Agreement between the Company and Scottish Enterprise dated June 22, 2009 (previously filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2009, originally filed with the SEC on August 13, 2009, and incorporated herein by reference).
- 21\* Subsidiaries of Cyclacel Pharmaceuticals, Inc.
- 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\* Certification 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).

Indicates  
management  
compensatory  
plan, contract or  
arrangement.

\* Filed herewith.

\*\* Furnished  
herewith.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned.

**CYCLACEL PHARMACEUTICALS,  
INC.**

Date: March 29, 2010

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Spiro Rombotis	President & Chief Executive Officer (Principal Executive Officer) and Director	March 29, 2010
Spiro Rombotis		
/s/ Paul McBarron	Chief Operating Officer & Executive Vice President, Finance (Principal Financial and Accounting Officer) and Director	March 29, 2010
Paul McBarron		
/s/ Dr. David U Prichard	Chairman	March 29, 2010
Dr. David U Prichard		
/s/ Dr. Christopher Henney	Vice Chairman	March 29, 2010
Dr. Christopher Henney		
/s/ Dr. Nicholas Bacopoulos	Director	March 29, 2010
Dr. Nicholas Bacopoulos		
/s/ Sir John Banham	Director	March 29, 2010
Sir John Banham		
/s/ Daniel Spiegelman	Director	March 29, 2010
Daniel Spiegelman		