

**CLOSING IN  
ON THE ENEMY**



**Cyclacel Pharmaceuticals, Inc.**

2010 ANNUAL REPORT

## Recent Milestones

2010

<b>JANUARY</b> Preclinical data reported that seliciclib found effective against lung cancer cell lines including K-RAS mutations	<b>JANUARY</b> Raised \$13.1 million in registered direct offerings	<b>JUNE</b> Added to Russell Microcap Index	<b>OCTOBER</b> Raised \$15.2 million private placement	<b>DECEMBER</b> Reported one-year survival data from Phase 2 sapacitabine study in older patients with MDS at ASH Annual Meeting	<b>DECEMBER</b> Reported topline results from APPRAISE Phase 2b study of seliciclib in patients with NSCLC
<b>JANUARY</b> Preclinical data demonstrated potential for seliciclib in treating breast cancer resistant to letrozole	<b>JUNE</b> Reported interim data from Phase 2 sapacitabine study in patients with MDS at 2010 ASCO Annual Meeting	<b>SEPTEMBER</b> Reached an agreement with the FDA on a SPA for pivotal Phase 3 trial of sapacitabine in AML (SEAMLESS trial)	<b>NOVEMBER</b> Published reports highlighted novel combinations of sapacitabine with targeted agents for the treatment of cancer	<b>DECEMBER</b> Preclinical data demonstrated activity of CYC065 in multiple myeloma	

## Clinical Drug Pipeline

Product Candidate	Indication	Phase 1	Phase 2	Phase 3
Sapacitabine	Acute myeloid leukemia (AML)			
	Myelodysplastic syndromes (MDS)			
	Non-small cell lung cancer (NSCLC)			
Seliciclib	Non-small cell lung cancer (NSCLC)			
	Nasopharyngeal cancer (NPC)			
Sapacitabine + seliciclib	Solid tumors			
CYC116	Solid tumors			

## DEAR FELLOW STOCKHOLDERS,

The year 2010 was a remarkable period for Cyclacel on several fronts and across our diverse pipeline of oral product candidates for the treatment of cancer. Of greatest significance was the agreement we reached with the U.S. Food and Drug Administration (FDA) for a Special Protocol Assessment (SPA), which defined a registration plan for oral sapacitabine capsules, our lead product candidate. In early 2011, we opened enrollment of SEAMLESS, the pivotal Phase 3 randomized trial

and breast cancer refractory to letrozole or trastuzumab. In late 2010, we unblinded the APPRAISE Phase 2b randomized study of oral seliciclib capsules in patients with NSCLC. While there was no difference in progression free survival, a difference in overall survival was observed favoring seliciclib over placebo. We hope to gain further insight on seliciclib and its activity against NSCLC after analyzing available biopsy samples from APPRAISE patients.

The achievement of several key milestones in 2010 and our scientific expertise in cell cycle biology provide a strong foundation to continue building shareholder value.

of sapacitabine in elderly patients with acute myeloid leukemia (AML) who are not candidates for intensive induction therapy.

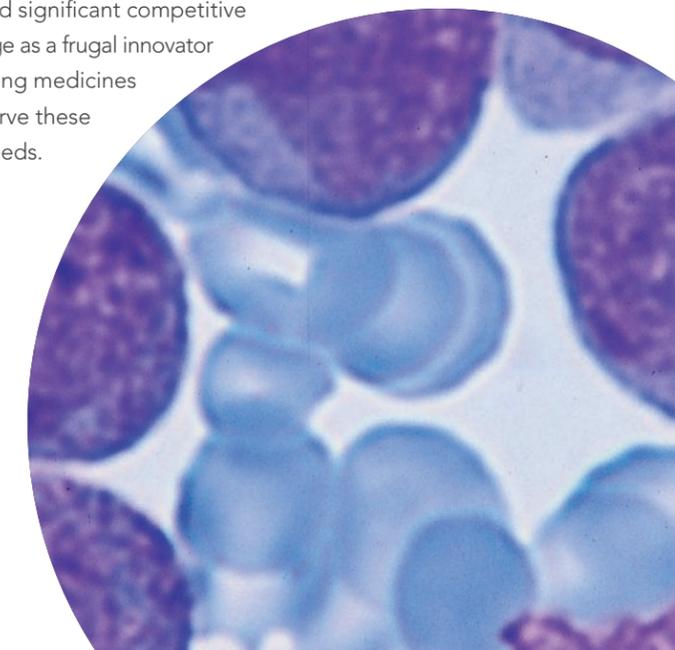
The achievement of several key milestones in 2010 and our scientific expertise in cell cycle biology provide a strong foundation to continue building shareholder value from Cyclacel's portfolio of orally available, cell cycle modulating drugs.

We have been encouraged by the interest from U.S. hematologists in the SEAMLESS trial and sapacitabine's promise. The views of some of these physicians, who participated in Phase 2 clinical trials of sapacitabine in AML, are portrayed in the next section of this year's annual report. Their views are personal assessments and do not necessarily represent the views of Cyclacel or their affiliated institutions. We are grateful to these clinical investigators and their patients who are participating in our trials and we dedicate this annual report to them.

Developed nations are confronting rising healthcare costs and entitlements in an era of aging demographics and financial turmoil. The treatment of cancer is a highly-visible and politically-important topic. As our population ages, society is seeking novel medicines to treat cancers, which are also associated with a high quality of life for patients. Cyclacel's business strategy is to build significant competitive advantage as a frugal innovator developing medicines which serve these social needs.

In late 2010, we also reported Phase 2 survival data of sapacitabine in patients with myelodysplastic syndromes (MDS) and continued to enroll a Phase 2 trial of sapacitabine in patients with non-small cell lung cancer (NSCLC). These studies underscore the breadth of sapacitabine's potential as a treatment for both solid tumors and hematological malignancies.

In early 2010, independent investigators published evidence that seliciclib is active in preclinical tests against highly-resistant cancers, such as KRAS-mutant NSCLC



## SAPACITABINE

In September 2010, we reached agreement with the FDA for a SPA regarding the design of the SEAMLESS study in elderly patients with AML. The SPA agreement indicates 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 in accordance with the SPA. In early 2011, we opened enrollment of the SEAMLESS pivotal Phase 3 study under the SPA in multiple centers across the United States.

With the initiation of the SEAMLESS trial, we are moving closer to our ultimate goal of getting sapacitabine to market. We continue to receive strong support from the hematology community for sapacitabine and its potential. There are few therapeutic alternatives for elderly patients who suffer from AML. Physicians often indicate in medical conferences that the standard of care in elderly AML is to offer patients a clinical trial. The opening of the SEAMLESS trial represents an important new treatment alternative that may be available to participating patients and their physicians. All of us at Cyclacel, who deeply care about patients in this area of unmet medical need, are proud to have reached this important milestone.

In December 2010, we reported one-year survival data from a Phase 2 randomized clinical trial of sapacitabine in older patients with MDS refractory to the hypomethylating agents, azacitidine and/or decitabine, which are approved as front-line treatment for high-risk MDS. Approximately half of the patients in our study had progressed on azacitidine, one-third on decitabine, a quarter on both agents and 18% had also progressed on previous treatment with lenalidomide. The study was a three-arm trial designed to select an optimal dosing schedule in the event that more than one dosing schedule was active.

We were encouraged to see activity in all three schedules. The primary endpoint of one-year survival was achieved in 29% of patients in Arm A, 30% in Arm B and 35% in Arm C. Median overall survival was 217 days for Arm A (range of 15 to 663 days), 232 days for Arm B (range of 37 to over 811 days) and 236 days for Arm C

(range of 16 to over 672 days). The survival data indicate that sapacitabine is promising and warrants further development in this setting. We plan to initiate discussions with the FDA regarding potential registration pathways in MDS patients refractory to hypomethylating agents.

During the year we continued to treat patients in a Phase 2, open label, single arm, multicenter, clinical trial of sapacitabine in patients with NSCLC, who have failed one or more prior chemotherapy regimens. This study builds on data from two Phase 1 studies of sapacitabine that demonstrated prolonged stable disease of four months or longer in heavily-pretreated NSCLC patients. The primary objective of the Phase 2 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, one-year survival, overall survival and safety.

In October 2010, we published preclinical model data demonstrating that sapacitabine works synergistically with histone deacetylase (HDAC) inhibitors to induce tumor cell death *in vitro* and *in vivo*.

## SELICICLIB

In December 2010, we announced top line data from the APPRAISE, Phase 2b, randomized discontinuation, double-blinded, placebo-controlled study of oral seliciclib capsules as a third line or later treatment in patients with NSCLC. The data showed no difference in median progression free survival (PFS) between the seliciclib and placebo arms (48 versus 53 days respectively). However an increase in median overall survival favoring seliciclib over placebo (388 versus 218 days respectively) was observed.

This is a provocative finding in light of the poor prognosis for such heavily-pretreated patients. To further understand seliciclib's activity in this setting, we plan to collect and analyze available biopsy samples from APPRAISE patients who granted informed consent. The purpose of the biopsy analysis is to examine whether there is a biological marker or genetic profile basis for the difference in overall survival which may correlate with seliciclib's activity.

In early 2010, independent investigators published preclinical model data showing that seliciclib is active against highly-resistant cancers, such as KRAS-mutant NSCLC and breast cancer refractory to letrozole or trastuzumab. Cyclin E overexpression was found by the investigators to be associated with the development of resistance to certain existing anticancer treatments and an indicator of poor prognosis in breast and lung cancers. The authors highlighted the ability of seliciclib and also CYC065, our next-generation CDK inhibitor, to suppress cyclin E.

## OTHER DEVELOPMENTS

During the year, investigators from Massachusetts General Hospital Cancer Center announced preclinical data demonstrating that CYC065 showed anticancer activity and induced apoptosis against myeloma cells derived from patients, even in the presence of growth stimulatory effects of both cytokines and stromal cells in the bone marrow. In early 2011, investigators from Vall d'Hebron University Hospital published preclinical data demonstrating that cyclin E plays a major role in making Human Epidermal growth factor Receptor 2 positive (HER2+) breast cancer resistant to trastuzumab. Future efforts to progress our CYC116, Aurora kinase inhibitor, second generation CDK inhibitors and Polo Kinase inhibitors will be undertaken when appropriate resources become available.

## FINANCIAL CONDITION

During 2010 we raised approximately \$36 million through private placement and direct offerings and ended the year with approximately \$29.5 million in cash and cash equivalents. We expect our cash resources are sufficient to meet anticipated short-term working capital needs and fund on-going sapacitabine clinical trials for at least the next twelve months. We continue to be frugal in managing our financial resources while at the same time building shareholder value.

## 2011 OUTLOOK

Our major objectives for 2011 are to:

- Continue enrolment of the SEAMLESS pivotal Phase 3 study of sapacitabine in AML;
- Present additional sapacitabine data in hematological malignancies both as a single agent and in combination with other anticancer agents;
- Report interim Phase 2 sapacitabine data in NSCLC; and
- Report biomarker analysis from the APPRAISE Phase 2b study of seliciclib in NSCLC.

Throughout 2010, our team at Cyclacel has delivered on its goals and objectives by advancing sapacitabine to Phase 3 in AML under a SPA with FDA, building value on possible line extensions in MDS and NSCLC, and potentially building a scientific and business rationale for enhancing value in our CDK inhibitor program in NSCLC. As we enroll the SEAMLESS Phase 3 study, we continue to develop alternative commercialization strategies in targeted indications, both on our own and with potential partners.

The methodical, resilient and highly professional work ethic of our employees is a major reason for our continued progress both in terms of scientific and business objectives. It is a privilege to work alongside such a group. We are excited about our prospects in 2011, continuing to pursue our business strategy and serving patient needs with the help of our clinical investigators. Thank you for your continued support.



Spiro Rombotis  
President and Chief Executive Officer  
March 31, 2011



## ACUTE MYELOID LEUKEMIA (AML)

For over a decade Cyclacel has been dedicated to the understanding of the biology of the cancer cell cycle and translating advances in this area of science into novel therapeutics to benefit cancer patients. The recent opening for enrollment of the first Phase 3 trial in Cyclacel's history represents a culmination of the work of many employees, advisors and collaborators.

### SEAMLESS PHASE 3 STUDY

The Phase 3 study, called SEAMLESS, is a pivotal, randomized trial of sapacitabine in elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia (AML) who are not candidates for intensive induction chemotherapy. SEAMLESS builds on promising one-year survival observed in elderly patients aged 70 years or older with newly diagnosed AML or AML in first relapse enrolled in a Phase 2 study of single agent sapacitabine.

The study is being conducted under a Special Protocol Assessment (SPA) agreement that Cyclacel reached with the U.S. Food and Drug Administration (FDA). The SEAMLESS study is chaired by Hagop M. Kantarjian, M.D., Chairman and Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center, Houston, Texas. As the Principal Investigator of both Phase 1 and Phase 2 trials of sapacitabine in hematologic malignancies, Dr. Kantarjian has been instrumental in helping Cyclacel move sapacitabine to Phase 3 status for the front-line treatment of elderly patients suffering from AML.

### AML: A LIFE-THREATENING DISEASE

AML is a cancer of the blood cells that progresses rapidly and if not treated, could be fatal in a few months. AML is generally a disease of older people and is uncommon before the age of 40. The average age at the time of AML diagnosis is about 67 years. There are more than 12,300 new cases of AML, of which about half occurred in older patients, and nearly 9,000 deaths caused by this cancer each year in the United States underscoring the high unmet medical need in this patient population.

Survival of older or elderly patients with AML is poor and has not improved in the last three decades. A recently published randomized study of patients with AML aged 70 years or older receiving front line treatment found that median overall survival in this group was approximately three months.<sup>1</sup> The reasons for poor survival include the inability to tolerate intensive therapy resulting from concomitant medical illnesses and organ dysfunction, and a greater resistance to therapy as a result of pre-existing or antecedent hematological disease (AHD), such as myelodysplastic syndromes (MDS) or myeloproliferative diseases (MPD). There are few treatment options for patients who are not candidates for standard induction chemotherapy.

<sup>1</sup> Harousseau JL, et al, *Blood* 2009 114 1166-1173.

## INVESTIGATOR PERSPECTIVES

Following are excerpts from interviews with three investigators who took part in the recently reported Phase 2 study of sapacitabine in AML and are also participating in the SEAMLESS Phase 3 study. They are: David Claxton, M.D., Penn State Cancer Institute, Hershey, PA; Stuart Goldberg, M.D., John Theurer Cancer Center, Hackensack, NJ; and Karen Seiter, M.D., New York Medical College, Valhalla, NY. These investigators are leukemia experts who are also experienced investigators in clinical trials, specifically in acute myeloid leukemia, myelodysplastic syndromes, lymphoma, stem cell and bone marrow transplantation.

All three investigators agreed that there is a high unmet medical need in the population of elderly patients with AML. They noted that finding a therapeutic alternative to offer to their elderly patients who are unable to tolerate intensive chemotherapy was a significant factor which attracted them to consider the sapacitabine studies. "These patients have few options and are often too frail to make it through conventional 7+3 chemotherapy," commented Dr. Seiter.

“These patients have few options and are often too frail to make it through conventional 7+3 chemotherapy.”

– KAREN SEITER, M.D.

Events over the past eighteen months have exacerbated this unmet patient need. Several drugs under clinical investigation in older or elderly patients with AML have failed in randomized Phase 2 or Phase 3 studies or encountered clinical or regulatory setbacks. Dr. Goldberg remarked that one of these drugs, gemtuzumab ozogamicin, was on the market after receiving accelerated approval for relapsed or refractory AML. However, as a confirmatory study failed to demonstrate an improvement in overall survival, it was voluntarily withdrawn from the market.

In light of the challenges posed by the disease and the decline in investigational drug protocols on offer for elderly patients with AML, what attracted these investigators to participate in sapacitabine clinical studies?

Dr. Seiter commented that "preclinical safety and efficacy demonstrated by the test drug, as well as unmet medical need, were important factors." In addition she noted that investigator enthusiasm for a new drug is often determined by their initial clinical experience with the new agent. Citing data she presented at a joint NCI-ASCO symposium on Cancer Trial Accrual in April 2010, it was shown that if investigators observed clinical benefit with few toxicities in their first few patients, they were more likely to continue contributing patients to the trial, as opposed to when they encountered difficulties.

Dr. Claxton agreed that manageable toxicities and clinical benefit of an investigational drug could increase investigator enthusiasm in entering patients into a clinical trial. "We saw reduced blast counts in a number of the first few patients we treated with sapacitabine. As long you can manage toxicities as they may come along and you see clinical benefit, you get excited as an investigator."

As is common with anticancer drugs in clinical trials, there is a learning curve for investigators treating patients with sapacitabine for the first time. All three investigators agreed that it is important to monitor patient blood counts, especially in the first few treatment cycles. Depending on baseline values, doses in some patients may need to be reduced or held until counts recover. After the initial cycles, patients who respond often do well with the dose adjustments. The investigators found this to be one of the most interesting aspects of sapacitabine therapy. They observed that while the agent has the ability to reduce excessive blast counts in AML patients who are often frail and have comorbidities, following the initial few cycles many patients can take the drug over long periods of time as an oral therapy.

## Sapacitabine Orphan Drug Protection

Sapacitabine has been designated an Orphan Drug by FDA and EMA for use in the treatment of patients with both AML and MDS.

Under the Orphan Drug law, companies developing drugs for a disorder affecting fewer than 200,000 people in the United States may enjoy market exclusivity for seven years in parallel with available patent life and may be eligible for certain tax incentives. The European Union's orphan designation confers similar benefits and 10 years of exclusivity.

“ We saw reduced blast counts in a number of the first few patients we treated with sapacitabine. As long you can manage toxicities as they may come along and you see clinical benefit, you get excited as an investigator. ”

– DAVID CLAXTON, M.D.

Dr. Goldberg noted that oral dosing allows patients to be followed by their community hematologists/oncologists in partnership with the clinical investigator, allowing local physicians to participate in the treatment plan. Unlike conventional chemotherapy, it may take several cycles of treatment for patients to achieve a response, which can sometimes occur as late as 9 cycles. This feature of the sapacitabine treatment experience provides a rationale for continuing treatment.

The investigators were eager to share anecdotal stories of patients they treated in sapacitabine trials:

Dr. Seiter shares the story of an elderly woman treated in the Phase 2 trial of sapacitabine who achieved 24 cycles of treatment with the drug. This patient often comes to the hospital while pushing her elderly husband who is wheel-chair bound and has to carry oxygen with him because of respiratory difficulties. New staff are frequently surprised to learn that it is not the husband but the wife who is the patient being treated for AML.

Dr. Claxton recounts his enthusiasm in reviewing the charts of some of his patients in the Phase 2 AML study showing remarkable declines in blasts in the first several cycles. He specifically recalls a 70-year old patient with secondary AML and a history of prior chemotherapy and radiation for lung cancer who entered remission on sapacitabine and then enjoyed a 14-month remission with excellent quality of life.

Dr. Goldberg recalls the case of an AML patient from the Phase 2 sapacitabine study. The patient was an 80-year old grandmother, who while on treatment with sapacitabine, was physically able to continue working at her job as a school crossing guard and also join her grandchildren on a family vacation in Florida. Dr. Goldberg believes that “the oral dosing of sapacitabine is a quality of life game changer”. “Subjecting elderly patients to 7 + 3 chemotherapy and probably prolonged hospitalization near the end of life is both unfair and unacceptable, and something that can be avoided with oral delivery of sapacitabine,” continued Dr. Goldberg.

“The oral dosing of sapacitabine is a quality of life game changer. ”

– STUART GOLDBERG, M.D.

All three investigators remain enthusiastic and are eager to participate in the SEAMLESS Phase 3 study. They have volunteered to mentor and share their experiences with new investigators that may participate in the Phase 3 trial who have no or limited experience with the drug.

Cyclacel is very grateful for the dedication and support of all clinical investigators who contributed their expertise in treating patients with AML to sapacitabine clinical trials, including the recently reported Phase 2 clinical trial of sapacitabine in AML, and those participating in the SEAMLESS Phase 3 study.

## Directory

### Corporate Headquarters

200 Connell Drive, Suite 1500  
Berkeley Heights, NJ 07922  
United States of America  
T: +1 908 517 7330  
F: +1 866 271 3466

1 James Lindsay Place  
Dundee DD1 5JJ  
United Kingdom  
T: +44 1382 206 062  
F: +44 1382 206 067

### Website

[www.cyclacel.com](http://www.cyclacel.com)

### Accountants

Ernst & Young  
George House  
50 George Square  
Glasgow G2 1RR  
United Kingdom  
T: +44 141 626 5000

### Transfer Agents

American Stock Transfer  
& Trust Company  
6201 15th Avenue, 2nd Floor  
Brooklyn, NY 11219  
T: +1 718 921 8124

### Attorneys

Mintz Levin Cohn Ferris  
Glovsky & Popeo PC  
Chrysler Center  
666 Third Avenue  
New York, NY 10017  
T: +1 212 935 3000

### SEC Form 10-K

Enclosed is a copy of our Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission. Additional copies are available without charge upon request to:

Cyclacel Pharmaceuticals, Inc.  
Attn: Investor Relations  
200 Connell Drive, Suite 1500  
Berkeley Heights, NJ 07922  
United States of America  
T: +1 908 517 7330

### Executive Management

Spiro Rombotis  
President and Chief Executive Officer

Paul McBarron  
Executive Vice President, Finance and  
Chief Operating Officer, Secretary

Judy Chiao, M.D.  
Vice President, Clinical Development  
and Regulatory Affairs

Robert Sosnowski  
Vice President, Sales and Marketing

Susan Davis, Ph.D.  
Director, Business Development

### Board of Directors

David U'Prichard, Ph.D.  
Chairman

Nicholas Bacopoulos, Ph.D.

Sir John Banham

Christopher S. Henney, Ph.D., D.Sc.  
Vice Chairman

Daniel K. Spiegelman

Spiro Rombotis  
President and Chief Executive Officer

Paul McBarron  
Executive Vice President, Finance and  
Chief Operating Officer, Secretary

### Forward-Looking Statements

This annual report contains certain forward-looking statements. Actual results may differ materially from those predicted herein due to certain risks and uncertainties inherent in the Company's business, which are discussed in the Company's Form 10-K for the fiscal year ended December 31, 2010. Further information on the factors and risks that could affect the Company's business, financial condition and results of operations are contained in Cyclacel's public disclosure filings with the U.S. Securities and Exchange Commission, which are available at [www.sec.gov](http://www.sec.gov).

### Stock Listing

Cyclacel's stock is traded on NASDAQ under the symbol CYCC for the common stock and CYCCP for the preferred stock. For more information, please visit [www.cyclacel.com](http://www.cyclacel.com).

### Annual Meeting

Cyclacel stockholders are invited to attend our annual meeting, which will be held at 12:30 p.m. Eastern on May 24, 2011 at our corporate headquarters at 200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922.

*Cell cycle pioneers:  
Improving patient lives with  
orally-available innovative medicines*



**CYCLACEL<sup>®</sup>**

[www.cyclacel.com](http://www.cyclacel.com)

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, 2010

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  
(State or Other Jurisdiction  
of Incorporation or  
Organization)

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

200 Connell Drive  
Suite 1500  
Berkeley Heights, New Jersey  
(Address of principal executive  
offices)

07922  
(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, 2010 (based upon the closing sale price of \$1.72 of such shares on The NASDAQ Global Market on June 30, 2010) was \$63,554,944.

As of March 30, 2011, there were 46,598,688 shares of the registrant's common stock outstanding.

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

None.

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## Explanatory Note

### Overview of Restatement

The Board of Directors of Cyclacel Pharmaceuticals, Inc. (the “Company”), based on the recommendation of its Audit Committee and in consultation with management, has concluded that the following previously issued consolidated financial statements must be restated and should no longer be relied upon because the Company erroneously accrued and included as a current liability its undeclared cumulative preferred stock dividends in such financial statements:

- (a) consolidated balance sheets as of March 31, 2009, June 30, 2009, September 30, 2009, December 31, 2009, March 31, 2010, June 30, 2010, and September 30, 2010 and statement of stockholders’ equity for the year ended December 31, 2009; and
- (b) Selected Financial Data as of and for the year ended December 31, 2009.

As a result, in this Annual Report on Form 10-K for the year ending December 31, 2010, the Company:

- (c) restates its consolidated balance sheet as of December 31, 2009 and its statement of stockholders’ equity for the year ended December 31, 2009;
- (d) amends its Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) as it relates to the year ended December 31, 2009;
- (e) restates its Selected Financial Data as of and for the year ended December 31, 2009; and
- (f) restates its unaudited consolidated balance sheets as of March 31, 2009, June 30, 2009, September 30, 2009, March 31, 2010, June 30, 2010, and September 30, 2010.

### Background on the Restatement

The restated financial statements correct the following error:

#### *Accounting for Preferred Stock Dividends*

During March 2011, the Company became aware of an error with respect to the historical accounting for undeclared dividends associated with the Company’s outstanding preferred stock. The Company’s management determined that undeclared cumulative preferred stock dividends need only be disclosed in the financial statements or in the notes thereto, and not accrued and included as a current liability in the Company’s Consolidated Balance Sheets, as the Company had recorded in prior periods. The effect of correcting the error has been recorded in the applicable restated periods.

### Effects of the Restatement

The following table sets forth the effects of the restatement on affected items within our previously reported consolidated balance sheets:

	As of						
	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009	March 31, 2010	June 30, 2010	September 30, 2010
	\$000	\$000	\$000	\$000	\$000	\$000	\$000
	(unaudited)	(unaudited)	(unaudited)		(unaudited)	(unaudited)	(unaudited)
<b>Other current liabilities</b>							
As originally reported	578	777	1,336	n/a	n/a	n/a	n/a
Adjustment	(307)	(614)	(921)	n/a	n/a	n/a	n/a
As restated	<u>271</u>	<u>163</u>	<u>415</u>	<u>n/a</u>	<u>n/a</u>	<u>n/a</u>	<u>n/a</u>

<b>Accrued and other current liabilities</b>							
As originally reported	n/a	n/a	n/a	6,709	5,818	5,255	5,641
Adjustment	<u>n/a</u>	<u>n/a</u>	<u>n/a</u>	<u>(1,228)</u>	<u>(1,443)</u>	<u>(1,032)</u>	<u>(1,213)</u>
As restated	<u><u>n/a</u></u>	<u><u>n/a</u></u>	<u><u>n/a</u></u>	<u><u>5,481</u></u>	<u><u>4,375</u></u>	<u><u>4,223</u></u>	<u><u>4,428</u></u>
<b>Current liabilities</b>							
As originally reported	8,549	10,686	9,328	9,822	9,511	8,155	7,965
Adjustment	<u>(307)</u>	<u>(614)</u>	<u>(921)</u>	<u>(1,228)</u>	<u>(1,443)</u>	<u>(1,032)</u>	<u>(1,213)</u>
As restated	<u><u>8,242</u></u>	<u><u>10,072</u></u>	<u><u>8,407</u></u>	<u><u>8,594</u></u>	<u><u>8,068</u></u>	<u><u>7,123</u></u>	<u><u>6,752</u></u>
<b>Total liabilities</b>							
As originally reported	9,966	11,212	9,595	9,822	9,511	8,155	7,965
Adjustment	<u>(307)</u>	<u>(614)</u>	<u>(921)</u>	<u>(1,228)</u>	<u>(1,443)</u>	<u>(1,032)</u>	<u>(1,213)</u>
As restated	<u><u>9,659</u></u>	<u><u>10,598</u></u>	<u><u>8,674</u></u>	<u><u>8,594</u></u>	<u><u>8,068</u></u>	<u><u>7,123</u></u>	<u><u>6,752</u></u>
<b>Additional paid-in capital</b>							
As originally reported	222,886	222,932	225,864	226,881	244,991	248,314	250,466
Adjustment	<u>307</u>	<u>614</u>	<u>921</u>	<u>1,228</u>	<u>1,528</u>	<u>1,632</u>	<u>1,813</u>
As restated	<u><u>223,193</u></u>	<u><u>223,546</u></u>	<u><u>226,785</u></u>	<u><u>228,109</u></u>	<u><u>246,519</u></u>	<u><u>249,946</u></u>	<u><u>252,279</u></u>
<b>Deficit accumulated during the development stage</b>							
As originally reported	(207,778)	(214,824)	(217,948)	(222,285)	(227,815)	(234,240)	(238,049)
Adjustment	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>(85)</u>	<u>(600)</u>	<u>(600)</u>
As restated	<u><u>(207,778)</u></u>	<u><u>(214,824)</u></u>	<u><u>(217,948)</u></u>	<u><u>(222,285)</u></u>	<u><u>(227,900)</u></u>	<u><u>(234,840)</u></u>	<u><u>(238,649)</u></u>
<b>Total stockholders' equity</b>							
As originally reported	15,201	8,248	7,947	4,644	17,265	14,154	12,426
Adjustment	<u>307</u>	<u>614</u>	<u>921</u>	<u>1,228</u>	<u>1,443</u>	<u>1,032</u>	<u>1,213</u>
As restated	<u><u>15,508</u></u>	<u><u>8,862</u></u>	<u><u>8,868</u></u>	<u><u>5,872</u></u>	<u><u>18,708</u></u>	<u><u>15,186</u></u>	<u><u>13,639</u></u>

n/a – not applicable

The effects of the restatement did not in any way affect our results of operations, reported loss per share, or cash flows.

The adjustments made as a result of the restatement are also discussed in Note 3 — “Restatement of Previously Issued Financial Statements” of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K. To further review the effects of the accounting errors identified and the restatement adjustments see Part II — Item 6. “Selected Financial Data”, Part II — Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Note 17 — “Selected Quarterly Information” of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K. For a description of control deficiencies identified by management as a result of our internal reviews, and management’s plan to remediate those deficiencies, see Part II — Item 9A. “Controls and Procedures”.

The Company has not amended and does not intend to amend its previously filed Annual Report on Form 10-K/A and Quarterly Reports on Form 10-Q for the periods affected by the restatement. The information that has been previously filed or otherwise reported for these periods has been restated and is superseded by the information in this Annual Report on Form 10-K. As such, the consolidated financial statements and related financial information contained in such previously filed reports should no longer be relied upon, nor should any earnings releases or other communications relating to the Company’s financial performance during these periods be relied upon.

## 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 biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases. 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 February 1, 2011, we paid a quarterly cash dividend in the amount of \$0.15 per share on the Company's 6% Convertible Exchangeable Preferred Stock (“Preferred Stock”). The dividend was paid to the holders of record of the Preferred Stock as of the close business on January 21, 2011.

On January 11, 2011, we opened enrollment of the SEAMLESS pivotal Phase 3 trial for our sapacitabine oral capsules as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia (AML) who are not candidates for intensive induction chemotherapy under a Special Protocol Assessment, or SPA, reached with the U.S. Food & Drug Administration, or FDA.

#### 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 company dedicated to the development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious diseases. We are focused on delivering leading edge therapeutic management of cancer patients based on a clinical development pipeline of novel drug candidates.

##### *Clinical programs*

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

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

Recent highlights of our sapacitabine clinical program are:

- In January 2011, we opened enrollment of the SEAMLESS pivotal Phase 3 trial as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy under an SPA, reached with the FDA;
- In December 2010, we announced one-year survival data for sapacitabine Phase 2 trial for older patients with MDS refractory to the hypomethylating agents azacitidine and/or decitabine at the 2010 American Society of Hematology (ASH) annual meeting;
- In October 2010, we published preclinical model data demonstrating sapacitabine works synergistically with histone deacetylase (HDAC) inhibitors to induce tumor cell death in vitro and in vivo;
- In July 2010, we announced that the FDA granted orphan drug designation to our sapacitabine product candidate for the treatment of both AML and MDS; and
- In June 2010, we reported interim response data for the ongoing Phase 2 clinical trial of sapacitabine in older patients with MDS at the American Society of Clinical Oncology, or ASCO, meeting.

The planning, execution and results of our clinical programs are significant factors that can affect our operating and financial results.

#### *Advancing our additional research and development programs*

We have additional clinical programs in development awaiting further 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. Highlights of some recent developments related to our other research and development programs include:

- In December 2010, we announced topline data from the “APPRAISE”, Phase 2b, randomized discontinuation, double-blinded, placebo-controlled study of oral seliciclib capsules as a third line or later treatment in patients with NSCLC showing no difference in median progression free survival (PFS) between the seliciclib and placebo arms (48 versus 53 days respectively), but an increase in median overall survival (OS) favoring seliciclib over placebo (388 versus 218 days);
- In December 2010, preclinical data from a Cyclacel collaboration was presented at the 2010 ASH Annual Meeting demonstrating that CYC065 is cytotoxic at sub-micromolar concentrations against myeloma cell lines and CD138+ myeloma cells derived from patients. CYC065 demonstrated antiproliferative activity even in the presence of the growth stimulatory effects of both cytokines and bone marrow stromal cells. CYC065 induced apoptosis in myeloma cells as evidenced by the appearance of cleaved PARP;
- In April 2010, preclinical data from a Cyclacel collaboration was presented at the 2010 Annual Meeting of the American Association of Cancer Research (AACR) introducing CYC065, Cyclacel’s oral CDK inhibitor, which has the same target profile as seliciclib, and showing that CYC065 induced apoptosis in HER2 positive breast cancer cell lines refractory to trastuzumab (Herceptin®). CYC065 was also shown in preclinical studies to have anticancer activity in AML cell lines, including those with human mixed-lineage leukemia (MLL) rearrangements, and chronic lymphocytic leukemia (CLL) cells;
- In February 2010, a peer-reviewed journal article demonstrated that seliciclib reversed resistance to the aromatase inhibitor letrozole (Femara®) and inhibited growth of hormone

receptor positive breast cancer cells that had become insensitive to the effects of letrozole; and

- In January 2010, a peer-reviewed journal article demonstrated that seliciclib was effective against lung cancer cell lines and, in particular, those with activating mutations in K-RAS and N-RAS proteins.

### ***Our pipeline and expertise in cell cycle biology***

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 drug candidates that act on the cell cycle including nucleoside analogues, cyclin dependent kinase, or CDK inhibitors and Aurora kinase/Vascular Endothelial Growth Factor Receptor 2, or AK/VEGFR2 inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitor and AK inhibitor drugs, we believe that our drug candidates are differentiated in that they are orally-available and interact with unique target profiles and mechanisms. For example we believe that our sapacitabine is the only orally-available nucleoside analogue to be tested in a Phase 3 trial for AML and in a Phase 2 trial in MDS and seliciclib is the most advanced orally-available CDK inhibitor in Phase 2 trials.

We have retained rights to commercialize our clinical development candidates and our business strategy is to enter into selective partnership arrangements with these programs.

### ***Commercial products***

We market directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. All three products are approved in the United States under FDA 510 (k) or medical device registrations. As described below under “Results of Operations,” for the three years ended December 31, 2008, 2009 and 2010, we recognized product revenue totaling \$0.8 million, \$0.9 million and \$0.6 million, respectively.

### ***General***

From our inception in 1996 through December 31, 2010, 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 2010, our accumulated deficit during the development stage was approximately \$241.8 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical 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 public offerings, private placements, 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. Beginning in 2008, we recognized revenue from sales of commercial products, for the first time, following the ALIGN acquisition in October 2007. We have recognized revenues from inception through December 31, 2010 totaling approximately \$9.1 million of which approximately \$2.3 million is derived from product sales, approximately \$3.1 million from fees under collaborative agreements and approximately \$3.7 million of grant revenue from various government grant awards.

Although our resources are primarily directed towards advancing our anticancer drug candidate sapacitabine through in-house development activities we are also progressing, but with significantly lower levels of investment, 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 continued focus on sapacitabine clinical development and related cost reduction program, research and development expenditures for the year ended December 31, 2010 decreased \$3.4 million, or 34%, from \$9.8 million for the year ended December 31, 2009 to \$6.4 million for the year ended December 31, 2010. Research and development expenditures for the year ended December 31, 2009 were reduced by \$9.1 million, or 48%, from \$18.9 million for the year ended December 31, 2008 to \$9.8 million for the year ended December 31, 2008.

### ***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 3 trial on-going	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, 7, 9	G1/S checkpoint and others
Seliciclib, CYC202	NPC	Phase 2 randomized trial. Lead-in phase only on-going	CDK2, 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.

The American Cancer Society estimates that approximately 16,000 to 20,000 new cases of myelodysplastic syndromes are diagnosed annually in the United States. Patients currently receive hypomethylating agents as first-line treatment. There is no approved 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 non-small cell or 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 3 trials in AML and in Phase 2 for MDS, and seliciclib is the most advanced 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 has been significantly curtailed.

### *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®, 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. In January 2011, we opened enrollment of the SEAMLESS pivotal Phase 3 trial, which will evaluate sapacitabine oral capsules as a front-line treatment in elderly patients aged 70 years or older with newly-diagnosed AML who are not candidates for intensive induction chemotherapy. The study will be conducted under an SPA.

#### *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.

*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 2010, at the ASH annual meeting, we reported 1-year survival data from a Phase 2 randomized trial of oral sapacitabine capsules, a novel nucleoside analogue, in older patients with MDS refractory to hypomethylating agents, such as azacitidine and decitabine.

The study uses a selection design with the objective of identifying a dosing schedule that produces a better 1-year survival rate in the event that all three dosing schedules are active. The study enrolled 61 patients aged 60 or older with MDS refractory to hypomethylating agents randomized across three dosing

schedules of sapacitabine: 21 patients in Arm A, a 7-day low dose regimen (200 mg b.i.d.); 20 patients in Arm B, a 7-day high dose regimen (300 mg b.i.d.) and 20 patients in Arm C, a 3-day high dose regimen (400 mg b.i.d.). Approximately 77% of patients were aged 70 years or older and 84% were scored as intermediate-2 or high risk by IPSS, the International Prognostic Scoring System. Baseline blast counts were between 11% and 29% in 51% of the patients. All patients were previously treated with hypomethylating agents: 43% with azacitidine, 34% with decitabine and 23% were double refractory patients as they were treated with both azacitidine and decitabine (7 on Arm A, 4 on Arm B and 3 on Arm C). Approximately 16% were previously treated with lenalidomide in addition to hypomethylating agents.

The primary endpoint of 1-year survival was achieved in 29% of the patients on Arm A, 30% of the patients on Arm B and 35% of the patients on Arm C. The median overall survival was 217 days on Arm A (range of 15 to 663 days), 232 days on Arm B (range of 37 to over 811 days) and 236 days on Arm C (range of 16 to over 672 days). Overall response rate, a secondary endpoint consisting of the rate of CR, CRp, PR, CRi or hematological improvement, was 24% for patients on Arm A, 35% for patients on Arm B and 15% for patients on Arm C. Two patients achieved a CR both on Arm A. Approximately 20% of all patients received sapacitabine for 4 to 6 cycles and 15% for 7 or more cycles. The mortality rate from all causes within thirty days of randomization was 6.6%.

*Randomized Phase 3 pivotal trial, SEAMLESS, as a front-line treatment in elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy*

On January 11, 2011, we opened enrollment of the SEAMLESS pivotal Phase 3 trial for the Company's sapacitabine oral capsules as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy. The study is being conducted under a SPA agreement that Cyclacel reached with the FDA. SEAMLESS builds on promising 1-year survival observed in elderly patients aged 70 years or older with newly diagnosed AML or AML in first relapse enrolled in a Phase 2 study of single agent sapacitabine.

The SEAMLESS study is chaired by Hagop M. Kantarjian, M.D., Chairman and Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center, Houston, Texas. SEAMLESS is a multicenter, randomized, Phase 3 study comparing three treatment arms. In Arm A sapacitabine is administered in alternating cycles with decitabine, in Arm B sapacitabine is administered alone and in Arm C decitabine is administered alone. The primary efficacy endpoint is overall survival. The study is designed to demonstrate an improvement in overall survival of either of two pairwise comparisons: (1) Arm A versus Arm C or (2) Arm B versus Arm C. Approximately 150 patients per arm or a total of 450 patients from approximately 50 centers will be enrolled. SEAMLESS will be monitored by a Data Safety Monitoring Board (DSMB). A prespecified interim analysis for futility will be performed and reviewed by the DSMB.

On September 13, 2010, we reached agreement with the FDA regarding the SPA, on the design of a pivotal Phase 3 trial, the SEAMLESS trial. An 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, an 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 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.

***Orphan Designation***

*European Union*

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.

## *United States*

In June 2010, we announced that the FDA granted orphan drug designation to our sapacitabine product candidate for the treatment of both AML and MDS. An orphan designation in the United States confers a range of benefits to sponsor companies, including market exclusivity for a period of seven years from the date of drug approval, the opportunity to apply for grant funding from the United States government to defray costs of clinical trial expenses, tax credits for clinical research expenses and a potential waiver of the FDA's application user fee. Orphan status is granted by the FDA to promote the development of new drug therapies for the treatment of diseases that affect fewer than 200,000 individuals in the United States.

## ***Seliciclib***

Although our current clinical development priorities are focused on sapacitabine only, 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, 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.

On December 21, 2010, we announced topline results from APPRAISE, our Phase 2b, randomized discontinuation, double-blinded, placebo-controlled, study of oral seliciclib capsules as a third line or later treatment in patients with NSCLC. Topline results, after unblinding the treatment assignment among

randomized patients, showed that there was no difference between the seliciclib and placebo arms in terms of progression free survival, or PFS, (48 versus 53 days respectively) but an increase in median overall survival was observed favoring the seliciclib arm over the placebo arm (388 versus 218 days respectively). A total of 187 patients from 21 centers in the United States were entered in the study after having progressed on at least two prior therapeutic regimens for their NSCLC. Of these, 53 (28%) were randomized, 27 on seliciclib and 26 on placebo. Forty-five out of 53 randomized patients (85%) received 3 or more prior therapies and 45 out of 53 randomized patients (85%) previously received at least one EGFR inhibitor drug (22 on seliciclib and 23 on placebo). Fourteen patients were crossed-over to the seliciclib arm after their cancer progressed while they were receiving placebo. Study data demonstrated seliciclib to be safe at the administered dose. There was no difference between the seliciclib and placebo arms in terms of PFS of 48 days on the seliciclib arm versus 53 days on the placebo arm. However an increase in median overall survival was observed of 388 days on the seliciclib arm versus 218 days on the placebo arm.

APPRAISE was a double-blinded, randomized study of single agent seliciclib versus best supportive care in patients with NSCLC treated with at least two prior systemic therapies. APPRAISE was led by Chandra P. Belani, M.D. at Milton S. Hershey Medical Center, Penn State University. The study's main objective was to learn the anti-tumor activity of seliciclib as a single agent in refractory NSCLC and help determine further development strategies. The study design was randomized discontinuation. All patients received seliciclib at a dose of 1200 mg twice a day for three days for at least three cycles of two weeks each. Patients who achieved stable disease after three cycles were randomized to continue on seliciclib or receive placebo with best supportive care. Patients in the placebo arm who progressed were given the option to cross-over and again receive seliciclib. The primary efficacy endpoint of APPRAISE was 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 seliciclib 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 seliciclib 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 seliciclib 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 continued with the 191 patients already enrolled until the last enrolled patient had completed follow-up. In accordance with the protocol, we remain blinded to the study data during the whole process.

#### *Phase 2 clinical trials in patients with NPC*

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

Seliciclib treatment resulted in prolonged stable disease in 70% of previously-treated NPC patients, including 3 with stable disease lasting longer than 8 months, suggesting seliciclib inhibits tumor growth in NPC. The data support further clinical development of oral seliciclib in NPC.

### ***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, which 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.

### ***CYC065***

In December 2010, at the ASH conference, we announced the presentation of new preclinical data for CYC065, a novel, orally-available, cell cycle kinase inhibitor currently in IND-directed development. CYC065 and other compounds in a related series target the same key CDK/cyclin complexes which are targeted by seliciclib. CYC065 retains the specificity and mechanism of action of seliciclib, but has increased anti-proliferative potency and improved pharmaceutical properties.

The data was presented by Noopur Raje, M.D., Director of the Center for Multiple Myeloma at Massachusetts General Hospital Cancer Center in Boston and Associate Professor of Medicine at Harvard Medical School. Dr. Raje and colleagues presented results of a study entitled, "CYC065, a Potent Derivative of Seliciclib Is Active In Multiple Myeloma In Preclinical Studies". The data demonstrate that CYC065 is cytotoxic at sub-micromolar concentrations against myeloma cell lines and CD138+ myeloma cells derived from patients. CYC065 demonstrated antiproliferative activity even in the presence of the growth stimulatory effects of both cytokines and bone marrow stromal cells. CYC065 induced apoptosis in myeloma cells as evidenced by the appearance of cleaved PARP.

Cyclacel discovered CYC065 and other novel CDK inhibitors in collaboration with the Cancer Research UK Centre for Cancer Therapeutics at The Institute of Cancer Research (ICR), London, UK.

### ***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. In our polo-like kinase or Plk inhibitor program we have discovered potent and selective small molecule inhibitors of Plk1, a kinase active during cell division, targeting the mitotic phase of the cell cycle. 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 and conditions associated with aberrant cell proliferation including glaucoma, graft-versus-host disease,

idiopathic pulmonary fibrosis, lupus nephritis, 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 disease area until such times that these programs can be partnered and/or progressed should funding become available.

### ***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 classes 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.

### **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 as well as in diseases characterized by uncontrolled cell proliferation. Published data indicate potential benefit in graft-versus-host disease, 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 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, downstream of insulin action, is an essential element in the body's regulation of blood sugar, and is a recognized target for the treatment of Type 2 diabetes. GSK-3 is a serine/threonine protein kinase 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 obese 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.

#### ***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 2008 and 2009, we reduced our workforce across all locations. With the execution of the revised operating plan and continued cost-containment efforts, we currently anticipate that our cash and cash equivalents of approximately \$29.5 million at December 31, 2010 is sufficient to meet our anticipated short-term working capital needs and to fund our on-going sapacitabine clinical trials for 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 the Phase 3 trial in AML and Phase 2 trial in MDS and seliciclib is the most advanced 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.

***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 13 United States patents, we own 6 patents that were granted by the European Patent Office, or EPO, for designated European countries, and 24 issued patents in other countries. The European granted patents expire between 2019 and 2025. In addition to the licenses we hold under the 8 patents issued in the United States, we hold licenses under 54 issued patents worldwide, seven granted by the EPO for

designated European countries and 47 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, specific regimens, pharmaceutical forms of our compounds and synthetic routes where available and appropriate. Claims covering combination therapies, specific regimens 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 or dosed in a certain way. 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 18 patent applications pending in the United States, 14 before the EPO, one pending PCT application still in the international application phase, and over 50 pending patent applications in other countries. 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 29 pending patent applications worldwide to which we have a license or an option to take a license.

Our patent filings for the second-generation CDK inhibitor research program exemplify our patent strategy. Out of several series of discovered in this program we 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 6 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 earliest few applications from this family have resulted in the issuance of European and United States patents with substance of matter claims covering a specific compounds showing activity in preclinical and discovery programs.

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.

### **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.

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 distribution rights to the three commercial products marketed by ALIGN Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. Each of the agreements covering the three products expires in June 2015, at which time we will explore options to renew such agreements. 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.

### **Manufacturing**

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

Sinclair contracts with third party manufacturers to supply finished goods that meet our needs with respect to Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. If any of Sinclair's third party manufacturers 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 and advertise our ALIGN products in industry publications. If commercially justified, 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.

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 can be designed to evaluate the impact of the drug candidate in combination with currently approved drugs.

- *Phase 2:* These clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trial.
- *Phase 3:* These clinical trials are commonly referred to as pivotal clinical trials. If the Phase 2 clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase 3 clinical trials are then undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

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

#### *New Drug Application*

The results of drug candidate development, preclinical testing and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. Once the submission has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or an additional pivotal Phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators do. Once issued, the FDA may withdraw a drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In 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.

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.

#### **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 Astra-Zeneca, Celgene,

Cephalon, Eisai, Eli Lilly, Genzyme, GlaxoSmithKline, Hospira, Johnson & Johnson, Sunesis and Vion. There are two other orally-available CDK inhibitors in Phase 2 clinical trials. PD-0332991 (Pfizer/Onyx) and PHA-848125 (Nerviano Medical Sciences) target different subsets of CDK enzymes and have a different mechanism of action from seliciclib. There are a number of companies, including AstraZeneca, Bayer-Schering, Eisai, Merck, Nerviano Medical Sciences, Pfizer, Piramal Life Sciences, and Roche 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, Nerviano Medical Sciences, Onconova, Takeda-Millennium and Takmira Pharmaceuticals Corporation 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.

### **Employees**

As of March 30, 2011, we had 18 employees. 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.

### **Available information**

We file 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 reports 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. We have not incorporated by reference in this Annual Report on Form 10K the information on, or accessible through, our website. Copies are also available, without charge, from Cyclacel Pharmaceuticals, Inc., 200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922.

## **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.*

### **Risks Associated with Development and Commercialization of Our Drug Candidates**

***Clinical trial designs that were discussed with the authorities prior to their commencement may subsequently be considered insufficient for approval at the time of application for regulatory approval. Thus, our SPA regarding our SEAMLESS trial does not guarantee marketing approval or approval of our sapacitabine oral capsules for the treatment of acute myeloid leukemia.***

On September 13, 2010, we reached agreement with the FDA regarding an SPA on the design of a pivotal Phase 3 trial for our sapacitabine oral capsules as a front-line treatment in elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia, or AML, who are not candidates for intensive induction chemotherapy, or the SEAMLESS trial. An SPA provides trial sponsors with an agreement from the FDA 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. On January 11, 2011, we opened enrollment of the SEAMLESS trial.

An SPA, however, neither guarantees approval nor provides any assurance that a marketing application would be approved by the FDA. There are companies that have been granted SPAs but have ultimately failed to obtain final approval to market their drugs. The FDA may revise previous guidance or decide to ignore previous guidance at any time during the course of clinical activities or after the completion of clinical trials. The FDA may raise issues relating to, among other things, safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Even with successful clinical safety and efficacy data, including such data from a clinical trial conducted pursuant to an SPA, we may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

***The development program for our lead drug candidate sapacitabine is based, in part, on intellectual property rights we license from others and any termination of this license could seriously harm our business.***

Pursuant to the Daiichi-Sankyo license under which we license certain patent rights for sapacitabine, our lead drug candidate, 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. As it is unlikely that regulatory approval for the product will be obtained by September 2011 it is the Company’s intention to negotiate an appropriate amendment to this date on various grounds, among other things, changes that have taken place in the regulatory environment, as provided within the agreement. If negotiation was not successful, litigation could ensue and there would be no assurances as to the result thereof. Termination of the license agreement could seriously harm our

business. 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.

In general, the license may be terminated by us for technical, scientific, efficacy, safety, or commercial reasons on six months notice, or twelve months if after a launch of a sapacitabine-based product, or by either party for material default.

Although we are currently in compliance with all of our material obligations under this license, if we were to breach any such obligations, our counterparty may be entitled to terminate the license. This would restrict or delay or eliminate our ability to develop and commercialize these drug candidates, which could adversely affect our business.

***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.

***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;
- 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.

***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;
- 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.

***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.

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. There are two other-orally available CDK inhibitor in Phase 2 clinical trials. PD-0332991 (Pfizer/Onyx) and PHA-848125 (Nerviano Medical Sciences) target different subsets of CDK enzymes and have a different mechanism of action from seliciclib. We believe that seliciclib is currently the most advanced orally available CDK-specific agent in Phase 2 clinical trials but that there are a number of companies, including AstraZeneca, Bayer-Schering, Eisai, Merck, Nerviano Medical Sciences, Pfizer, Piramal Life Sciences, and Roche 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, Nerviano Medical Sciences, Onconova, Takeda-Millennium and Tekmira Pharmaceuticals Corporation 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 Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges achieve and maintain market acceptance. If our drug candidates are approved by the FDA or by another regulatory authority, the resulting drugs, if any, may not gain market acceptance among physicians, healthcare providers and payors, patients and the medical community. The degree of market acceptance of any of our approved drugs or devices will depend on a variety of factors, including:

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

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

***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.

***Intellectual property rights and distribution rights for our drug candidate seliciclib and ALIGN products are licensed from others, and any termination of these licenses could harm our business.***

We have in-licensed certain patent rights in connection with the development program of our drug candidate seliciclib. 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. We are also obligated to use reasonable efforts to develop and commercialize products based on the licensed patents.

We have in-licensed from Sinclair the distribution rights to the ALIGN products. This license agreement imposes obligations on us and is expected to expire in 2015. 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. In addition, if we unable to extend the term of the license agreement, it would prevent us from distributing the ALIGN products.

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 the seliciclib or sell the ALIGN products, which could adversely affect our business.

***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.

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 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 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 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® Cream, Numoisyn® Liquid and Numoisyn® Lozenges and to recognize revenues on a timely basis is substantially dependent on our ability to maintain commercially reasonable agreements with each of these wholesale distributors and the extent to which these distributors, over whom we have no control, comply with such agreements. Our agreements with wholesaler distributors may contain terms that are not favorable, given our relative lack of market leverage as a company with only three approved products or other factors, which could adversely affect our commercialization of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. 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® Cream, Numoisyn® Liquid or Numoisyn® Lozenges. Although we attempt to monitor wholesaler inventory of Xclair® Cream, Numoisyn® Liquid or Numoisyn® 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® Cream, Numoisyn® Liquid or Numoisyn® Lozenges held by wholesalers can also cause our operating results to fluctuate unexpectedly. For the years ended December 31, 2009 and 2010, approximately 85% and 87%, 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 customer 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 customer demand, as they make estimates to determine customer 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®, Numoisyn® Liquid or Numoisyn® Lozenges in the United States through the use of internal sales forecasts and the expiration dates of product shipped, among other factors.

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

Our successful commercialization of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges in the United States will depend on our ability to establish and maintain an effective sales and marketing organization in the United States. We hired trained and deployed additional marketing personnel and a 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® Cream, Numoisyn® Liquid and Numoisyn® Lozenges and the results of our clinical trials. Prior to our launches of these products, we had never sold or marketed any products.

For our product candidates currently under development, our strategy is to develop compounds through the Phase 2 stage of clinical testing and market or co-promote certain of our drugs on our own. We have limited sales, marketing or distribution capabilities. We will depend primarily on strategic alliances with third parties, which have established distribution systems and sales forces, to commercialize our drugs. To the extent that we are unsuccessful in commercializing any drugs or devices ourselves or through a strategic alliance, product revenues will suffer, we will incur significant additional losses and our share price will be negatively affected.

***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.

## **Risks Related to Our Business and Financial Condition**

***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. 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 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, our most advanced drug candidates for the treatment of cancer, is currently in Phase 3 for AML and Phase 2 for MDS. Seliciclib is currently in Phase 2 clinical trials. A combination trial of sapacitabine and seliciclib is 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 and 2010, our accumulated deficit was \$222.3 million and \$241.8 million, respectively. Our net loss for the years ended December 31, 2008, 2009 and 2010 was \$40.4 million, \$19.6 million and \$16.0 million, respectively. Our net loss applicable to common stockholders from inception through December 31, 2010 was \$282.9 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® Cream, Numoisyn® Liquid and Numoisyn® 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.

***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.

***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;
- 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.

***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.

***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

### **Risks Related to our Intellectual Property**

***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.

***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 United States and 2012 outside the United States. 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.

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;
- 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.

### **Risks Related to Securities Regulations and Investment in Our Securities**

*Failure to achieve and maintain internal controls in accordance with Sections 302 and 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse affect on our business and stock price.*

During March 2011, we identified a deficiency in respect of our internal controls over financial reporting, specifically our controls over the accounting for cumulative preferred stock dividends, that constitutes a material weakness as described in the SEC's guidance regarding Management's Report on Internal Control Over Financial Reporting as of December 31, 2010. As a result of this deficiency, the financial statements included in our Form 10-K for the year ended December 31, 2009, filed on March 29, 2010, as amended by Amendment No. 1 to our Annual Report of Form 10-K/A for the year ended December 31, 2009 filed on May 17, 2010 and as further amended by Amendment No. 2 to our Annual Report on Form 10-K/A for the year ended December 31, 2009 filed on May 19, 2010, included errors related to the presentation and disclosure of undeclared cumulative preferred stock dividends in the consolidated balance sheet and in the statement of stockholders' equity. Unaudited balance sheets for the each of the first three quarters of 2009 and 2010 also contained errors. In addition, in May 2010, we filed an amendment to our Annual Report on Form 10-K for the year ended December 31, 2009, to report a restatement of our financial statements and report a material weakness in our internal control over financial

reporting as of December 31, 2009, specifically related to the operational failure of the controls in place to ensure the correct computation of net loss per share and presentation of preferred stock dividends in the consolidated statement of cash flows.

We have completed a formal process to evaluate our internal controls, including the remediation of the material weakness related to controls over the presentation of preferred stock dividends in the net loss per share calculation and in the statement of cash flows, for purposes of Section 404, and we concluded that the material weakness reported on Form 10-K/A for the year ended December 31, 2009 has been remediated as of December 31, 2010. However our overall assessment was that we did not maintain effective control over financial reporting as of December 31, 2010, as described above.

If we fail to maintain our internal controls or fail to implement required new or improved controls, as such control standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting. Effective internal controls are necessary for us to produce reliable financial reports and are important in the prevention of financial fraud. If we cannot produce reliable financial reports or prevent fraud, our business and operating results could be harmed.

***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, 2010, our internal control over financial reporting was ineffective. As our business grows and changes, there can be no assurances that we can maintain the effectiveness of our internal controls over financial reporting.

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

***Our common stock may have a volatile public trading price.***

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

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.

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

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

Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the Board of Directors approves the transaction. Our Board of Directors could use this provision to prevent changes in management. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

***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 subsequently amended, most recently as of January 1, 2011), 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 December 31, 2010, there were 1,213,142 shares of our preferred stock issued and outstanding. If the transaction were one in which proceeds were received by the Company for distribution to stockholders, and the terms of the Certificate of Designation governing the preferred stock were strictly complied with, approximately \$13,344,563 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.

***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 our preferred stock, and there is no assurance that future quarterly dividends will be declared.***

Delaware law may limit our ability to pay cash dividends on our preferred stock. Under Delaware law, cash dividends on our 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 our 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.

On February 1, 2011, we paid a quarterly cash dividend with respect to fourth quarter of fiscal year 2010. The Board of Directors considered numerous factors in determining whether to declare the quarterly dividend, including the requisite financial analysis and determination of a surplus. While the Board of Directors will analyze the advisability of the declaration of dividends in future quarters, there is no assurance that future quarterly dividends will be declared.

***We have not declared quarterly dividends on our 6% preferred stock for a total of six quarterly dividend periods. As a result, we will have to grant additional rights to our holders of preferred stock with respect to the management of the Company.***

Although our Board of Directors declared the quarterly cash dividend with respect to the fourth quarter of fiscal year 2010, which was paid on February 1, 2011, there are still dividends that have accrued and are unpaid on the preferred stock for at least six quarters. As a result, the holders of our preferred stock are now entitled to nominate and elect two directors to the Company's board of directors. This right accrued to the Preferred Stockholders as of August 2, 2010. We held a special meeting of the holders of our preferred stock to elect two directors to our Board of Directors, which was adjourned because a quorum of the holders of our preferred stock was not present in person or represented by proxy to transact business at the meeting. A quorum was not reached at such adjourned meeting either, and the meeting was not further adjourned. The holders of our preferred stock will have the opportunity at our 2011 annual meeting of stockholders to elect two directors to our Board of Directors. Once elected, the directors elected by the preferred stockholders will have the ability to participate in the management of the Company until all such dividends have been paid in full.

***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 and cause dilution to existing holders of our common stock.***

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 in the first quarter of 2010. In addition, 710,271 shares of preferred stock were converted to 1,416,203 shares of common stock during the second quarter of 2010. 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.

***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.

***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.

#### **Item 1B. Unresolved Staff Comments**

None.

#### **Item 2. Properties**

In October 2006, we entered into a five-year lease for office space of approximately 6,500 square feet in Berkeley Heights, New Jersey, which is our corporate headquarters. In October 2000, we entered into a 25-year lease for our research and development facility in Dundee, Scotland. We 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. On April 27, 2010, we were served with a complaint filed by Celgene Corporation in the United States District Court for the District of Delaware seeking a declaratory judgment that four of our own patents, claiming the use of romidepsin injection in T-cell lymphomas, are invalid and not infringed by Celgene's products, but directly involve the use and administration of Celgene's ISTODAX<sup>®</sup> (romidepsin for injection) product. On June 17, 2010, we filed our answer and counterclaims to the declaratory judgment complaint. We have filed counterclaims charging Celgene with infringement of each of our four patents and seeking damages for Celgene's infringement as well as injunctive relief. The four patents directly involve the use and administration of Celgene's ISTODAX<sup>®</sup> (romidepsin for injection) product.

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

## 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:

	High	Low
<b>2010</b>		
Quarter ended March 31, 2010 .....	\$4.08	\$1.00
Quarter ended June 30, 2010 .....	\$2.97	\$1.38
Quarter ended September 30, 2010.....	\$1.98	\$1.40
Quarter ended December 31, 2010 .....	\$1.95	\$1.44
<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

#### Holder of Common Stock

On March 30, 2011, we had approximately 75 registered holders of record of our common stock. On March 29, 2011, the closing sale price of our common stock as reported by NASDAQ was \$1.38 per share.

## **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 the Board of Directors declared a quarterly dividend on January 11, 2011. The dividend on the Preferred Stock was paid on February 1, 2011 to the holders of record as of the close business on January 21, 2011. As previously disclosed, the Board of Directors did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009 and the first, second and third quarters of fiscal year 2010. The Board of Directors considered numerous factors in determining to declare the quarterly dividend, including the requisite financial analysis and determination of a surplus. While the Board of Directors will analyze the advisability of the declaration of dividends in future quarters, there is no assurance that future quarterly dividends will be declared.

## **Item 6. Selected Financial Data**

This section presents our historical financial data. The consolidated statement of operations data for the years ended December 31, 2008, 2009, 2010 and for the period from August 13, 1996 (inception) to December 31, 2010 and the consolidated balance sheet data as of December 31, 2010 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The Consolidated Balance Sheet Data as of December 31, 2009 has been restated to reflect adjustments to our previously issued consolidated financial statements. The adjustments are also discussed in Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in Note 3 – “Restatement of Previously Issued Financial Statements” included in Item 8 of this Annual Report on Form 10-K.

The statement of operations data for the years ended 2006 and 2007 and the balance sheet data as of December 31, 2006, 2007 and 2008 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.

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 from
	2006	2007	2008	2009	2010	August 13, 1996 (inception) to December 31, 2010
(in thousands, except per share data)						
<b>Consolidated Statements of Operations:</b>						
<b>Revenues:</b>						
Collaboration and research and development revenue	\$ 231	\$ 10	\$ —	\$ —	\$ 100	\$ 3,100
Product revenue	—	—	838	910	574	2,322
Grant revenue	156	119	39	1	12	3,648
<b>Total revenues</b>	<u>387</u>	<u>129</u>	<u>877</u>	<u>911</u>	<u>686</u>	<u>9,070</u>
<b>Operating expenses:</b>						
Cost of goods sold	—	—	429	545	418	1,392
Research and development	21,205	19,569	18,869	9,766	6,414	176,593
Selling, general and administrative	12,598	12,033	15,354	8,538	10,120	81,966
Goodwill and intangibles impairment	—	—	7,934	—	—	7,934
Other restructuring costs	225	1,554	489	366	—	2,634
<b>Total operating expenses</b>	<u>34,028</u>	<u>33,156</u>	<u>43,075</u>	<u>19,215</u>	<u>16,952</u>	<u>270,519</u>
<b>Operating loss</b>	<u>(33,641)</u>	<u>(33,027)</u>	<u>(42,198)</u>	<u>(18,304)</u>	<u>(16,266)</u>	<u>(261,449)</u>
Total other income (expense)	2,138	6,933	63	(2,214)	(412)	5,264
<b>Loss before taxes</b>	<u>(31,503)</u>	<u>(26,094)</u>	<u>(42,135)</u>	<u>(20,518)</u>	<u>(16,678)</u>	<u>(256,185)</u>
Income tax benefit	2,245	2,041	1,749	948	657	17,879
<b>Net loss</b>	<u>(29,258)</u>	<u>(24,053)</u>	<u>(40,386)</u>	<u>(19,570)</u>	<u>(16,021)</u>	<u>(238,306)</u>
Dividend on preferred ordinary shares	(2,827)	—	—	—	—	(38,123)
Deemed dividend on convertible exchangeable preferred shares	—	—	—	—	(3,515)	(3,515)
Dividend on convertible exchangeable preferred shares	—	(307)	(1,227)	(1,228)	(167)	(2,929)
<b>Net loss applicable to common shareholders</b>	<u>\$ (32,085)</u>	<u>\$ (24,360)</u>	<u>\$ (41,613)</u>	<u>\$ (20,798)</u>	<u>\$ (19,703)</u>	<u>\$ (282,873)</u>
<b>Net loss per share – basic and diluted</b>	<u>\$ (2.40)</u>	<u>\$ (1.23)</u>	<u>\$ (2.04)</u>	<u>\$ (0.94)</u>	<u>\$ (0.52)</u>	
<b>Shares used in computing basic and diluted net loss per share</b>	<u>13,390,933</u>	<u>19,873,911</u>	<u>20,433,129</u>	<u>22,196,840</u>	<u>37,844,695</u>	

**As of December 31,**

	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b> (as restated)	<b>2010</b>
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents.....	\$ 44,238	\$ 30,987	\$ 24,220	\$ 11,493	\$ 29,495
Short-term investments .....	9,764	27,766	1,502	—	—
Working capital .....	50,244	49,065	20,387	4,775	24,516
Total assets .....	63,276	75,912	30,957	14,466	31,459
Long-term liabilities, net of current portion .....	(1,436)	(3,231)	(1,688)	—	—
Total stockholders' equity .....	53,919	57,969	20,642	5,872	24,924

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.

## **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, 2010 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 of Restatement**

The Board of Directors, based on the recommendation of its Audit Committee and in consultation with management, has concluded that the following previously issued consolidated financial statements must be restated and should no longer be relied upon because we erroneously accrued and included as a current liability undeclared cumulative preferred stock dividends in such financial statements:

- (a) consolidated balance sheets as of March 31, 2009, June 30, 2009, September 30, 2009, December 31, 2009, March 31, 2010, June 30, 2010, and September 30, 2010 and its statement of stockholders’ equity for the year ended December 31, 2009; and
- (b) Selected Financial Data as of and for the year ended December 31, 2009.

As a result, in this Annual Report on Form 10-K for the year ending December 31, 2010, we:

- (c) restate our consolidated balance sheet as of December 31, 2009 and statement of stockholders’ equity for the year ended December 31, 2009;
- (d) amend our Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) as it relates to the year ended December 31, 2009 and each of the first, second and third quarters of fiscal 2010;
- (e) restate our Selected Financial Data as of and for the year ended December 31, 2009; and
- (f) restate our unaudited consolidated balance sheets as of March 31, 2009, June 30, 2009, September 30, 2009, March 31, 2010, June 30, 2010, and September 30, 2010.

### **Background on the Restatement**

The restated financial statements correct the following error:

#### *Accounting for Preferred Stock Dividends*

During March 2011, we became aware of an error with respect to the historical accounting for undeclared dividends associated with our outstanding preferred stock. We determined that undeclared cumulative preferred stock dividends need only be disclosed in the financial statements or in the notes thereto, and not accrued and included as a current liability in the our consolidated balance sheets, as was

recorded in prior periods. The effect of correcting the error has been recorded in the applicable restated periods.

The adjustments made as a result of the restatement are also discussed in Note 3 — “Restatement of Previously Issued Financial Statements”, of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K. To further review the effects of the accounting errors identified and the restatement adjustments see Part II — Item 6. “Selected Financial Data” and Note 17 – “Selected Quarterly Information” of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K. For a description of control deficiencies identified by management as a result of our internal reviews, and management’s plan to remediate those deficiencies, see Part II — Item 9A. “Controls and Procedures”.

We have not amended and do not intend to amend our previously filed Annual Report on Form 10-K/A and Quarterly Reports on Form 10-Q for the periods affected by the restatement. The information that has been previously filed or otherwise reported for these periods has been restated and is superseded by the information in the Annual Report on Form 10-K. As such, the consolidated financial statements and related financial information contained in such previously filed reports should no longer be relied upon, nor should any earnings releases or other communications relating to the Company’s financial performance during these periods be relied upon.

## **Overview**

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 awaiting further 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.

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 3 trial in AML and in Phase 2 for MDS and seliciclib is the most advanced 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 continued focus on sapacitabine clinical development and related cost reduction program, research and development expenditures for the year ended December 31, 2010 decreased \$3.4 million, or 34%, from \$9.8 million for the year ended December 31, 2009 to \$6.4 million for the year ended December 31, 2010. Research and development expenditures for the year ended December 31, 2009 were reduced by \$9.1 million, or 48%, from \$18.9 million for the year ended December 31, 2008 to \$9.8 million for the year ended December 31, 2009.

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 Dundee, Scotland.

From our inception in 1996 through December 31, 2010, 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, 2010, our accumulated deficit during the development stage was approximately \$241.8 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 are comprised research and development expenses and selling, 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, collaborations, interest on investments, government grants and research and development tax credits. We have recognized revenues from inception through December 31, 2010 totaling approximately \$9.1 million, of which approximately \$3.1 million is derived from fees under collaborative agreements, approximately \$3.7 million of grant revenue from various United Kingdom government grant awards, and approximately \$2.3 million from product sales. We have also recognized \$17.9 million in research and development tax credits, which are reported as income tax benefits on the consolidated statements of operations, from the United Kingdom's tax authority, H.M. Revenue & Customs since inception.

#### **Recent Events**

On February 1, 2011, we paid a quarterly cash dividend in the amount of \$0.15 per share on the Company's 6% Convertible Exchangeable Preferred Stock, or Preferred Stock. The dividend was paid to the holders of record of the Preferred Stock as of the close business on January 21, 2011.

The Board of Directors considered numerous factors in determining whether to declare the quarterly dividend, including the requisite financial analysis and determination of a surplus. While the Board of Directors will analyze the advisability of the declaration of dividends in future quarters, there is no assurance that future quarterly dividends will be declared.

## Results of Operations

Years ended December 31, 2009 and 2010 compared to years ended December 31, 2008 and 2009, respectively.

### Revenues

The following table summarizes the components of our revenues for the years ended December 31, 2008, 2009 and 2010:

	Years ended			\$ Differences		% Differences	
	2008	2009	2010	2008 to 2009	2009 to 2010	2008 to 2009	2009 to 2010
	(in thousands)						
Collaboration and research and development revenue	\$ —	\$ —	\$ 100	\$ —	\$ 100	— %	100%
Product Revenue	838	910	574	72	(336)	9 %	(37)%
Grant revenue	39	1	12	(38)	11	(97)%	1,100%
Total revenue	<u>\$ 877</u>	<u>\$ 911</u>	<u>\$ 686</u>	<u>\$ 34</u>	<u>\$ (225)</u>	4 %	(25)%

Collaboration and research and development revenue in 2010 is derived from an agreement with a pharmaceutical company under which we provided one of our compounds for evaluation. 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, 2009 and 2010, we recognized approximately \$0.8 million, \$0.9 million, and \$0.6 million in revenues, respectively. The decrease in product revenue for the year ended December 31, 2010 versus that in the prior year was due to a higher than anticipated amount of product returns approximating \$0.2 million, related to expiring product with a two-year shelf-life previously sold into the marketplace. Additionally, we increased our provisions for product returns and have fully reserved against shipped products approaching and within six months of expiration. Additionally, we increased our provisions for product returns and have fully reserved against shipped products approaching and within six months of expiration.

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 and European Union grant awards. For the years ended 2008, 2009 and 2010, we had grant revenue of \$39,000, \$1,000 and \$12,000, respectively. The increase in 2010 was as a result of finalizing a three year European Union grant which concluded in 2010.

### The future

This was the third full year of ALIGN product sales since we acquired ALIGN in October 2007. We expect to continue to maintain the sales of ALIGN products in 2011 through the support of a small sales and marketing infrastructure. We do not expect grant revenue to increase over the next 12 months as no awards are expected in this period.

### Cost of goods sold

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2008 to 2009</u>	<u>2009 to 2010</u>	<u>2008 to 2009</u>	<u>2009 to 2010</u>
			(in thousands)				
Cost of goods sold	\$ 429	\$ 545	\$ 418	\$ 116	\$ (127)	27%	(23)%

Cost of goods sold includes the cost of ALIGN products that have been delivered to our customers and for which revenues have been recognized. The reduction in the cost of sales in 2010 was due to lower product revenues. Total cost of goods sold represented 51% and 60% of product revenue for the years ended December 31, 2008 and 2009, respectively. The cost of sales for the year ended December 31, 2010 represented 73% of product revenues and in the future we expect to maintain a similar margin level as we incurred in 2009.

### Research and development expenses

From our inception, 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 has been realized in 2009 and 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.

The following table provides information with respect to our research and development expenditures for the years ended December 31, 2008, 2009 and 2010:

	Years ended			\$ Differences		% Differences	
	2008	2009	2010	2008 to 2009	2009 to 2010	2008 to 2009	2009 to 2010
Sapacitabine	\$ 6,601	\$ 7,001	\$ 5,222	\$ 400	\$ ( 1,779)	6 %	(25) %
Seliciclib	2,906	(84)	53	(2,990)	137	(103) %	163 %
CYC116	1,695	162	25	(1,533)	(137)	(90) %	(85) %
Other costs related to research and development programs, management and exploratory research	<u>7,667</u>	<u>2,687</u>	<u>1,114</u>	<u>(4,980)</u>	<u>(1,573)</u>	(65) %	(59) %
Total research and development expenses	<u>\$ 18,869</u>	<u>\$ 9,766</u>	<u>\$ 6,414</u>	<u>\$ (9,103)</u>	<u>\$ (3,352)</u>	(48) %	(34) %

Research and development expenses represented 44%, 51% and 38% of our operating expenses for the years ended December 31, 2008, 2009 and 2010, respectively. Included in research and development expenses is stock-based compensation of approximately \$0.7 million, \$0.3 million and \$0.4 million for the years ended December 31, 2008, 2009 and 2010, respectively.

*Fiscal 2010 as compared to fiscal 2009.* Research and development costs decreased by 34%, or approximately \$3.4 million, from approximately \$9.8 million for the year ended December 31, 2009 to approximately \$6.4 million for the year ended December 31, 2010. Approximately \$1.7 million was due to closing out of all programs other than sapacitabine. Research and development costs associated with the sapacitabine program decreased by approximately \$1.6 million due largely to capsule manufacture costs incurred in 2009 that were not necessary in 2010.

*Fiscal 2009 as compared to fiscal 2008.* Research and development costs decreased by 48%, 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 sapacitabine clinical trials and, as a result, the research and development costs were reduced by approximately \$9.1 million in 2009 from 2008. Sapacitabine program costs increased by approximately \$0.4 million due to the increase in clinical trial costs of running the AML and MDS programs.

#### *The future*

We will continue to concentrate our resources on the development of sapacitabine. We anticipate that overall research and development expenditures in 2011 will increase as we enroll the SEAMLESS pivotal Phase 3 trial.

### 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, 2008, 2009 and 2010:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2008 to</u>	<u>2009 to</u>	<u>2008 to</u>	<u>2009 to</u>
			(in thousands)	<u>2009</u>	<u>2010</u>	<u>2009</u>	<u>2010</u>
Total selling, general and administrative expenses	\$15,354	\$8,538	\$10,120	\$ (6,816)	\$1,582	(44)%	19%

Total selling, general and administrative expenses represented 36%, 44% and 60 % of our operating expenses for the years ended December 31, 2008, 2009 and 2010, respectively.

*Fiscal 2010 as compared to fiscal 2009.* Selling, general and administrative expenses increased by 19%, or \$1.6 million, to \$10.1 million for the year ended December 31, 2010, from approximately \$8.5 million for the year ended December 31, 2009. This was primarily due to increased consultancy and professional costs of approximately \$1.0 million, an increase in stock compensation costs of \$0.9 million, and an increase in legal costs of \$0.5 million. This was partially offset by reductions in employment related costs of \$0.4 million and intellectual property costs of \$0.2 million.

*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 costs 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.

#### *The future*

We expect our selling, general and administrative expenditures in 2011 to remain at the same level or to be less than our expenditures in 2010.

### Goodwill and intangible asset impairment

The following table summarizes the goodwill and intangibles impairment charges for the years ended December 31, 2008, 2009 and 2010:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2008 to</u>	<u>2009 to</u>	<u>2008 to</u>	<u>2009 to</u>
			(in thousands)	<u>2009</u>	<u>2010</u>	<u>2009</u>	<u>2010</u>
Goodwill and intangibles impairment	\$ 7,934	\$ —	\$ —	\$ (7,934)	\$ —	(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 ASC, Codification Topic 360, entitled “Property, Plant and Equipment,” or ASC 360. An impairment charge of approximately \$3.6 million 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 asset group comprising the intangible assets on September 30, 2008.

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 fair value of the reporting unit to be less than its carrying value on December 31, 2008, leading to a write-down of the goodwill residing in that reporting unit.

*The future*

Previously recognized goodwill and intangible assets acquired have been fully impaired as of December 31, 2008. Accordingly, there can be no further write-downs of these assets in 2011.

Restructuring charge

The following table summarizes the restructuring charges for years ended December 31, 2008, 2009 and 2010:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2008 to 2009</u>	<u>2009 to 2010</u>	<u>2008 to 2009</u>	<u>2009 to 2010</u>
				(in thousands)			
Total restructuring charge	\$ 489	\$ 366	\$ —	\$ (123)	\$ —	(25) %	— %

*Fiscal 2010 as compared to fiscal 2009.* There was no restructuring charge for the year ended December 31, 2010, as compared to a charge of \$0.4 million for the year ended December 31, 2009. During 2009, we reduced our workforce by twenty-six (26) people as part of a revision of our operating plan to concentrate our resources on the advancement of our lead drug, sapacitabine. There were no such reductions in 2010.

*Fiscal 2009 as compared to fiscal 2008.* The restructuring charge decreased by 25% 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 began revising our operating plan to concentrate 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 accrued a charge of \$0.1 million in respect of costs of exiting the lease of our redundant Cambridge, England, research facility.

*The future*

During the fourth quarter of 2010, we did not renew the lease on a manufacturing facility in Bothell, Washington. We have met all our obligations against the lease and there will be no further accretion expense associated with the restructuring liability.

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, 2008, 2009 and 2010:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2008 to 2009</u>	<u>2009 to 2010</u>	<u>2008 to 2009</u>	<u>2009 to 2010</u>
			(in thousands)				
Payment under guarantee	\$ —	\$ (1,652)	\$ —	\$ (1,652)	\$1,652	(100) %	100 %
Change in valuation of warrants liability.....	3,502	(299)	(338)	(3,801)	(39)	(109) %	(13) %
Amendment to CEFF warrants	—	(44)	—	(44)	44	(100) %	100 %
Foreign Exchange gain/(loss)	(4,501)	(144)	(68)	4,357	76	97 %	53 %
Interest income	1,380	102	37	(1,278)	(65)	(93) %	(64) %
Interest expense	(318)	(177)	(43)	141	134	44 %	76 %
Total other income (expense), net	<u>\$ 63</u>	<u>\$ (2,214)</u>	<u>\$ (412)</u>	<u>\$ (2,277)</u>	<u>\$1,802</u>	<u>(3,614) %</u>	<u>81 %</u>

*Fiscal 2010 as compared to fiscal 2009.* Total other income (expense), net, decreased by approximately \$1.8 million from a loss of \$2.2 million in 2009 to a loss of \$0.4 million in 2010, mainly due the \$1.6 million charge for the payment under guarantee to the Scottish Enterprise in 2009 and, to a lesser extent, the reduction in interest income of \$0.1 million arising from lower yields available on lower average interest bearing cash and cash equivalents and \$0.1 million in interest expense. The differences related to these items are explained further below.

*Change in valuation of warrants liability*

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 are classified as and are being accounted for as a liability. The value of the warrants is being marked to market each reporting period as a derivative gain or loss until exercised or expiration. For each of the years ended December 31, 2009 and 2010, we recognized an expense of approximately \$0.3 million in 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 are 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, 2010, unfavorable unrealized foreign exchange movements related to intercompany loans

recorded in other comprehensive income totaled \$2.1 million compared to favorable unrealized foreign exchange movements of \$5.7 million in 2009.

Foreign exchange gains/losses not related to intercompany loans are recorded in income (expense). Foreign exchange gain/(loss) was a \$68,000 expense for the year ended December 31, 2010, compared to a \$144,000 expense for the year ended December 31, 2009.

#### *Interest Income*

Interest income decreased by approximately \$65,000, from \$102,000 for the year ended December 31, 2009 to \$37,000 for the year ended December 31, 2010. 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 2010 as compared to 2009.

#### *Interest Expense*

Interest expense decreased by \$134,000, from \$177,000 for year ended December 31, 2009 to \$43,000 for the year ended December 31, 2010. This is due largely to the reduction in accretion expense associated with the Bothell restructuring lease, which expired in December 2010. For each of the years ended December 31, 2009 and 2010, we recorded accretion expense associated with the Bothell restructuring lease of \$127,000 and \$42,000, respectively.

*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 warrants liability*

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 are classified as and are being accounted for as a liability. 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)*

For the year ended December 31, 2009 favorable unrealized foreign exchange movements recorded in other comprehensive income totaled \$5.7 million compared to unfavorable foreign exchange movements of \$12.3 million in 2008.

Foreign exchange gains/losses not related to 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 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*

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 2009 as compared to 2008.

*Interest Expense*

Interest expense decreased approximately \$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 the years ended December 31, 2008 and 2009, we recorded accretion expense associated with the Bothell restructuring lease of \$0.2 million and \$0.1 million, respectively on the consolidated statement of operations as interest expense.

*The future*

The valuation of the warrants 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 intercompany 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.

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, 2008, 2009 and 2010:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2008 to 2009</u>	<u>2009 to 2010</u>	<u>2008 to 2009</u>	<u>2009 to 2010</u>
			(in thousands)				
Total income tax benefit	\$ 1,749	\$ 948	\$ 657	\$ (801)	\$ (291)	(46)%	(31)%

*Fiscal 2010 as compared to fiscal 2009.* Research and development tax credits recoverable decreased by 31%, or approximately \$0.3 million, from approximately \$0.9 million for the year ended 2009 to approximately \$0.7 million for the year ended December 31, 2010. 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 is 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 2009.

*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.

### *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 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, 2009 and 2010:

	<u>December 31, 2009 (as restated)</u>	<u>December 31, 2010 (in thousands)</u>	<u>\$ Difference</u>	<u>% Difference</u>
Cash and cash equivalents	\$ 11,493	\$ 29,495	\$ 18,002	157 %
Working capital:				
Current assets	\$ 13,369	\$ 31,051	\$ 17,682	132 %
Current liabilities	(8,594)	(6,535)	2,059	(24)%
Total working capital	<u>\$ 4,775</u>	<u>\$ 24,516</u>	<u>\$ 19,741</u>	413 %

At December 31, 2010, we had cash and cash equivalents of \$29.5 million as compared to \$11.5 million at December 31, 2009. The higher balance at December 31, 2010 was primarily due to:

- The completion of a private placement during October 2010, which resulted in approximately \$14.0 million in net proceeds;
- Two registered direct offerings in January 2010 for net proceeds of approximately \$11.9 million; and
- The issuance of 2.8 million common shares for approximately \$4.9 million as part of the committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge and the exercise of options and warrants totaling \$2.6 million during 2010.

Current liabilities decreased by 24%, or \$2.1 million, from \$8.6 million at December 31, 2009 to \$6.5 million at December 31, 2010. Of the \$2.1 million decrease, \$1.0 million relates to the full satisfaction of the Xcyte restructuring liability in 2010 and \$0.9 million relates to the amount payable under guarantee to Scottish Enterprise as part of the amendment in July 2009 to the March 2006 Agreement, which was paid during 2010. In addition, there were reductions in costs related to intellectual property of approximately \$0.2 million and Sinclair distribution agreement of approximately \$0.7 million, offset by an increase in warrants liability of \$0.3 million.

Since our inception, we have not generated any significant product revenues and have relied primarily on the proceeds from sales of common and preferred equity securities, as well as warrants, 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, 2010, we had an accumulated deficit of \$241.8 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 and other financial commitments for at least the next twelve months. Current business and capital market risks could have a detrimental effect 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, 2008, 2009 and 2010 is summarized as follows:

	Year ended December 31,		
	2008	2009	2010
		(in thousands)	
Net cash used in operating activities	\$ (29,905)	\$ (14,886)	\$ (16,044)
Net cash provided by investing activities	\$ 27,342	\$ 1,559	\$ 33
Net cash provided by (used in) financing activities	\$ (1,238)	\$ 3,545	\$ 33,396

#### *Operating activities*

Net cash used in operating activities increased by \$1.1 million, to \$16.0 million in 2010 from \$14.9 million in 2009. Net cash used in operating activities during the year ended 31 December 2010 of \$16.0 million resulted primarily from our net loss of \$16.0 million, adjusted for material non-cash activities comprising change in valuation of liability-classified warrants, depreciation and amortization and non-cash stock based compensation expense amounting to \$2.5 million and a net reduction of \$2.4 million due to a decrease in prepaid expenses and other current assets combined with a net decrease in accounts payable and other current liabilities.

Net cash used in operating activities decreased by \$15.0 million, from \$29.9 million in 2008 to \$14.9 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 \$14.9 million resulted from our net operating loss of \$19.6 million, adjusted for material non-cash activities comprised of the change in valuation of liability-classified warrants, depreciation and amortization, fixed asset impairment, and non-cash stock based compensation expense, amounting to \$2.1 million and a net increase of \$2.5 million due to a decrease in prepaid expenses and other current assets combined with a net increase in accounts payable and other current liabilities.

#### *Investing activities*

Net cash provided by investing activities in the year ended December 31, 2010 amounted to \$33,000. During the year ended December 31, 2009, cash provided by investing activities amounted to \$1.6 million. 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 \$8,000 for the year ended December 31, 2010 compared to expenditures of \$15,000 for the year ended December 31, 2009 and \$366,000 for the year ended December 31, 2008.

#### *Financing activities*

Net cash provided by financing activities increased by \$29.9 million, from a source of \$3.5 million for the year ended December 31, 2009 to a source of \$33.4 million for the year ended December 31, 2010.

For the year ended December 31, 2010 the net cash provided by financing activities increased primarily due to the completion of a private placement of approximately \$14.0 million in net proceeds during October 2010, the two registered direct offerings in January 2010 for net proceeds of approximately \$11.9 million, the issuing of 2.8 million common shares for approximately \$4.9 million as part of the CEFF with Kingsbridge Capital Limited, or Kingsbridge and the exercise of options and warrants totaling \$2.6 million during 2010.

For year ended December 31, 2009, the net cash provided by financing activities of \$3.5 million related primarily to net proceeds received from the “registered” direct offering 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 year period. The CEFF expired on December 10, 2010.

During December 2009 we sold an aggregate of 1,255,024 shares of our common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of \$1.0 million.

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.

### ***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, 2009 and 2010, we cannot 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 and cash equivalents will be sufficient to fund our operations for at least the next 12 months. We cannot be certain that any of our programs will be successful or that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in development, should they succeed. Additionally, we plan to continue to evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

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

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

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

## **Off-Balance Sheet Arrangements**

As of December 31, 2010, 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® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. We recognize revenue from these product sales when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured.

We offer a general right of return on these product sales and 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 pharmacies. To estimate product sold through to pharmacies, we rely on third-party information, including information obtained from significant distributors with respect to their inventory levels and sell-through to pharmacies. For 2010, we recorded \$0.2 million of product returns due to a higher than anticipated amount of returns.. From the first quarter of 2010, our supplier has increased the product shelf-life to three years on one of our products to assist us in the management of the product supply chain.

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

Certain of our revenues are earned from collaborative agreements. We recognize revenue when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or 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 we 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 approved funding amounts. Grant revenues are not refundable.

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

We grant 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.

We measure compensation cost for all stock-based awards at fair value on date of grant and recognize 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.

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 are 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 second, third and fourth quarters of 2010, we revised downward the forfeiture rates on certain stock options granted mostly due to the high probability of those options becoming fully vested over the next twelve months, which resulted in an additional expense of \$0.5 million. During the quarter ended March 31, 2009, we revised the forfeiture rates because actual forfeiture rates were higher than those 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 each of the quarters ended September 30, 2009 and June 30, 2009, we revised the forfeiture rates because actual forfeiture rates were higher than those previously estimated primarily due to the lapsing of stock option grants on the termination of employees. For the nine months ended September 30, 2009, we recognized a net cumulative credit of approximately \$0.5 million with respect to the revised forfeiture rates. Related to the workforce reduction in the second and third quarters of 2009, we amended the exercise period in which the employees would be able to exercise their vested stock options from thirty (30) days post termination date to nine months. In addition, we allowed the individuals to continue to vest stock options until November 18, 2009 as if they were still employed in recognition of past work. Per ASC 718, we considered this a Type III modification and thus we recorded stock-based compensation expense of \$0.3 million during the second and third quarters of 2009.

### ***Warrants Liability***

#### *February 2007 Financing*

ASC 815, "Derivatives and Hedging" ("ASC 815") requires freestanding contracts that are settled in our own stock, including common stock warrants to be designated as equity instruments, assets or liabilities. Under the provisions of ASC 815, 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 815, 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. We recorded a charge of approximately \$0.3 million to reflect the change in fair value for each of the years ended December 31, 2010 and December 31, 2009. 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.

### **Recent Accounting Pronouncements**

In April 2010, the FASB issued Accounting Standards Update (“ASU”) No. 2010-17 “*Revenue Recognition-Milestone Method (Topic 605): Milestone Method of Revenue Recognition, a consensus of the FASB Emerging Issues Task Force*” (“ASU 2010-17”). The amendments in ASU No. 2010-17 deal with research and development contracts that are tied to completing a phase of a study or achieving a specific result in a research project. The objective of ASU 2010-17 is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Prior to issuance of ASU No. 2010-17, authoritative guidance on the use of the milestone method did not exist. An entity’s decision to use the milestone method of revenue recognition over other proportional revenue recognition methods is a policy decision made by the entity. Use of the milestone method will require certain disclosures. The guidance provided by ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted, with certain restrictions. The adoption of this new ASU did not have a material impact on our consolidated financial statements.

In January 2010, the FASB issued an amendment to the accounting standards related to the disclosures about an entity’s use of fair value measurements. Among these amendments, entities will be required to provide enhanced disclosures about transfers into and out of the Level 1 (fair value determined based on quoted prices in active markets for identical assets and liabilities) and Level 2 (fair value determined based on significant other observable inputs) classifications, provide separate disclosures about purchases, sales, issuances and settlements relating to the tabular reconciliation of beginning and ending balances of the Level 3 (fair value determined based on significant unobservable inputs) classification and provide greater disaggregation for each class of assets and liabilities that use fair value measurements. Except for the detailed Level 3 roll-forward disclosures, the new standard is effective for the Company for interim and annual reporting periods beginning after December 31, 2009. The adoption of this accounting standards amendment did not have a material impact on the Company’s consolidated financial statements. The requirement to provide detailed disclosures about the purchases, sales, issuances and settlements in the roll-forward activity for Level 3 fair value measurements is effective for the Company for interim and annual reporting periods beginning after December 31, 2010. The adoption of these new disclosure requirements did not have a material impact on our consolidated financial statements.

In February 2010, the FASB issued an amendment to the accounting standards related to the accounting for, and disclosure of, subsequent events in an entity’s consolidated financial statements. This standard amends the authoritative guidance for subsequent events that was previously issued and among other things exempts Securities and Exchange Commission registrants from the requirement to disclose the date through which it has evaluated subsequent events for either original or restated financial statements. This standard does not apply to subsequent events or transactions that are within the scope of other applicable GAAP that provides different guidance on the accounting treatment for subsequent events or transactions. The adoption of this standard did not have a material impact on our consolidated financial statements.

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

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

### **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 was recorded in the consolidated statement of operations within the separate line item foreign exchange gains/(losses), within other income (expense). This was 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, and will continue to be recorded as such 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. We realized losses of \$0.1 million for each of the years ended December 31, 2010 and 2009.

### **Common Stock Price Risk**

In February 2007, we issued common stock and warrants. Pursuant to ASC 815, 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 consolidated statements of operations. The change in fair value recognized in the financial statements for each of the years ended December 31, 2009 and 2010 was a loss of approximately \$0.3 million. Fair value of the derivative instruments will be affected by estimates of various factors that may affect the respective instrument, including our stock price, the risk free rate of return and expected volatility in the fair value of our stock price. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

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

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**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Cyclacel Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Cyclacel Pharmaceuticals, Inc. (a development stage company) as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010 and the period from August 13, 1996 (inception) to December 31, 2010. 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010 and for the period from August 13, 1996 (inception) to December 31, 2010, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 3 to the consolidated financial statements, the consolidated balance sheet as of December 31, 2009 and the consolidated statement of stockholders' equity for the year ended December 31, 2009 have been restated to reverse and accrual of undeclared cumulative preferred stock dividends.

/s/ ERNST & YOUNG LLP

London, England

March 31, 2011

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

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

	<b>December 31,</b>	
	<b>2009</b>	<b>2010</b>
	<b>(as restated)</b>	<b>2010</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,493	\$ 29,495
Inventory	145	174
Prepaid expenses and other current assets	1,731	1,382
Total current assets	13,369	31,051
Property, plant and equipment (net)	901	408
Deposits and other assets	196	—
Total assets	\$ 14,466	\$ 31,459
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,709	\$ 1,723
Accrued and other current liabilities	5,481	4,132
Warrants liability	342	680
Current portion of other accrued restructuring charges	1,062	—
Total current liabilities	8,594	6,535
Total liabilities	8,594	6,535
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2009 and 2010, respectively; 2,046,813 and 1,213,142 shares issued and outstanding at December 31, 2009 and 2010, respectively. Aggregate preference in liquidation of \$21,696,218 and \$13,344,562 at December 31, 2009 and December 31, 2010, respectively.	2	1
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2009 and 2010, respectively; 25,743,363 and 46,564,914 shares issued and outstanding at December 31, 2009 and 2010, respectively	26	47
Additional paid-in capital	228,109	266,666
Accumulated other comprehensive income	20	31
Deficit accumulated during the development stage	(222,285)	(241,821)
Total stockholders' equity	5,872	24,924
Total liabilities and stockholders' equity	\$ 14,466	\$ 31,459

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

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

	Year ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2010	Period from August 13, 1996 (inception) to December 31, 2010
<b>Revenues:</b>				
Collaboration and research and development revenue	\$ —	\$ —	\$ 100	\$ 3,100
Product Revenue	838	910	574	2,322
Grant revenue	39	1	12	3,648
<b>Total revenues</b>	<u>877</u>	<u>911</u>	<u>686</u>	<u>9,070</u>
<b>Operating expenses:</b>				
Cost of goods sold	429	545	418	1,392
Research and development	18,869	9,766	6,414	176,593
Selling, general and administrative	15,354	8,538	10,120	81,966
Goodwill and intangibles impairment	7,934	—	—	7,934
Other restructuring costs	489	366	—	2,634
<b>Total operating expenses</b>	<u>43,075</u>	<u>19,215</u>	<u>16,952</u>	<u>270,519</u>
<b>Operating loss</b>	<u>(42,198)</u>	<u>(18,304)</u>	<u>(16,266)</u>	<u>(261,449)</u>
Other income (expense):				
Costs associated with aborted 2004 IPO	—	—	—	(3,550)
Payment under guarantee	—	(1,652)	—	(1,652)
Change in valuation of derivative	—	—	—	(308)
Change in valuation of warrants liability	3,502	(299)	(338)	6,070
Warrant re-pricing	—	(44)	—	(44)
Foreign exchange gains / (losses)	(4,501)	(144)	(68)	(4,255)
Interest income	1,380	102	37	13,680
Interest expense	(318)	(177)	(43)	(4,677)
Total other income (expense), net	<u>63</u>	<u>(2,214)</u>	<u>(412)</u>	<u>5,264</u>
<b>Loss before taxes</b>	<u>(42,135)</u>	<u>(20,518)</u>	<u>(16,678)</u>	<u>(256,185)</u>
Income tax benefit	1,749	948	657	17,879
<b>Net loss</b>	<u>(40,386)</u>	<u>(19,570)</u>	<u>(16,021)</u>	<u>(238,306)</u>
Dividend on preferred ordinary shares	—	—	—	(38,123)
Deemed dividend on convertible exchangeable preferred shares	—	—	(3,515)	(3,515)
Dividend on convertible exchangeable preferred shares	(1,227)	(1,228)	(167)	(2,929)
<b>Net loss applicable to common shareholders</b>	<u>\$ (41,613)</u>	<u>\$ (20,798)</u>	<u>\$ (19,703)</u>	<u>\$ (282,873)</u>
Net loss per share – basic and diluted	<u>\$ (2.04)</u>	<u>\$ (0.94)</u>	<u>\$ (0.52)</u>	
Weighted average common shares outstanding	<u>20,433,129</u>	<u>22,196,840</u>	<u>37,844,695</u>	

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

**CYCLACEL PHARMACEUTICALS, INC.**  
(A Development Stage Company)

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

(In \$000s, except share and per share amounts)

	Preferred Stock		Common Stock		Additional paid-in capital \$000	Accumulated other comprehensive income/(loss) \$000	Deferred compensation \$000	Deficit accumulated during development stage \$000	Total \$000
	No.	\$000	No.	\$000					
On incorporation	—	—	—	—	—	—	—	—	—
Issue of shares for cash	—	—	—	—	1	—	—	—	1
Comprehensive loss:									
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
Comprehensive loss:									
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
Comprehensive loss:									
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.

**CYLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (cont'd)**

(In \$000s, except share and per share amounts)

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

**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		Common Stock		Additional paid-in capital	Accumulated other comprehensive income/(loss)	Deferred compensation	Deficit accumulated during development stage	Total
	No.	\$000	No.	\$000	\$000	\$000	\$000	\$000	\$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
Comprehensive loss:									
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)	(15,076)
Exercise of share options for cash	—	—	—	—	12	—	—	—	12
Deferred stock-based compensation	—	—	—	—	(84)	—	84	—	—
Amortization of deferred stock-based compensation	—	—	—	—	—	—	305	—	305
Comprehensive loss:									
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)	(32,147)

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

**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		Common Stock		Additional paid-in capital	Accumulated other comprehensive income/(loss)	Deferred compensation	Deficit accumulated during development stage	Total
	No.	\$000	No.	\$000	\$000	\$000	\$000	\$000	\$000
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
Comprehensive loss:									
Translation adjustment	—	—	—	—	—	(1,343)	—	—	(1,343)
Loss for the year	—	—	—	—	—	—	—	(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)	37,648
Issues of shares for cash , net of issuance costs	—	—	430,571	1	8,540	—	—	—	8,541
Exercise of warrants for cash	—	—	22,630	—	—	—	—	—	—
Deferred stock-based compensation	—	—	—	—	(2,050)	—	132	—	(1,918)
Comprehensive loss:									
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
Comprehensive loss:									
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

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

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (cont'd)**

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated other comprehensive income/(loss)	Deferred compensation	Deficit accumulated during development stage	Total
	No.	\$000	No.	\$000	\$000	\$000	\$000	\$000	\$000
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
Comprehensive loss:									
Translation adjustment	—	—	—	—	—	416	—	—	416
Loss for the year	—	—	—	—	—	—	—	(29,258)	(29,258)
Comprehensive loss for the year	—	—	—	—	—	—	—	—	(28,842)
Balance at December 31, 2006	<u>2,046,813</u>	<u>2</u>	<u>16,157,953</u>	<u>16</u>	<u>194,714</u>	<u>(2,537)</u>	<u>—</u>	<u>(138,276)</u>	<u>53,919</u>

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

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (cont'd)**

	Preferred Stock		Common Stock		Additional paid-in capital \$000	Accumulated other comprehensive income/(loss) \$000	Deferred compensation \$000	Deficit accumulated during development stage \$000	Total \$000
	No.	\$000	No.	\$000					
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)
Translation adjustment	—	—	—	—	—	(93)	—	—	(93)
Loss for the year	—	—	—	—	—	—	—	(24,053)	(24,053)
Comprehensive loss for the year	—	—	—	—	—	—	—	—	(24,146)
Balance at December 31, 2007	<u>2,046,813</u>	<u>2</u>	<u>20,433,129</u>	<u>20</u>	<u>222,906</u>	<u>(2,630)</u>	<u>—</u>	<u>(162,329)</u>	<u>57,969</u>
Stock-based compensation	—	—	—	—	1,698	—	—	—	1,698
Preferred stock dividends declared	—	—	—	—	(1,227)	—	—	—	(1,227)
Comprehensive loss:									
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	(12,330)	—	—	(12,330)
Translation adjustment	—	—	—	—	—	14,918	—	—	14,918
Loss for the year	—	—	—	—	—	—	—	(40,386)	(40,386)
Comprehensive loss for the year	—	—	—	—	—	—	—	—	(37,798)
Balance at December 31, 2008	<u>2,046,813</u>	<u>2</u>	<u>20,433,129</u>	<u>20</u>	<u>223,377</u>	<u>(42)</u>	<u>—</u>	<u>(202,715)</u>	<u>20,642</u>

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

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (cont'd)**

	Preferred Stock		Common Stock		Additional paid-in capital (as restated)	Accumulated other comprehensive income/(loss)	Deferred compensation	Deficit accumulated during development stage	Total (as restated)
	No.	\$000	No.	\$000	\$000	\$000	\$000	\$000	\$000
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
Comprehensive loss:									
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	5,651	—	—	5,651
Translation adjustment	—	—	—	—	—	(5,589)	—	—	(5,589)
Loss for the year	—	—	—	—	—	—	—	(19,570)	(19,570)
Comprehensive loss for the year	—	—	—	—	—	—	—	—	(19,508)
Balance at December 31, 2009, as restated	<u>2,046,813</u>	<u>2</u>	<u>25,743,363</u>	<u>26</u>	<u>228,109</u>	<u>20</u>	<u>—</u>	<u>(222,285)</u>	<u>5,872</u>

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

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (cont'd)**

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated other comprehensive income/(loss)	Deferred compensation	Deficit accumulated during development stage	Total
	No.	\$000	No.	\$000	\$000	\$000	\$000	\$000	\$000
Issue of common stock for cash on registered direct offering, net of expenses	—	—	5,200,000	5	11,892	—	—	—	11,897
Issue of common stock upon draw down of Committed Equity Finance Facility	—	—	2,818,925	3	4,860	—	—	—	4,863
Warrant exercise	—	—	2,618,266	3	2,496	—	—	—	2,499
Issue of common stock on private placement, net of expenses	—	—	8,323,190	8	13,972	—	—	—	13,980
Stock-based awards exercised	—	—	205,571	—	77	—	—	—	77
Preferred stock conversions	(833,671)	(1)	1,655,599	2	3,514	—	—	(3,515)	—
Stock-based compensation	—	—	—	—	1,746	—	—	—	1,746
Comprehensive loss:									
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	(2,073)	—	—	(2,073)
Translation adjustment	—	—	—	—	—	2,084	—	—	2,084
Loss for the year	—	—	—	—	—	—	—	(16,021)	(16,021)
Comprehensive loss for the year	—	—	—	—	—	—	—	—	(16,010)
Balance at December 31, 2010	<u>1,213,142</u>	<u>1</u>	<u>46,564,914</u>	<u>47</u>	<u>266,666</u>	<u>31</u>	<u>—</u>	<u>(241,821)</u>	<u>24,924</u>

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

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

	Year ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2010	Period from August 13, 1996 (inception) to December 31, 2010
	\$000	\$000	\$000	\$000
<b>Operating activities:</b>				
Net loss	(40,386)	(19,570)	(16,021)	(238,306)
Adjustments to reconcile net loss to net cash used in operating activities:				
Accretion of guaranteed stock	(10)	—	—	—
Amortization of interest payable on notes payable	79	2	—	100
Amortization of investment premiums, net	(1,444)	20	—	(2,297)
Change in valuation of derivative	—	—	—	308
Change in valuation of warrants	(3,502)	299	338	(6,070)
Warrant re-pricing	—	44	—	44
Depreciation	1,154	668	457	12,314
Amortization of intangible assets	708	—	—	886
Fixed asset impairment	—	221	—	221
Unrealized foreign exchange (gains) losses	4,831	—	—	7,747
Deferred revenue	—	—	—	(98)
Compensation for warrants issued to non employees	—	—	—	1,215
Shares issued for IP rights	—	—	—	446
Loss (gain) on disposal of property, plant and equipment	2	83	(13)	99
Goodwill and intangibles impairment	7,934	—	—	7,934
Stock-based compensation	1,698	810	1,746	18,141
Provision for restructuring	—	—	—	1,779
Amortization of issuance costs of Preferred Ordinary 'C' shares	—	—	—	2,517
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	1,732	1,716	516	(232)
Accounts payable and other current liabilities	(2,701)	821	(3,067)	(5,890)
Net cash used in operating activities	<u>(29,905)</u>	<u>(14,886)</u>	<u>(16,044)</u>	<u>(199,142)</u>

**CYCLACEL PHARMACEUTICALS, INC.**  
(A Development Stage Company)

**CONSOLIDATED STATEMENTS OF CASH FLOWS (cont'd)**

	Year ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2010	Period from August 13, 1996 (inception) to December 31, 2010
	\$000	\$000	\$000	\$000
<b>Investing activities:</b>				
Purchase of ALIGN	—	—	—	(3,763)
Purchase of property, plant and equipment	(366)	(15)	(8)	(8,831)
Proceeds from sale of property, plant and equipment	—	91	41	158
Purchase of short-term investments on deposit, net of maturities	(3,057)	—	—	(156,657)
Cash proceeds from redemption of short term securities	30,765	1,483	—	162,729
Net cash provided by (used in) investing activities	<u>27,342</u>	<u>1,559</u>	<u>33</u>	<u>(6,364)</u>
<b>Financing activities:</b>				
Payments of capital lease obligations	(11)	—	—	(3,719)
Proceeds from issuance of ordinary and preferred ordinary shares, net of issuance costs	—	—	30,820	121,678
Proceeds from issuance of common stock and warrants, net of issuance costs	—	3,845	2,576	82,404
Proceeds from the exercise of stock options and warrants, net of issuance costs	—	7	—	170
Payment of preferred stock dividend	(1,227)	(307)	—	(1,534)
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 (used in) provided by financing activities	<u>(1,238)</u>	<u>3,545</u>	<u>33,396</u>	<u>234,553</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(2,966)</u>	<u>(2,945)</u>	<u>617</u>	<u>448</u>
Net (decrease) increase in cash and cash equivalents	(6,767)	(12,727)	18,002	29,495
Cash and cash equivalents, beginning of period.	<u>30,987</u>	<u>24,220</u>	<u>11,493</u>	<u>—</u>
Cash and cash equivalents, end of period	<u>24,220</u>	<u>11,493</u>	<u>29,495</u>	<u>29,495</u>

	Year ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2010	Period from August 13, 1996 (inception) to December 31, 2010
	\$000	\$000	\$000	\$000
Supplemental cash flow information:				
Cash received during the period for:				
Interest	723	59	11	11,715
Taxes	2,033	1,523	1,082	17,522
Cash paid during the period for:				
Interest	—	(78)	(155)	(1,914)
Schedule of non-cash transactions:				
Unpaid costs related to the issuance of common stock	—	—	80	80
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 payable on ALIGN acquisition	—	—	—	1,122

**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 diseases. 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.

Cyclacel’s 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.

On January 11, 2011, the Company opened enrollment of the SEAMLESS pivotal Phase 3 trial for the Company’s sapacitabine oral capsules as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy under a Special Protocol Assessment, or SPA, reached with the U.S. Food & Drug Administration, or FDA.

The Company has additional clinical programs in development awaiting further clinical data. These programs include research around compounds known as seliciclib and CYC116. 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, the Company markets directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® 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 property, raising capital and recruiting and training personnel.

***Basis of Presentation***

The accompanying consolidated financial statements as of December 31, 2009 and 2010, and for each of the three years in the period ended December 31, 2010, have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. 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 GAAP 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 are based on historical experience and on various other assumptions that the Company believes to be reasonable under the circumstances. Actual results may differ from these estimates. Cyclacel believes the judgments and estimates required by the following accounting policies to be significant in the preparation of the Company’s consolidated financial statements.

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

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, 2009 and 2010, approximately 85%, 86% and 87%, respectively, of the Company's product sales in the United States were to three wholesalers: Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen. As of December 31, 2008, 2009 and 2010, these three wholesalers accounted for 83%, 98% and 99%, respectively, of the Company's trade accounts receivable (which are reported as a component of Prepaid Expenses and Other Current Assets). 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 the Company will continue to have significant customer concentration in the future.

Drug candidates developed by the Company typically will require approvals or clearances from the 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***

Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange (losses)/gains in the statement of operations.

The assets and liabilities of the Company's international subsidiary are translated from its functional currency into United States dollars at exchange rates prevailing at the balance sheet date. Average rates of exchange during the period are used to translate the statement of operations, while historical rates of exchange are used to translate any equity transactions.

Translation adjustments arising on consolidation due to differences between average rates and balance sheet rates, as well as unrealized foreign exchange gains or losses arising from translation of intercompany loans that are of a long-term-investment nature, are recorded in other comprehensive income.

### ***Segments***

After considering its business activities and geographic reach, the Company has concluded that it operates in just 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.

### ***Cash and Cash Equivalents***

Cash equivalents are stated at cost, which is substantially the same as fair 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 to safeguard and preserve funds, to maintain liquidity sufficient to meet Cyclacel's cash flow requirements and to attain a market rate of return.

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

An allowance for doubtful accounts is provided, as necessary, on trade receivables based on their respective aging categories and historical collection experience, taking into consideration the type of payer, historical and projected collection outcomes, and current economic and business conditions that could affect the collectability of the Company's receivables. The allowance for doubtful accounts is reviewed, 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 likely the receivable will not be recovered.

### ***Inventory***

Cyclacel values inventories at the lower of cost or market value. The Company determines cost using the first-in, first-out method. As of December 31, 2009 and 2010, all inventories were classified as finished goods. The Company analyzes its inventory levels at least quarterly to identify any items that may expire prior to sale, inventory that has a cost basis in excess of net 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 sales forecasts. The Company writes down the value of inventory to the extent that inventory is expected to expire before being sold. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required in future periods.

During 2009, the Company wrote-down approximately \$0.1 million of inventory, based upon current inventory levels, expiration dates, and future sales. This amount was recorded within cost of sales on the consolidated statement of operations. There were no such write-downs during the year ended December 31, 2010. 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.

### ***Fair Value of Financial Instruments***

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. The carrying amounts of these financial instruments approximate their respective fair values due to the nature of the accounts, notably 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 on sale is reflected as a component of operating income or loss. Expenditures for maintenance and repairs are charged to operating expenses as incurred.

During 2009 and 2010, the Company sold fixed assets related to the closed Cambridge facility totaling \$0.1 million and approximately \$28,000, respectively.

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

The Company reviews property, plant and equipment for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company assesses 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.

Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset (or asset group) exceeds its fair value.

Measurement of fair value is determined using the income-based valuation methodology. The income-based valuation approach measures the fair 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.

### ***Goodwill and intangible assets impairment***

In September 2008, the Company recorded an impairment charge of approximately \$2.7 million in order to fully write down the goodwill acquired in the purchase of Xcyte Therapies, Inc. (“Xcyte”) in accordance with Accounting Standards Codification (“ASC”) 350, “*Intangibles – Goodwill and Other*” (“ASC 350”). This impairment charge was identified through the annual impairment review process and was triggered primarily by a decline in the Company’s stock price that reduced market capitalization below the book value of the net assets of the Company’s single reporting unit.

Also in September 2008, the Company recorded an impairment charge of \$3.6 million related to intangible assets acquired in the acquisition of the Company’s ALIGN reporting unit in accordance with ASC 360, “*Property, Plant and Equipment*” (“ASC 360”). This one-time non-cash charge was triggered by the Company’s downward 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 asset group comprising the intangible assets on September 30, 2008.

In December 2008, the Company recorded an impairment charge of approximately \$1.6 million in order to fully write down the goodwill related to the acquisition of the Company’s ALIGN reporting unit in accordance with ASC 350. The Company considered the negative impact the existing 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.

These impairment charges are recorded in “Goodwill and intangibles impairment” in the Company’s Consolidated Statements of Operations.

### ***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 or 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 guidelines, 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 pharmacies. To estimate product sold through to pharmacies, the Company relies on third-party information, including information obtained from significant distributors with respect to their inventory levels and sell-through to pharmacies. During 2010, the Company recorded \$0.2 million of product returns due to a higher than anticipated amount of returns related to expiring product. Since the first quarter of 2010, the Company’s supplier increased the product shelf-life to three years on one of the Company’s products to assist in the management of the product supply chain.

#### ***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 or 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.

### ***Patent Costs***

Patent prosecution costs 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.

The Company treats a lease as a capital lease when the Company enters into a lease which entails taking substantially all the risks and rewards of ownership of an asset,. The asset is recorded in the balance sheet 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 specifies 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.

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 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.

	<u>Year ended December 31, 2008</u>	<u>Year ended December 31, 2009</u>	<u>Year ended December 31, 2010</u>
Stock options	3,674,899	3,349,876	3,489,932
Restricted Stock and Restricted Stock Units	141,700	91,145	59,885
Convertible preferred stock	870,980	870,980	516,228
Common stock issuable to Kingsbridge	—	328,602	—
Options issued in connection with the October 2010 financing	—	—	6,242,398
Common stock warrants	<u>3,809,272</u>	<u>7,044,363</u>	<u>10,005,192</u>
Total shares excluded from calculation	<u>8,496,851</u>	<u>11,684,966</u>	<u>20,313,635</u>

### ***Derivative Instruments***

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 use of different assumptions may have a material effect on the estimated fair value amount and the Company's results of operations.

Inputs used to determine fair value of financial and non-financial assets and liabilities are categorized using a fair value hierarchy that prioritizes observable and unobservable inputs into three broad levels, from Level 1, which is the most reliable, to Level 3, which is the least reliable (see "Note 6 – Fair Value"). Management reviews the categorization of fair value inputs on a periodic basis and may determine that it is necessary to transfer an input from one level of the fair value hierarchy to another based on changes in events or circumstances, such as a change in the observability of an input. Any such transfer will be recognized at the end of the reporting period.

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

The Company grants stock options, restricted stock units and restricted stock to officers, employees and directors under the Amended and Restated Equity Incentive Plan ("2006 Plan"), which was approved on March 16, 2006 and subsequently amended and restated on April 14, 2008. The Company also has outstanding options under various stock-based compensation plans for employees and directors. These

plans are described more fully in Note 12 - "Stock-Based Compensation Arrangements". The Company accounts for these plans under ASC 718 "*Compensation – Stock Compensation*" ("ASC 718").

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 the Company's common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using the Black-Scholes 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. Such value is recognized as 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 current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. The Company considers many factors when estimating expected forfeitures, including type of awards granted, employee class, and historical experience. Actual results and future estimates may differ substantially from current estimates.

### ***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 items of other comprehensive income.

### ***Recent Accounting Pronouncements***

In April 2010, the FASB issued Accounting Standards Update ("ASU") No. 2010-17 "*Revenue Recognition-Milestone Method (Topic 605): Milestone Method of Revenue Recognition, a consensus of the FASB Emerging Issues Task Force*" ("ASU 2010-17"). The amendments in ASU No. 2010-17 deal with research and development contracts that are tied to completing a phase of a study or achieving a specific result in a research project. The objective of ASU 2010-17 is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Prior to issuance of ASU No. 2010-17, authoritative guidance on the use of the milestone method did not exist. An entity's decision to use the milestone method of revenue recognition over other proportional revenue recognition methods is a policy decision made by the entity. Use of the milestone method will require certain disclosures. The guidance provided by ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted, with certain restrictions. The adoption of this new ASU did not have a material impact on the Company's consolidated financial statements.

In January 2010, the FASB issued an amendment to the accounting standards related to the disclosures about an entity's use of fair value measurements. Among these amendments, entities will be required to provide enhanced disclosures about transfers into and out of the Level 1 (fair value determined based on quoted prices in active markets for identical assets and liabilities) and Level 2 (fair value determined based on significant other observable inputs) classifications, provide separate disclosures about purchases, sales, issuances and settlements relating to the tabular reconciliation of beginning and ending balances of the Level 3 (fair value determined based on significant unobservable inputs) classification and provide greater disaggregation for each class of assets and liabilities that use fair value measurements. Except for the detailed Level 3 roll-forward disclosures, the new standard is effective for the Company for interim and

annual reporting periods beginning after December 31, 2009. The adoption of this accounting standards amendment did not have a material impact on the Company's consolidated financial statements. The requirement to provide detailed disclosures about the purchases, sales, issuances and settlements in the roll-forward activity for Level 3 fair value measurements is effective for the Company for interim and annual reporting periods beginning after December 31, 2010. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In February 2010, the FASB issued an amendment to the accounting standards related to the accounting for, and disclosure of, subsequent events in an entity's consolidated financial statements. This standard amends the authoritative guidance for subsequent events that was previously issued and among other things exempts Securities and Exchange Commission registrants from the requirement to disclose the date through which it has evaluated subsequent events for either original or restated financial statements. This standard does not apply to subsequent events or transactions that are within the scope of other applicable GAAP that provides different guidance on the accounting treatment for subsequent events or transactions. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

### **3 Restatement of Previously Issued Financial Statements**

The Company has restated its consolidated balance sheet as of December 31, 2009 and its statement of stockholder's equity for the year ended December 31, 2009. The Company has also restated its unaudited consolidated balance sheets for each of the first three quarters in 2009 and 2010 in Note 17 – "Selected Quarterly Financial Data".

#### **Background on the Restatement**

The restated financial statements correct the following error:

##### *Accounting for Preferred Stock Dividends*

During March 2011, the Company became aware of an error with respect to the historical accounting for undeclared dividends associated with the Company's outstanding preferred stock. The Company's management determined that undeclared cumulative preferred stock dividends need only be disclosed in the financial statements or in the notes thereto, and not accrued and included as a current liability in the Company's consolidated balance sheets, as the Company had recorded in prior periods. The effect of correcting the error has been recorded in the applicable restated periods.

The effect of correcting the error is reflected on the restated Consolidated Balance Sheet as of December 31, 2009 as presented below:

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**CONSOLIDATED BALANCE SHEET**

**At December 31, 2009**

**(In \$000s, except share amounts)**

	<u>As Previously Reported on Form 10-K/A</u>	<u>Adjustments</u>	<u>As Restated</u>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 11,493	\$ —	\$ 11,493
Inventory	145	—	145
Prepaid expenses and other current assets	1,731	—	1,731
Total current assets	<u>13,369</u>		<u>13,369</u>
Property, plant and equipment (net)	901	—	901
Deposits and other assets	196	—	196
Total assets	<u>\$ 14,466</u>	<u>\$ —</u>	<u>\$ 14,466</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable	\$ 1,709	\$ —	\$ 1,709
Accrued and other current liabilities	6,709	(1,228)	5,481
Warrants liability	342	—	342
Current portion of other accrued restructuring charges	1,062	—	1,062
Total current liabilities	<u>9,822</u>	<u>(1,228)</u>	<u>8,594</u>
Total liabilities	<u>9,822</u>	<u>(1,228)</u>	<u>8,594</u>
Commitments and contingencies			
Stockholders' equity:			
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and 2,046,813 shares issued and outstanding. Aggregate preference in liquidation of \$21,696,218	2	—	2
Common stock, \$0.001 par value; 100,000,000 shares authorized and 25,743,363 shares issued and outstanding	26	—	26
Additional paid-in capital	226,881	1,228	228,109
Accumulated other comprehensive income	20	—	20
Deficit accumulated during the development stage	<u>(222,285)</u>	<u>—</u>	<u>(222,285)</u>
Total stockholders' equity	<u>4,644</u>	<u>1,228</u>	<u>5,872</u>
Total liabilities and stockholders' equity	<u>\$ 14,466</u>	<u>\$ —</u>	<u>\$ 14,466</u>

## 4 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.

Pursuant to the Daiichi-Sankyo license under which the Company licenses certain patent rights for sapacitabine, its lead drug candidate, the Company is under an obligation to use reasonable endeavors to develop a product and obtain regulatory approval to sell a product and has 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 the Company's 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 the Company or its 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 the Company wishes 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 the Company for technical, scientific, efficacy, safety, or commercial reasons on six months notice, or twelve months, if after a launch of a sapacitabine-based product, or by either party for material default. In addition, pursuant to the Daiichi-Sankyo license, the Company is 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 the Company's control or arising from the activities of third parties, difficulties outside of the Company's 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 the Company 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.

In connection with the asset acquisition of ALIGN on October 5, 2007, the Company acquired distribution rights for the exclusive rights to sell and distribute three products in the United States. Each of the agreements covering the three products expires in June 2015, after which the Company has no rights to distribute these products. The Company, as part of securing long term supply arrangements, had commitments to make payments totaling approximately \$1.3 million, \$0.6 million of which was paid in 2009 and the remainder of \$0.7 million was paid 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, 2011 this equates to \$0.1 million.

## 5 Cash and Cash Equivalents

The following is a summary of cash and cash equivalents at December 31, 2009 and 2010:

	December 31,	
	2009	2010
	\$000	\$000
Cash	2,996	429
Deposits with original maturity of less than three months	8,497	29,066
Total cash and cash equivalents	11,493	29,495

## 6 Fair Value

### 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.

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 considering counterparty credit risk in its measurement of fair value.

The fair value of the Company’s warrants liability was determined using the following inputs as of December 31, 2010:

	Fair Value Measurements Using Fair Value Hierarchy		
	Level 1	Level 2	Level 3
	\$000	\$000	\$000
Warrants liability	—	—	680

### Warrants Liability

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 is being marked to market each reporting period as a derivative gain or loss on the consolidated statement of operations until exercised or expiration. The fair value of the warrants was approximately \$0.3 and \$0.7 million. The Company used the Black-Scholes option-pricing model with the following assumptions to value the warrants:

	<u>December 31,</u>	
	<u>2009</u>	<u>2010</u>
Exercise price	\$8.44	\$8.44
Expected term	4.13 Yrs	3.13 Yrs
Risk free interest rate	2.13%	1.02%
Expected volatility	96%	121%
Expected dividend yield over expected term	—	—

During 2010, 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 2009 and 2008, the Company recognized the change in the value of warrants as a loss of approximately \$0.3 million and a gain of approximately \$3.5 million, respectively, on the consolidated statement of operations. The following table reconciles the beginning and ending balance of Level 3 inputs for the year ended December 31, 2010:

	<u>Level 3</u>
	<u>\$000</u>
Balance as of December 31, 2009	342
Change in valuation of warrants liability	<u>338</u>
Balance as of December 31, 2010	<u><u>680</u></u>

The Company has reassessed the categorization of its warrants liability within the fair value hierarchy of ASC 820 as of December 31, 2010 from Level 2 to Level 3 due to management’s determination that a significant input, while based on observable data, was unobservable due to the subjectivity of the assumptions used in determining that input.

## 7 Prepaid Expenses and Other Current Assets

The following is a summary of prepaid expenses and other current assets at December 31, 2009 and 2010:

	<u>December 31,</u>	
	<u>2009</u>	<u>2010</u>
	<u>\$000</u>	<u>\$000</u>
Research and development tax credit receivable	1,096	660
Prepayments	456	317
Other current assets	<u>179</u>	<u>405</u>
	<u><u>1,731</u></u>	<u><u>1,382</u></u>

## 8 Property, Plant and Equipment

Property, plant and equipment consisted of the following:

	Useful lives in years from date of acquisition	December 31,	
		2009	2010
		\$000	\$000
Leasehold improvements	5 to 15 yrs	860	844
Research and laboratory equipment	3 to 5 yrs	7,673	6,281
Office equipment and furniture	3 to 5 yrs	1,280	1,267
		9,813	8,392
Less: accumulated depreciation and amortization		(8,912)	(7,984)
		901	408

The depreciation and amortization of property, plant and equipment amounted to \$1.2 million, \$0.7 million and \$0.5 million for each of the years ended December 31, 2008, 2009 and 2010, respectively.

Depreciation and amortization expense for the period from inception or August 13, 1996 through December 31, 2010 was \$12.3 million. At December 31, 2009 and 2010 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 13 – “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 360, which are shown within research and development expense on the consolidated statement of operations. There were no impairments of property, plant and equipment during the year ended December 31, 2010.

## 9 Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following:

	December 31,	
	2009	2010
	(as restated)	\$000
	\$000	\$000
Accrued research and development	2,654	2,793
Accrued IP / Patent costs	283	26
Accrued compensation	136	112
Amount payable under distribution agreement (1)	651	—
Amount payable under guarantee (2)	796	—
Other current liabilities	961	1,201
	5,481	4,132

(1) For more information please see Note 4 – “Significant Contracts”.

(2) For more information please see Note 10 – “Commitments and Contingencies”.

## 10 Commitments and Contingencies

### *General*

Please refer to Note 4 – “Significant Contracts” for 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, 2010:

	<u>Operating lease obligations</u> \$000
2011	557
2012	545
2013	405
2014	405
2015	400
Thereafter	<u>4,270</u>
Total	<u>6,582</u>

Rent expense, which includes lease payments related to the Company’s research and development facilities and corporate headquarters and other rent related expenses, was \$0.9 million for each of the years ended December 31, 2008, 2009 and 2010.

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.

### *Guarantee*

On July 28, 2005 and amended on March 27, 2006, Cyclacel Group plc (“Group”) signed a convertible Loan Note Instrument constituting convertible unsecured loan notes (the “Loan”) and entered into a Facility Agreement (“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.

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 consolidated balance sheet as at December 31, 2009.

### ***Purchase Obligations***

At December 31, 2010, the Company had obligations in relation to the purchase of manufactured products within the ALIGN business of \$0.1 million.

### ***Preferred Dividends***

Pursuant to the terms of the Company's outstanding preferred stock, since inception through January 2009, the Company paid quarterly dividends when they have become due. However, as part of the program to reduce expenditure, the Board of Directors did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009 and the first three quarters of 2010. On February 1, 2011, the Company paid a quarterly cash dividend in the amount of \$0.15 per share on the Company's 6% Convertible Exchangeable Preferred Stock. Accrued and unpaid dividends in arrears on preferred stock were \$1.3 million, or \$1.05 per preferred share, as of December 31, 2010.

### ***Legal proceedings***

On April 27, 2010, the Company was served with a complaint filed by Celgene Corporation in the United States District Court for the District of Delaware seeking a declaratory judgment that four of its own patents, claiming the use of romidepsin injection in T-cell lymphomas, are invalid and not infringed by Celgene's products, but directly involve the use and administration of Celgene's ISTODAX® (romidepsin for injection) product. On June 17, 2010, the Company filed its answer and counterclaims to the declaratory judgment complaint. The Company filed counterclaims charging Celgene with infringement of each of its four patents and seeking damages for Celgene's infringement as well as injunctive relief. The four patents directly involve the use and administration of Celgene's ISTODAX® (romidepsin for injection) product.

## **11 Stockholders' Equity**

### ***Preferred stock***

As of December 31, 2010, there were 1,213,142 shares of Preferred Stock issued and outstanding at an issue price of \$10.00 per share. 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 declared and paid these dividends when due. 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.

The Preferred Stock is convertible at the option of the holder at any time into the Company's shares of 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. During 2010, 833,671 shares of Preferred Stock were converted into 1,655,599 shares of the Company's common stock, which is described in more detail below. Since inception through December 31, 2010, holders have voluntarily converted 1,776,858 shares of Preferred Stock into common stock. The Company has reserved 516,228 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at December 31, 2010. The shares of Preferred Stock have been retired and canceled and shall upon cancellation be restored to the status of authorized but unissued shares of preferred stock, subject to reissuance by the Board of Directors as shares of Preferred Stock of one or more series.

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..

The Certificate of Designations governing the Preferred Stock provides that if the Company fails to pay dividends on its Preferred Stock for six quarterly periods, holders of Preferred Stock are entitled to nominate and elect two directors to the Company's Board of Directors. This right accrued to the Preferred Stock Stockholders as of August 2, 2010. On October 4, 2010, the Company held a special meeting of the holders of its Preferred Stock for the purpose of electing two directors to the Company's Board of Directors. The meeting was adjourned to Monday, November 1, 2010, because a quorum of the holders of the Company's Preferred Stock was not present in person or represented by proxy to transact business at the meeting. The adjournment was approved by a vote of 324,678 shares of Preferred Stock, with no shares voted against the adjournment, thus constituting approval by more than the majority of the holders of the Preferred Stock represent in person or by proxy at the meeting and entitled to vote on the adjournment. The previously adjourned meeting was held on November 1, 2010. A quorum was not reached at the November 1, 2010 meeting either, with 505,773 shares of Preferred Stock present in person and by proxy at the meeting, representing only 41.69% of the issued and outstanding shares of the Company's Preferred Stock. The meeting was not further adjourned. The holders of the Company's preferred stock will have the opportunity at the 2011 annual meeting of stockholders to elect two directors to the Company's Board of Directors. Once elected, the directors will have the ability to participate in the management of the Company until all such dividends have been paid in full.

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

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, 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.

### *Conversion of Convertible Preferred Stock*

During 2010, Cyclacel entered into agreements to exchange the Company's Preferred Stock into shares of common stock. There were no exchanges of the Company's Preferred Stock into shares of common stock in 2009. The table below provides details of the aggregate activities in 2010:

	<u>Year ended December 31, 2010</u>
Preferred shares exchanged	833,671
Common shares issued:	
At stated convertible option	354,752
Incremental shares issued under the exchange transaction	<u>1,300,847</u>
Total common shares issued	<u>1,655,599</u>

As the Preferred Stock stockholders received additional shares of common stock issued to them upon conversion as compared to what they would have been entitled to receive under the stated rate of exchange, the Company recorded the excess of (1) the fair value of all securities and other consideration transferred to the holders of the Preferred Stock and (2) the fair value of securities issuable pursuant to the original conversion terms as an increase in the net loss attributable to common shareholders. Specifically, the Company recorded deemed dividends related to the additional shares issued under the exchange transactions of approximately \$3.5 million for the year ended December 31, 2010.

### *Common Stock*

#### *January 2010 Registered Direct Financings*

On January 25, 2010, the Company 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 the Company's common stock and one warrant to purchase 0.30 of one share of its common stock. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance at an exercise price of \$2.85 per share of common stock. As of December 31, 2010, warrants issued to the investors have been classified as equity. The transaction date fair value of the warrants of \$1.0 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate - 2.39%, expected volatility - 90%, expected dividend yield - 0%, and a remaining contractual life of 5.00 years. As of December 31, 2010, all the warrants are outstanding. Net proceeds of approximately \$5.4 million were allocated based on relative transaction date fair values in the following manner: \$4.5 million (\$1.93 per share) to common shares and \$0.9 million (\$1.29 per warrant) to the warrants.

On January 13, 2010, the Company 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 the Company's common stock and one warrant to purchase 0.25 of one share of its 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 at an exercise price of \$3.26 per share of common stock. As of December 31, 2010, warrants issued to the investors have been classified as equity. The transaction date fair value of the warrants of \$1.3 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate - 2.55%,

expected volatility - 90%, expected dividend yield - 0%, and a remaining contractual life of 5.00 years. As of December 31, 2010, all the warrants are outstanding. Net proceeds of approximately \$6.5 million were allocated based on relative transaction date fair values in the following manner: \$5.6 million (\$1.95 per share) to common shares and \$0.9 million (\$1.32 per warrant) to the warrants.

#### *October 2010 Private Placement*

On October 7, 2010, the Company completed a private placement pursuant to which it sold approximately \$15.2 million of its units to several institutional investors, for net proceeds of approximately \$14.0 million. The units consist of one share of common stock and 0.5 of a warrant, with each whole warrant representing the right to purchase one share of common stock at an exercise price of \$1.92 per share for a period of five years. As of December 31, 2010, options and warrants issued to the investors have been classified as equity. The investors purchased a total of 8,323,190 units at a price of \$1.82625 per unit. The investors also have the right to acquire up to 4,161,595 additional units at a price of \$1.67 per unit (for \$6.9 million in gross proceeds) at any time up to nine months after closing on July 6, 2011. As of December 31, 2010, none of the additional units had been exercised. The transaction date fair value of the warrants and additional optional units was \$5.1 million and \$2.8 million, respectively. Net proceeds of approximately \$14.0 million were allocated based on relative transaction date fair values in the following manner: \$8.9 million (\$1.07 per share), \$3.3 million (\$0.79 per warrant) and \$1.8 million (\$0.43 per optional unit) to common shares, warrants and the additional optional units, respectively.

In connection with the October 2010 private placement, the Company granted to the investors certain registration rights pursuant to a Registration Rights Agreement, dated October 7, 2010, in which the Company agreed, among other things, to register all of the shares of common stock acquired from the Company (including upon exercise of the warrants and/or the options) within thirty calendar days after the Company becomes eligible to use a registration statement on Form S-3, and use commercially reasonable efforts to have the registration statement declared effective as promptly as practicable thereafter. Upon the Company's failure to comply with the terms of the Registration Rights Agreement and certain other conditions, the Company will be required to make pro rata payments to each investor, as liquidated damages, in an amount equal to 1.5% of the aggregate purchase price paid by such investor. The Company also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the registration statement. The Company is currently in compliance with the applicable terms of the Registration Rights Agreement, and the securities that were registrable under the terms of the Registration Rights Agreement are currently subject to an effective registration statement.

#### *July 2009 Registered Direct Financing*

On July 29, 2009, the Company sold its 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 (each, a "Unit"). Each Unit consisted of (i) one share of the Company's common stock, (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 had a seven-month term from the date of issuance, were exercisable beginning six months from the date of issuance at an exercise price of \$1.00 per share of Common Stock. During the first quarter of 2010, all of The Series I Warrants were exercised for \$2.5 million. The Series II Warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance at an exercise price of \$1.00 per share of Common Stock. During the first quarter of 2010, 43,266 common shares were issued upon exercise of warrants with proceeds of \$43,266.

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. As of December 31, 2010, the

remaining Series II Warrants outstanding exercisable into 692,256 of the Company's shares of common stock have been classified as equity. 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 or CEFF*

On December 10, 2007 and as 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 over a three-year period. The CEFF lapsed on December 10, 2010.

Under the terms of the agreement, Cyclacel determined the exact timing and amount of any CEFF financings, subject to certain conditions. All amounts "drawn down" under the CEFF were settled via the issuance of Cyclacel's common stock. Cyclacel accessed 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 was issued and priced over an eight-day pricing period. Kingsbridge purchased 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 was 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 2010, the Company sold 2,818,925 shares of its common stock to Kingsbridge under the CEFF, in consideration of aggregate proceeds of \$4.9 million. Since inception to maturity on December 10, 2010, the Company sold an aggregate of 4,073,949 shares of its common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of \$5.9 million.

In connection with an amendment to the CEFF dated November 24, 2009, 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 the Company's 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 during the fourth quarter of 2009. The warrant is exercisable, subject to certain exceptions, until December 12, 2013. During the first quarter of 2010, Kingsbridge exercised its warrant to purchase 75,000 shares of common stock for approximately \$0.1 million.

As of December 31, 2010, the unexercised, remaining balance of the outstanding warrants issued to Kingsbridge have been classified as equity.

In connection with the CEFF, the Company granted to Kingsbridge certain registration rights pursuant to a Registration Rights Agreement, dated as of December 10, 2007, in which the Company agreed, among other things, to use commercially reasonable efforts to register all of the shares of common stock acquired from the Company (including upon any exercise of the warrant) and have the registration statement declared effective by the SEC as soon as reasonably practicable, but in any event no later than one hundred eighty

(180) calendar days after the closing date of the CEFF. The Company also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the registration statement. The Company is currently in compliance with the applicable terms of the Registration Rights Agreement, and the securities that were registrable under the terms of the Registration Rights Agreement are currently subject to an effective registration statement.

### *Common Stock Warrants*

In connection with the Company's February 16, 2007 "registered direct" offering the Company issued to investors warrants to purchase 1,062,412 shares of common stock. The warrants issued to the investors are being accounted for as a liability. 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 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, 2009 and 2010, the fair value of the warrants determined utilizing the Black-Scholes option pricing model was approximately \$0.3 million and \$0.7 million, respectively. The fair value at December 31, 2010 reflects the increase in the Company's common stock price of \$1.47 per share at December 31, 2010 as compared to the common stock price of \$1.04 per share at December 31, 2009. For each of the years ended December 31 2009 and 2010, the Company recognized the change in the value of warrants of approximately \$0.3 million, as a loss on the consolidated statement of operations.

The following table summarizes information about warrants outstanding at December 31, 2010:

<u>Issued in Connection With</u>	<u>Expiration Date</u>	<u>Common Shares Issuable</u>	<u>Weighted Average Exercise Price</u>
April 2006 stock issuance	2013	2,571,429	\$ 7.00
February 2007 stock issuance	2014	1,062,412	\$ 8.44
December 2007 CEFF	2013	100,000	\$ 1.40
July 2009 Series II stock issuance	2014	692,256	\$ 1.00
January 2010 stock issuance	2015	712,500	\$ 3.26
January 2010 stock issuance	2015	705,000	\$ 2.85
October 2010 stock issuance	2015	4,161,595	\$ 1.92
Total		10,005,192	\$ 4.01

### *Exercise of Stock Options*

During 2009, 17,180 shares of common stock were issued from the exercise of stock options resulting in proceeds of approximately \$7,000. During 2010, there were 174,311 stock option exercises totaling approximately \$0.1 million.

## **12 Stock-Based Compensation Arrangements**

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 ¼ of the award vesting one year from the date of grant and 1/48 of the award

granted vesting each month thereafter. During December 2010, annual awards granted to all employees vest 1/48 of the award each month after the grant date. Certain awards made to executive officers vest over three to five years, depending on the terms of their employment with the Company.

The Company recognizes 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. The Company evaluates its forfeiture assumptions quarterly and the expected forfeiture rate is adjusted when 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 2008, 2009 and 2010 as shown in the following table:

	Year ended December 31, 2008 \$000	Year ended December 31, 2009 \$000	Year ended December 31, 2010 \$000
Research and development	736	271	351
Selling, general and administrative	962	539	1,395
Stock-based compensation costs before income taxes	<u>1,698</u>	<u>810</u>	<u>1,746</u>

### **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 2010, the Company granted approximately 0.6 million options to employees and directors with a grant date fair value of \$0.6 million, of which approximately \$50,000 has been recorded as compensation cost in the consolidated statement of operations. 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 was expensed in 2009. As of December 31, 2010, the total remaining unrecognized compensation cost related to the non-vested stock options amounted to approximately \$1.2 million, which will be amortized over the weighted-average remaining requisite service period of 3.25 years.

During 2009 and 2010, the Company did not settle any equity instruments with cash.

The Company received approximately \$0.1 million from the exercise of 174,311 stock options during 2010. The total intrinsic value of options exercised during 2010 was approximately \$0.2 million. 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. The weighted average grant-date fair value of options granted during 2010 and 2009 was \$1.40 and \$0.39, respectively.

### Outstanding Options

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

<b>Cyclacel Pharmaceuticals, Inc.</b>	<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>
Options outstanding at December 31, 2008	3,674,899	\$ 4.36	8.74	\$ 2
Granted	221,000	\$ 0.39		
Exercised	(17,180)	\$ 0.43		
Cancelled/forfeited	(528,843)	\$ 3.76		
Options outstanding at December 31, 2009	3,349,876	\$ 4.21	7.76	\$ 698
Granted	607,300	\$ 1.82		
Exercised	(174,311)	\$ 0.43		
Cancelled/forfeited	(292,933)	\$ 4.54		
Options outstanding at December 31, 2010	3,489,932	\$ 3.96	7.22	\$ 938
Unvested at December 31, 2010	1,151,947	\$ 2.02	8.68	\$ 344
Vested and exercisable at December 31, 2010	2,337,985	\$ 4.92	6.50	\$ 594

The following table summarizes information about options outstanding at December 31, 2010:

<b>Exercise price (\$)</b>	<b>Number outstanding</b>	<b>Weighted Average remaining contractual life</b>	<b>Number exercisable</b>
0.29 – 1.98	1,341,890	8.54	584,162
2.15 – 4.95	394,000	8.13	138,677
5.26 – 5.81	524,033	6.83	397,953
6.30 – 8.30	1,208,009	5.68	1,195,193
15.00 – 45.30	22,000	4.11	22,000
	<u>3,489,932</u>		<u>2,337,985</u>

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

	Year ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2010
Expected term (years)	4.25 – 6 Yrs	0.75 – 5 Yrs	5 – 6 Yrs
Risk free interest rate	1.54 – 3.76%	0.325 – .84%	1.64 – 2.96%
Volatility	45 – 75%	65 – 169%	90 – 102%
Dividends	0.00%	0.00%	0.00%
Resulting weighted average grant date fair value	\$0.68	\$0.39	\$1.40

The expected term assumption was estimated using past history of early exercise behavior and expectations about future behaviors. Starting with the December 2010 annual grants to the Company's employees, the Company relied exclusively on its historical volatility as an input to the option pricing model as management believes that this rate will be representative of future volatility over the expected term of the options. Before December 2010, due to the Company's limited existence of being a public company, the expected volatility assumption has been 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 0 — 50% 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.

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 \$0.1 million from the exercise of 174,311 options during 2010. The Company received approximately \$7,000 from the exercise of 17,180 options during 2009. 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 incurred tax losses in 2009 and 2010, the Company was not able to benefit from the deduction for exercised stock options in the current reporting period.

The Company considers many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. During the second, third and fourth quarters of 2010, the Company revised downward the forfeiture rates on certain stock options granted mostly due to the high probability of those options becoming fully vested over the next twelve months, which resulted in an additional expense of \$0.5 million. During the quarter ended March 31, 2009, the Company revised the forfeiture rates because actual forfeiture rates were higher than those 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 each of the quarters ended September and June 30, 2009, the Company revised the forfeiture rates because actual forfeiture rates were higher than those previously estimated primarily due to the lapsing of stock option grants on the termination of employees. For the nine months ended September 30, 2009, the Company recognized a net cumulative credit of approximately \$0.5 million with respect to the revised forfeiture rates.

Related to the workforce reduction in the second and third quarters of 2009, the Company amended the exercise period in which the employees would be able to exercise their vested stock options from thirty (30) days post termination date to nine months. In addition, the Company allowed the individuals to continue to vest stock options until November 18, 2009 as if they were still employed in recognition of past work. Per ASC 718, the Company considered this a Type III modification and thus recorded stock-based compensation expense of \$0.3 million during the second and third quarters of 2009.

#### *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. As of December 31, 2010, the total remaining unrecognized compensation cost related to the non-vested restricted stock amounted to approximately \$14,000, which will be amortized over the weighted-average remaining requisite service period of 1.85 years. Summarized information for restricted stock grants for the year ended December 31, 2010 is as follows:

	<u>Restricted Stock Units</u>	<u>Weighted Average Grant Date Value Per Share</u>
Non-vested at December 31, 2009	36,458	\$0.44
Vested	(12,504)	\$0.44
Non-vested at December 31, 2010	<u>23,954</u>	\$0.44

#### *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. As of December 31, 2010, the total remaining unrecognized compensation cost related to the non-vested restricted stock amounted to approximately \$9,000, which will be amortized over the weighted-average remaining requisite service period of 1.85 years. Summarized information for restricted stock units grants for the year ended December 31, 2010 is as follows:

	<u>Restricted Stock Units</u>	<u>Weighted Average Grant Date Value Per Share</u>
Non-vested at December 31, 2009	54,687	\$0.44
Vested	(18,756)	\$0.44
Non-vested at December 31, 2010	<u>35,931</u>	\$0.44

### **13 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 were no longer utilized. All severance payments were paid as of December 31, 2008.

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. During 2009, the Company recorded approximately \$0.4 million for severance payments all of which were paid as of December 31, 2009. Accelerated depreciation 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 part of the 2009 restructuring activities, 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.

As a result of strategic decisions taken by Xcyte in March 2005 the Company restructured its operations and reduced its workforce. In connection with this restructuring Xcyte recorded charges and made provisions for termination benefits, lease restructuring, asset impairment and sales tax assessment. The sales tax assessment was settled in 2009 and the lease expired in 2010.

The table below presents a summary of and reconciliation of those provisions for the years ended December 31, 2009 and 2010:

	<u>Lease restructuring charges</u> \$000	<u>Sales tax assessment</u> \$000	<u>Total</u> \$000
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	—	127
Adjustment for sales tax assessment	—	102	102
Balance at December 31, 2009	<u>1,062</u>	<u>—</u>	<u>1,062</u>
Cash payments	(1,104)	—	(1,104)
Adjustments for lease-related deferred expenses and liabilities	<u>42</u>	<u>—</u>	<u>42</u>
Balance at December 31, 2010	<u>—</u>	<u>—</u>	<u>—</u>

#### *Lease restructuring charges*

Under the stock purchase agreement entered into with Xcyte Therapies, Cyclacel, assumed the accrued restructuring liability in relation to a manufacturing facility in Bothell, Washington. The lease term on this space expired on December 2010. The liability was computed as the present value of the difference between the remaining lease payments due less the estimate of net sublease income that could be reasonably obtained. Subsequent changes in the liability due to accretion are recognized in interest expense, and changes in estimates of sublease assumptions, etc. were recognized as adjustments to restructuring charges in future periods.

During the fourth quarter of 2010, the Company did not renew the lease on the Bothell facility. During 2010, the Company met all obligations related to the lease and there will be no further accretion expense associated with the restructuring liability.

#### *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 of this charge in 2008 and charged the remaining \$0.1 million to selling, general and administrative expenses on its consolidated statement of operations.

#### 14 Employee Benefit Plans

##### Pension Plan

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 for each of the years ended December 31, 2008, 2009 and 2010.

##### 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, 2008, 2009 and 2010, the Company made contributions of approximately \$0.1 million to the 401(k) Plan.

#### 15 Taxes

In the accompanying Consolidated Statements of Operations, "Loss before taxes" includes the following components for the years ended December 31, 2008, 2009 and 2010:

	Year ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2010
	\$000	\$000	\$000
Domestic	(11,337)	(3,013)	(4,664)
Foreign	(30,798)	(17,505)	(12,014)
Total loss before taxes	<u>(42,135)</u>	<u>(20,518)</u>	<u>(16,678)</u>

The benefit for income taxes consists of the following:

	Year ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2010
	\$000	\$000	\$000
Current – domestic	(4)	(12)	(10)
Current – foreign	1,753	960	667
Current – total	<u>1,749</u>	<u>948</u>	<u>657</u>

The Company has made a taxable loss in each of the operating periods since incorporation. The income tax credits of \$1.7 million, \$0.9 million and \$0.7 million for the years ended December 31, 2008, 2009 and 2010, 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:

	Year ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2010
	<u>\$000</u>	<u>\$000</u>	<u>\$000</u>
Loss before income taxes	(42,135)	(20,518)	(16,678)
Income tax expense computed at statutory federal tax rate	(14,361)	(6,976)	(5,672)
State income tax (net of federal benefit)	3	8	7
Disallowed expenses and non-taxable income	(1,939)	(773)	(490)
Tax losses	3,584	2,322	1,605
Research and development tax relief	(2,191)	(1,185)	(793)
Valuation allowance	11,161	4,605	3,984
Research and development tax credit rate difference	438	237	132
Foreign tax rate differential	1,556	814	570
	<u>(1,749)</u>	<u>(948)</u>	<u>(657)</u>

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

	December 31,	
	<u>2009</u>	<u>2010</u>
	<u>\$000</u>	<u>\$000</u>
Net operating loss carryforwards	42,534	43,056
Depreciation, amortization and impairment of property and equipment	1,996	1,925
Lease restructuring charges	399	—
Stock Options	775	1,228
Accrued Expenses	2,684	3,778
Other	67	89
Translation adjustment	(3,097)	(2,452)
Deferred Tax Assets	45,358	47,624
Valuation allowance for deferred tax assets	(45,358)	(47,624)
Net deferred taxes	<u>—</u>	<u>—</u>

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:

	December 31,	
	2009	2010
	\$000	\$000
Accumulated tax losses	127,633	132,521

As of December 31, 2009 and 2010, the Company had federal and foreign net operating losses or (NOLs) of \$142.0 million and \$147.7 million, respectively. 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.

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 the Company will recognize the benefits of the deferred tax assets. Accordingly, a valuation allowance of approximately \$47.6 million has been established at December 31, 2010. 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. The Company have not currently completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since the Company's 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.

Management has evaluated all significant tax positions at December 31, 2009 and 2010 concluding that there are no material uncertain tax positions.

Tax years 2007, 2008 and 2009 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the United Kingdom and the United States, as carryforward attributes generated in years past may still be adjusted upon examination by the United Kingdom's H.M. Revenue & Customs, the Internal Revenue Service (IRS) or state tax authorities if they have or will be used in a future period. The Company is currently not under examination by the 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.

## 16 Geographic Information

Geographic information for the years ended December 31, 2008, 2009 and 2010 is as follows:

	Year ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2010
	\$000	\$000	\$000
<b>Revenue</b>			
United States	838	910	574
United Kingdom	39	1	112
	<u>877</u>	<u>911</u>	<u>686</u>
<b>Net loss</b>			
United States	(11,341)	(3,007)	(4,662)
United Kingdom	(29,045)	(16,563)	(11,359)
	<u>(40,386)</u>	<u>(19,570)</u>	<u>(16,021)</u>
		<b>December 31,</b>	
	<u>2008</u>	<u>2009</u>	<u>2010</u>
	\$000	\$000	\$000
<b>Total Assets</b>			
United States	22,842	10,460	30,055
United Kingdom	8,115	4,006	1,404
	<u>30,957</u>	<u>14,466</u>	<u>31,459</u>
<b>Long Lived Assets, net</b>			
United States	516	330	161
United Kingdom	1,232	571	247
	<u>1,748</u>	<u>901</u>	<u>408</u>

## 17 Selected Quarterly Information (unaudited)

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

	For the three months ended				
	March 31, 2010	June 30, 2010	September 30, 2010	December 31, 2010	
		\$000, except per share amounts			
Revenues	271	119	159	137	
Loss before taxes	(5,244)	(4,163)	(3,950)	(3,321)	
Net loss applicable to common shareholders	(5,819)	(6,543)	(3,989)	(3,352)	
Net loss per share – basic and diluted (1)	\$(0.18)	\$(0.18)	\$(0.11)	\$(0.07)	

	For the three months ended				
	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009	
		\$000, except per share amounts			
Revenues	228	266	230	187	
Loss before taxes	(5,421)	(7,278)	(3,329)	(4,490)	
Net loss applicable to common shareholders	(5,370)	(7,352)	(3,431)	(4,645)	
Net loss per share – basic and diluted (1)	\$(0.26)	\$(0.36)	\$(0.15)	\$(0.19)	

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

The following consolidated balance sheets have been restated to correct for cumulative preferred stock dividends that were erroneously accrued and included as a current liability in previously filed quarterly financial statements (see Note 3 – “Restatement of Previously Issued Financial Statements”):

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED BALANCE SHEET (Unaudited)**  
**As of September 30, 2010**  
**(In \$000s, except share amounts)**

	<u>As Previously Reported on Form 10-Q</u>	<u>Adjustments</u>	<u>As Restated</u>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 18,482	\$ —	\$ 18,482
Inventory	144	—	144
Prepaid expenses and other current assets	1,057	—	1,057
Total current assets	<u>19,683</u>		<u>19,683</u>
Property, plant and equipment (net)	512	—	512
Deposits and other assets	196	—	196
Total assets	<u>\$ 20,391</u>	<u>\$ —</u>	<u>\$ 20,391</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable	\$ 1,340	\$ —	\$ 1,340
Accrued and other current liabilities	5,641	(1,213)	4,428
Warrants liability	785	—	785
Current portion of other accrued restructuring charges	199	—	199
Total current liabilities	<u>7,965</u>	<u>(1,213)</u>	<u>6,752</u>
Total liabilities	<u>7,965</u>	<u>(1,213)</u>	<u>6,752</u>
Commitments and contingencies			
Stockholders' equity:			
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and 1,213,142 shares issued and outstanding. Aggregate preference in liquidation of \$13,344,562	2	—	2
Common stock, \$0.001 par value; 100,000,000 shares authorized and 38,235,991 shares issued and outstanding	37	—	37
Additional paid-in capital	250,466	1,813	252,279
Accumulated other comprehensive income	(30)	—	(30)
Deficit accumulated during the development stage	(238,049)	(600)	(238,649)
Total stockholders' equity	<u>12,426</u>	<u>1,213</u>	<u>13,639</u>
Total liabilities and stockholders' equity	<u>\$ 20,391</u>	<u>\$ —</u>	<u>\$ 20,391</u>

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED BALANCE SHEET (Unaudited)**  
**As of June 30, 2010**  
**(In \$000s, except share amounts)**

	<u>As Previously Reported on Form 10-Q</u>	<u>Adjustments</u>	<u>As Restated</u>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 19,543	\$ —	\$ 19,543
Inventory	39	—	39
Prepaid expenses and other current assets	1,925	—	1,925
Total current assets	<u>21,507</u>		<u>21,507</u>
Property, plant and equipment (net)	606	—	606
Deposits and other assets	196	—	196
Total assets	<u>\$ 22,309</u>	<u>\$ —</u>	<u>\$ 22,309</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable	\$ 1,550	\$ —	\$ 1,550
Accrued and other current liabilities	5,255	(1,032)	4,223
Warrants liability	858	—	858
Current portion of other accrued restructuring charges	492	—	492
Total current liabilities	<u>8,155</u>	<u>(1,032)</u>	<u>7,123</u>
Total liabilities	<u>8,155</u>	<u>(1,032)</u>	<u>7,123</u>
Commitments and contingencies			
Stockholders' equity:			
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and 1,213,142 shares issued and outstanding. Aggregate preference in liquidation of \$13,162,591	1	—	1
Common stock, \$0.001 par value; 100,000,000 shares authorized and 36,920,343 shares issued and outstanding	37	—	37
Additional paid-in capital	248,314	1,632	249,946
Accumulated other comprehensive income	42	—	42
Deficit accumulated during the development stage	<u>(234,240)</u>	<u>(600)</u>	<u>(234,840)</u>
Total stockholders' equity	<u>14,154</u>	<u>1,032</u>	<u>15,186</u>
Total liabilities and stockholders' equity	<u>\$ 22,309</u>	<u>\$ —</u>	<u>\$ 22,309</u>

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED BALANCE SHEET (Unaudited)**  
**As of March 31, 2010**  
**(In \$000s, except share amounts)**

	<u>As Previously Reported on Form 10-Q</u>	<u>Adjustments</u>	<u>As Restated</u>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 24,200	\$ —	\$ 24,200
Inventory	107	—	107
Prepaid expenses and other current assets	1,558	—	1,558
Total current assets	<u>25,865</u>		<u>25,865</u>
Property, plant and equipment (net)	715	—	715
Deposits and other assets	196	—	196
Total assets	<u>\$ 26,776</u>	<u>\$ —</u>	<u>\$ 26,776</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable	\$ 1,782	\$ —	\$ 1,782
Accrued and other current liabilities	5,818	(1,443)	4,375
Warrants liability	1,131	—	1,131
Current portion of other accrued restructuring charges	780	—	780
Total current liabilities	<u>9,511</u>	<u>(1,443)</u>	<u>8,068</u>
Total liabilities	<u>9,511</u>	<u>(1,443)</u>	<u>8,068</u>
Commitments and contingencies			
Stockholders' equity:			
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and 1,923,413 shares issued and outstanding. Aggregate preference in liquidation of \$20,676,690 .....	2	—	2
Common stock, \$0.001 par value; 100,000,000 shares authorized and 35,411,325 shares issued and outstanding .....	35	—	35
Additional paid-in capital	244,991	1,528	246,519
Accumulated other comprehensive income	52	—	52
Deficit accumulated during the development stage	(227,815)	(85)	(227,900)
Total stockholders' equity	<u>17,265</u>	<u>1,443</u>	<u>18,708</u>
Total liabilities and stockholders' equity	<u>\$ 26,776</u>	<u>\$ —</u>	<u>\$ 26,776</u>

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED BALANCE SHEET (Unaudited)**

**As of September 30, 2009**  
**(In \$000s, except share amounts)**

	<u>As Previously Reported on Form 10-Q</u>	<u>Adjustments</u>	<u>As Restated</u>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 14,433	\$ —	\$ 14,433
Short-term investments	—	—	—
Inventory	140	—	140
Prepaid expenses and other current assets	1,652	—	1,652
Total current assets	16,225	—	16,225
Property, plant and equipment (net)	1,121	—	1,121
Deposits and other assets	196	—	196
Total assets	<u>\$ 17,542</u>	<u>\$ —</u>	<u>\$ 17,542</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable	\$ 1,463	\$ —	\$ 1,463
Accrued liabilities	5,228	—	5,228
Other current liabilities	1,336	(921)	415
Warrant liability	238	—	238
Current portion of other accrued restructuring charges	1,063	—	1,063
Total current liabilities	9,328	(921)	8,407
Other accrued restructuring charges, net of current	267	—	267
Other long term payables	—	—	—
Total liabilities	<u>9,595</u>	<u>(921)</u>	<u>8,674</u>
Stockholders' equity:			
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and 2,046,813 shares issued and outstanding. Aggregate preference in liquidation of \$20,673,000	2	—	2
Common stock, \$0.001 par value; 100,000,000 shares authorized and 24,433,129 shares issued and outstanding.	24	—	24
Additional paid-in capital	225,864	921	226,785
Accumulated other comprehensive loss	5	—	5
Deficit accumulated during the development stage	(217,948)	—	(217,948)
Total stockholders' equity	<u>7,947</u>	<u>921</u>	<u>8,868</u>
Total liabilities and stockholders' equity	<u>\$ 17,542</u>	<u>\$ —</u>	<u>\$ 17,542</u>

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED BALANCE SHEET (Unaudited)**

**As of June 30, 2009**  
**(In \$000s, except share amounts)**

	<u>As Previously Reported on Form 10-Q</u>	<u>Adjustments</u>	<u>As Restated</u>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 15,864	\$ —	\$ 15,864
Short-term investments	—	—	—
Inventory	306	—	306
Prepaid expenses and other current assets	1,797	—	1,797
Total current assets	<u>17,967</u>	<u>—</u>	<u>17,967</u>
Property, plant and equipment (net)	1,297	—	1,297
Deposits and other assets	196	—	196
Total assets	<u>\$ 19,460</u>	<u>\$ —</u>	<u>\$ 19,460</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable	\$ 1,440	\$ —	\$ 1,440
Accrued liabilities	6,921	—	6,921
Other current liabilities	777	(614)	163
Warrant liability	339	—	339
Current portion of other accrued restructuring charges	1,209	—	1,209
Total current liabilities	<u>10,686</u>	<u>(614)</u>	<u>10,072</u>
Other accrued restructuring charges, net of current	526	—	526
Other long term payables	—	—	—
Total liabilities	<u>11,212</u>	<u>(614)</u>	<u>10,598</u>
Stockholders' equity:			
Preferred stock, \$0.001 par value; 5,000,000 shares and 2,046,813 shares issued and outstanding. Aggregate preference in liquidation of \$20,673,000	2	—	2
Common stock, \$0.001 par value; 100,000,000 shares authorized and 20,433,129 shares issued and outstanding	20	—	20
Additional paid-in capital	222,932	614	223,546
Accumulated other comprehensive loss	118	—	118
Deficit accumulated during the development stage	(214,824)	—	(214,824)
Total stockholders' equity	<u>8,248</u>	<u>614</u>	<u>8,862</u>
Total liabilities and stockholders' equity	<u>\$ 19,460</u>	<u>\$ —</u>	<u>\$ 19,460</u>

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED BALANCE SHEET**

**At March 31, 2009**

**(In \$000s, except share amounts)**

	<b>As Previously Reported on Form 10-Q</b>	<b>Adjustments</b>	<b>As Restated</b>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 20,442	\$ —	\$ 20,442
Short-term investments	—	—	—
Inventory	460	—	460
Prepaid expenses and other current assets	2,529	—	2,529
Total current assets	23,431	—	23,431
Property, plant and equipment (net)	1,540	—	1,540
Deposits and other assets	196	—	196
Total assets	<u>\$25,167</u>	<u>\$ —</u>	<u>\$ 25,167</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable	1,812	\$ —	\$ 1,812
Accrued liabilities	5,045	—	5,045
Other current liabilities	578	(307)	271
Warrant liability	51	—	51
Current portion of other accrued restructuring charges	1,063	—	1,063
Total current liabilities	8,549	(307)	8,242
Other accrued restructuring charges, net of current	780	—	780
Other long term payables	637	—	637
Total liabilities	9,966	(307)	9,659
Stockholders' equity:			
Preferred stock, \$0.001 par value; 5,000,000 shares and 2,046,813 shares issued and outstanding at. Aggregate preference in liquidation of \$20,673,000	2	—	2
Common stock, \$0.001 par value; 100,000,000 shares authorized and 20,433,129 shares issued and outstanding	20	—	20
Additional paid-in capital	222,886	307	223,193
Accumulated other comprehensive loss	71	—	71
Deficit accumulated during the development stage	(207,778)	—	(207,778)
Total stockholders' equity	15,201	307	15,508
Total liabilities and stockholders' equity	<u>\$ 25,167</u>	<u>\$ —</u>	<u>\$ 25,167</u>

## **18 Subsequent Events**

On February 1, 2011, the Company paid a quarterly cash dividend in the amount of \$0.15 per share on the Company's 6% Convertible Exchangeable Preferred Stock ("Preferred Stock"). The dividend is payable to the holders of record of the Preferred Stock as of the close business on January 21, 2011.

The Board considered numerous factors in determining whether to declare the quarterly dividend, including the requisite financial analysis and determination of a surplus. While the Board will analyze the advisability of the declaration of dividends in future quarters, there is no assurance that future quarterly dividends will be declared.

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

None

#### **Item 9A. Controls and Procedures**

(a) *Disclosure Controls:*

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. An evaluation was performed under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, on the effectiveness of the Company's disclosure controls and procedures as of December 31, 2010.

Pursuant to this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2010, the end of the period covered by this report, our disclosure controls and procedures were not effective at the reasonable assurance level because of the material weakness described below under "Management's Report on Internal Control over Financial Reporting."

We have taken, and are taking, the actions described more fully below under "Plan for Remediation of the Material Weakness in Internal Control Over Financial Reporting" to remediate the material weakness in our internal control over financial reporting.

We have concluded that the consolidated financial statements in this Annual Report fairly present, in all material respects, our financial position, results of operations and cash flows as of the dates, and for the periods, presented, in conformity with GAAP.

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

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

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process, and it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting 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, 2010. Based upon that evaluation, management identified a material weakness in the Company's internal control over financial reporting as described below. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement to the annual or interim financial statements will not be prevented or detected on a timely basis.

As disclosed in Amendment No. 1 to our Annual Report on Form 10-K/A for the year ended December 31, 2009, filed on May 17, 2010, and as further amended by Amendment No. 2 to our Annual Report on Form 10-K/A filed on May 19, 2010, our management identified a deficiency in respect of our internal control over financial reporting. Specifically, we did not have an effectively-designed control in operation over the accounting for, presentation of and disclosure of cumulative preferred stock dividends to prevent or detect on a timely basis material misstatements in the computation of net loss per share and the financial statement presentation of our preferred stock dividends in the statement of cash flows. This deficiency in the design of our controls constituted a material weakness as described in SEC's guidance regarding Management's Report on Internal Control Over Financial Reporting as of December 31, 2009. As a result of this deficiency, the financial statements included in our Form 10-K for the year ended December 31, 2009, filed on March 29, 2010, included errors related to the presentation and disclosure of our preferred stock dividends in the net loss per share disclosure and in the statement of cash flows. As a result of this material weakness, management concluded that we did not maintain effective internal control over financial reporting as of December 31, 2009, based on the criteria established in "Internal Control — Integrated Framework", issued by the COSO.

In March 2011, our auditors identified a further error in respect of the accounting, presentation and disclosure of cumulative undeclared preferred stock dividends. Specifically, we erroneously included as a current liability its undeclared cumulative preferred stock dividends which resulted from the same material weakness as described above

As a result, Amendment No. 1 to our Annual Report on Form 10-K/A for the year ended December 31, 2009, filed on May 17, 2010 and as further amended by Amendment No. 2 to our Annual Report on Form 10-K/A filed on May 19, 2010, included errors in the consolidated balance sheet and in the statement of stockholders' equity. Unaudited consolidated balance sheets for each of the first three quarters in 2009 and 2010 also contained errors. As a result of this material weakness, management concluded that we did not maintain effective internal control over financial reporting as of December 31, 2010, based on the criteria established in "*Internal Control — Integrated Framework*", issued by the COSO.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

*(c) Plan for Remediation of the Material Weakness in Internal Control Over Financial Reporting*

To remediate this material weakness in internal controls, management is strengthening the financial reporting function through the hiring of experienced US-qualified CPA finance personnel and designing and placing into operation appropriate controls to prevent or detect on a timely basis any potential material misstatements in the accounting, presentation and disclosure of cumulative preferred dividends.

We anticipate that the actions described above will remediate the December 31, 2010 material weakness. The material weakness will only be considered remediated when the revised internal controls are operational for a period of time and are tested and management has concluded that the controls are operating effectively.

*(d) Changes in Internal Control Over Financial Reporting*

There were no changes in the Company's internal control over financial reporting that occurred during the fourth fiscal quarter ended December 31, 2010, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other information**

Not applicable.

### PART III

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

##### Executive Officers and Directors

Our executive officers and directors and their respective ages and positions as of March 22, 2011 are set forth in the table below. In addition, the holders of our preferred stock, voting separately as a class, are entitled to vote and elect two additional directors pursuant to the terms of the Company's Certificate of the Powers, Designations, Preferences and Rights of the 6% Convertible Exchangeable Preferred Stock. Lloyd Sems and Gregory T. Hradsky have been nominated by a holder of our Preferred Stock for election at our 2011 annual meeting of stockholders. We have included information regarding such nominees as well.

:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Spiro Rombotis	52	President and Chief Executive Officer; Director
Paul McBarron	50	Executive Vice President—Finance, Chief Financial Officer, Chief Operating Officer and Secretary; Director
Dr. Judy Chiao	51	Vice President, Clinical Development and Regulatory Affairs
Robert Sosnowski	52	Vice President, Sales & Marketing
<u>Non-Employee Directors</u>		
Dr. Nicholas Bacopoulos	62	Director
Sir John Banham	70	Director
Dr. Christopher Henney	69	Vice Chairman of the Board of Directors
Daniel K. Spiegelman	52	Director
Dr. David U'Prichard	62	Chairman of the Board of Directors; Common Stock Nominee for Class 2 Director
<u>Director Nominees</u>		
Lloyd Sems	39	Preferred Stock Director Nominee
Gregory T. Hradsky	50	Preferred Stock Director Nominee

***Spiro Rombotis.*** Mr. Rombotis joined Cyclacel in August 1997 and has over 28 years of experience with pharmaceutical and biotechnology companies. He was previously Vice President of International Operations and Business Development; Managing Director, Europe; and Director, Japanese joint venture, at The Liposome Company, Inc. He also served as Vice President of Pharmaceuticals for Central and Eastern Europe and as Director of International Marketing at Bristol-Myers Squibb Company. He was Head of European Marketing and Sales, Head of Corporate Development and one of the first employees of Centocor, Inc. and worked in Business Development at Novartis AG. He holds a B.A. from Williams College and an M.B.A. and Master's degree in Hospital Management with honors, from the Kellogg Graduate School of Management, where he serves on the Kellogg Biotech Advisory Board. He also serves on the Board of Trustees of BioNJ, the biotechnology industry trade group in New Jersey.

Mr. Rombotis is qualified for service on our Board of Directors due to his many years of experience in the pharmaceutical and biotechnology industries as well as his managerial expertise and leadership skills. As the Company's Chief Executive Officer, Mr. Rombotis brings to the Board of Directors valuable knowledge of the Company's business, operations, strategy and future development prospects.

***Paul McBarron.*** Mr. McBarron joined Cyclacel in January 2002 and has over 20 years of experience with pharmaceutical and biotechnology companies. He has served as a financial executive at Sterling Drug, Sanofi-Winthrop and SmithKline Beecham and most recently, from 1996 to 2001, as a senior member of the finance team at Shire Pharmaceuticals plc, where he held the positions of Director of Corporate Finance and

Group Financial Controller. He joined Shire when it was an emerging public company. He qualified as a chartered accountant with Ernst & Young and serves on the Life Sciences Industry Advisory Board for the Scottish Government.

Mr. McBarron is qualified for service on our Board of Directors based on his financial expertise and his extensive experience in the pharmaceutical industry. As the Company's Chief Financial Officer and Chief Operating Officer, Mr. McBarron also provides the Board of Directors with unique insight into the Company's financial and operations, as well as the Company's strategy.

**Judy Chiao, M.D.** Dr. Chiao joined Cyclacel in December 2004. From September 2002 to December 2004, she was at Aton Pharma, Inc., a wholly owned subsidiary of Merck & Co. Inc., most recently as Vice President, Oncology Clinical Research and Development. Prior to Aton's acquisition by Merck, she was responsible for leading the clinical development of Zolinza®, a histone deacetylase inhibitor, for hematologic and solid tumor indications. From July 2000 to December 2001, Dr. Chiao was a Senior Medical Reviewer, Division of Oncology Drug Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, where she was the agency's primary reviewer for a range of oncology drugs and regulatory subjects. She also presented the FDA's views in several New Drug Application reviews at Oncology Drug Advisory Committees. Dr. Chiao earned her Bachelor of Science in Chemistry (*summa cum laude*) at Columbia University, New York, and received her medical degree from Harvard Medical School. Her internship and residency in internal medicine was carried out at Columbia-Presbyterian Medical Center, New York and she held a Research Fellowship in Molecular Pharmacology at Sloan Kettering Institute for Cancer Research and a Clinical Fellowship in Hematology/Oncology at Memorial Sloan Kettering Cancer Center both in New York City. She has also been a member of a number of FDA-related working groups and has also been a Core Member of the Pharsight-FDA Cooperative Research and Development Agreement (CRADA) on clinical trial simulation and population pharmacokinetic analysis software for drug development.

**Robert Sosnowski.** Mr. Sosnowski joined Cyclacel in April 2008 and has more than 28 years experience in sales and marketing roles at several pharmaceutical and major biotechnology companies. Prior to joining Cyclacel, Mr. Sosnowski was President, Chief Executive Officer and Co-Founder, Dexgen Pharmaceuticals, Inc., a specialty pharmaceutical company, and Vice President, Sales and Marketing, Algos Pharmaceutical Corporation. In addition, he has held senior sales and marketing roles with Genentech, Inc., Centocor, Inc., The Liposome Company, Inc., Amgen, Inc. and The Upjohn Company. Mr. Sosnowski earned his Bachelor of Science degree in 1980 from the University of Connecticut.

**Nicholas Bacopoulos, Ph.D.** Dr. Bacopoulos joined the Board of Directors of Cyclacel in September 2008. He is currently the Chief Executive Officer of Kotinos Pharmaceuticals, Inc., a private company focused on the development of drugs for cancer and other disorders. Prior to that, Mr. Bacopoulos was a consultant to biotech and pharmaceutical companies. His previous leadership roles include Chief Executive Officer and President of Aton Pharma, Inc., where he led the development of Zolinza®, approved for the treatment of cutaneous T-cell lymphoma. Aton was subsequently acquired by Merck & Co., Inc. He was previously President and Head of Research and Development at OSI Pharmaceuticals, Inc. where he was involved with the global development of Tarceva®, approved for the treatment of non-small cell lung cancer and pancreatic cancer. Dr. Bacopoulos also worked for 17 years at Pfizer, where he held senior positions within Pfizer Central Research and Corporate Strategic Planning. He led the company's Cancer and Neuroscience Research groups, which developed several marketed drugs, including Geodon® and Zoloft®, and produced a significant pipeline of oncology drug candidates, several of which are in clinical trials. Dr. Bacopoulos also serves on the board of directors of Mersana Therapeutics, Inc. and Medexis Biotech, S.A., both privately-held biotechnology companies. He received his B.A. degree from Cornell College and his Ph.D. from the University of Iowa. He completed additional coursework and obtained a postdoctoral fellowship at Yale University School of Medicine.

Dr. Bacopoulos is qualified for service on our Board of Directors based on his senior executive level experience in pharmaceutical companies, his educational background and his breadth of knowledge in the development of drugs for cancer, which enable Dr. Bacopoulos to contribute to the Company's strategy and strategic initiatives.

**Sir John Banham.** Sir John Banham is currently the Chairman of Johnson Matthey plc and Sultan Scientific Limited, and senior non-executive director of Invesco Limited. He is past Director General of the Confederation of British Industry (CBI) and past Chairman of Whitbread plc, Geest plc, ECI Partners LLP, Tarmac plc and Kingfisher plc. His public sector appointments comprise first Controller of the Audit Commission and first Chairman of the Local Government Commission for England. He was formerly Honorary Treasurer of the United Kingdom's Cancer Research Campaign prior to its merger with Imperial Cancer Research. He is a graduate of Cambridge University in Natural Sciences and has honorary degrees from a number of British universities.

Sir John Banham is qualified for service on our Board of Directors based on his professional experience and public service involvement in the business and scientific arenas in which our Company operates.

**Christopher S. Henney, Ph.D. D.Sc.** Dr. Henney had served as one of Xcyte's directors since March 2005, and continued on as Vice Chairman of the Company. Previously, Dr. Henney co-founded three major publicly held U.S. biotechnology companies, Immunex, ICOS and Dendreon, and held a seat on the board of directors and executive positions at each company. From 1995 to January 2003, Dr. Henney was Chairman and Chief Executive Officer of Dendreon Corporation. Dr. Henney currently serves as the Chairman of Oncothyreon, Inc. and Anthera Pharmaceuticals, Inc. Dr. Henney received a Ph.D. in experimental pathology from the University of Birmingham and a D.Sc. from the same university for contributions to the field of immunology.

Dr. Henney is qualified for service on our Board of Directors based on his senior executive experience in biotechnology companies. Dr. Henney has extensive knowledge and educational background in the relevant industry and he provides the Board of Directors with valuable leadership skills.

**Daniel K. Spiegelman, M.B.A.** Mr. Spiegelman had served as one of Xcyte's directors since September 2004, and continued on as a director of the Company. Mr. Spiegelman has served as the Senior Vice President and Chief Financial Officer of CV Therapeutics, Inc. since September 1999. From January 1998 to September 1999, Mr. Spiegelman served as the Vice President and Chief Financial Officer of CV Therapeutics, Inc. From 1991 until 1998, Mr. Spiegelman was employed by Genentech, Inc., a biotechnology company, holding various positions in the Treasury department, including the position of Treasurer from 1996 to 1998. Mr. Spiegelman also serves as a member of the board of directors of Affymax, Inc., Omeros Inc, Oncothyreon, Inc. and Anthera Pharmaceuticals Inc, publicly-traded biopharmaceutical companies, as well as some private biotech companies. Mr. Spiegelman holds a B.A. in Economics from Stanford University and an M.B.A. from Stanford Graduate School of Business.

Mr. Spiegelman is qualified for service on our Board of Directors based on his extensive background in finance as well as his senior management experience with other biotechnology public companies. In addition, his current service on the board of directors of other public companies in the biopharmaceutical industry brings invaluable expertise to our Board of Directors.

**David U'Prichard, Ph.D.** Dr. U'Prichard joined the Board of Directors of Cyclacel in May 2004. He is currently President of Druid Consulting LLC, a pharmaceutical and biotechnology consulting firm, providing customized services to life sciences clients in the United States and Europe. He is also a Venture Partner with Red Abbey Venture Partners, private equity providers. Previously, he was Chief Executive Officer of 3-Dimensional Pharmaceuticals, Inc. from 1999 to 2003. In addition, he held a variety of positions within the pharmaceutical and biotechnology industries, including, President and Chairman of Research and Development for SmithKline Beecham Pharmaceuticals; Executive Vice President and International Research

Director, and a Member of the Board of Management of Zeneca Pharmaceuticals; General Manager, Research Department, ICI Pharmaceuticals, and Vice President Biomedical Research, ICI Pharmaceuticals; and Senior Vice President and Scientific Director for Nova Pharmaceutical Corporation. He is a director of Iroko Pharmaceuticals, Life Technologies, Inc., Naurex Inc. and Silence Therapeutics plc. and he served as a director of Alpharma, Inc., Guilford Pharmaceuticals Inc. and Lynx Therapeutics, Inc. He was Chairman of the Pennsylvania Biotechnology Association in 2004-2005. From 1992 to 1997, he was a member of the board of directors of the Biotechnology Industry Organization (BIO). He received a B.Sc. in Pharmacology from University of Glasgow in 1970 and a Ph.D. in Pharmacology from University of Kansas in 1975.

Dr. U'Prichard is qualified for service on our Board of Directors based on his significant senior level pharmaceutical industry experience and his extensive background in the consulting and financing realms of the pharmaceutical industry.

**Gregory T. Hradsky.** Mr. Hradsky has been nominated by a holder of our preferred stock to fill one of the two newly created directorships on our Board of Directors that will be created pursuant to the terms of the Certificate of the Powers, Designations, Preferences and Rights governing our 6% Convertible Exchangeable Preferred Stock. Based on information provided to us by such holder, Mr. Hradsky has been an independent financial consultant since February 2006. He has served on the board of directors of Sielox, Inc. since June 2008 where he is Chairman of the Audit Committee. Between May 2003 and February 2006, Mr. Hradsky was a Vice President of Avenue Capital Group, a global investment firm, where he managed a portfolio of distressed securities, post-reorganization equities and other investments. From 1999 until 2003, Mr. Hradsky was the founder and Managing Partner of Bellport Capital, an investment firm specializing in distressed securities. Prior to that, Mr. Hradsky was a Managing Director and Head of the Distressed Securities Group at UBS Securities LLC from 1993 until 1998. Mr. Hradsky joined UBS in 1991 as a research analyst focusing on distressed credits. Prior to UBS, Mr. Hradsky was a member of the Distressed Securities Group and the High Yield Research Department at the First Boston Corporation from 1988-1991. He began his career at T. Rowe Price Associates in 1983 and worked in the Fixed Income Department until 1986. Mr. Hradsky has a B.A. from Loyola College in Maryland and an M.B.A. from the Wharton School of the University of Pennsylvania.

**Lloyd Sems.** Mr. Sems has been nominated by a holder of our preferred stock to fill one of the two newly created directorships on our Board of Directors that will be created pursuant to the terms of the Certificate of the Powers, Designations, Preferences and Rights governing our 6% Convertible Exchangeable Preferred Stock. Based on information provided to us by such holder, Mr. Sems has served as President of Sems Capital, LLC and of Capital Edge, LLC, both of which he founded, since October 2003. He has also served as a director of Selectica, Inc. since June 2, 2008, and as Chairperson of the Nominating/Corporate Governance Committee of the Selectica Board since May 20, 2009. Previously, Mr. Sems served as Director of Research and Portfolio Manager for Watchpoint Asset Management. Mr. Sems holds a Bachelor of Science degree in Business Administration and Finance from Albright College. Mr. Sems also serves on the Board of Directors of Sport-Haley, Inc. (OTC Pink Sheets: SPOR), which he joined in April 2009. Mr. Sems also served on the Board of Directors of EMAK Worldwide, Inc. from February 2010 to April 2010.

### Corporate Governance

The Board of Directors. Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as amended, provide that our business is to be managed by or under the direction of the Board of Directors. Our Board of Directors is divided into three classes for purposes of election. One class is elected at each annual meeting of stockholders to serve for a three-year term. Our Board of Directors currently consists of seven members, classified into three classes as follows: (1) Sir John Banham and Daniel K. Spiegelman constitute Class 1, with a term ending at the 2013 annual meeting; (2) Spiro Rombotis and David

U'Prichard, Ph.D. constitute Class 2, with a term ending at the 2011 annual meeting; and (3) Paul McBarron, Nicholas Bacopoulos, Ph.D. and Christopher S. Henney, Ph.D., D.Sc. constitute Class 3, with a term ending at the 2012 annual meeting.

Audit Committee, Audit Committee Financial Expert. Our Audit Committee currently has three members, Daniel K. Spiegelman (Chairman), Sir John Banham and Dr. Christopher Henney. All members of the Audit Committee satisfy the current independence standards promulgated by the NASDAQ and SEC, as such standards apply specifically to members of audit committees. The Board of Directors has determined that Mr. Spiegelman is an "audit committee financial expert," as the SEC has defined that term in Item 407 of Regulation S-K.

Our Audit Committee oversees and monitors the processes management has in place to maintain the reliability and integrity of our accounting policies and financial reporting processes, to ensure the adequacy of internal accounting, financial reporting and disclosure controls, and to comply with legal and regulatory requirements that may impact our financial reporting and disclosure obligations. The Audit Committee is also responsible for reviewing the qualifications, independence and performance of, and selecting or replacing, if necessary, our independent registered public accounting firm and approving all audit and non-audit services and fees related thereto. In addition, the Audit Committee is responsible for reviewing, in consultation with our management and independent registered public accounting firm, the scope and results of (1) reviews of our quarterly financial statements, (2) audits of our annual financial statements, and (3) audits of our system of internal control over financial reporting and management's assessment of the effectiveness thereof. The Audit Committee may also perform other duties and responsibilities as the Audit Committee or the Board of Directors deems appropriate or necessary, including reviewing, evaluating and approving related-party or similar transactions or relationships.

*Compensation and Organization Development Committee.* Our Compensation and Organization Development Committee is composed entirely of directors who are not our current or former employees, all of whom qualify as independent under the definition promulgated by the NASDAQ and SEC. The Compensation and Organization Development Committee currently has three members: Dr. Christopher Henney (Chairman), Dr. Nicholas Bacopoulos and Dr. David U'Prichard. Generally, our Compensation and Organization Development Committee reviews, approves and makes recommendations regarding our compensation policies, practices and procedures to ensure that legal and fiduciary responsibilities of the Board of Directors are carried out and that such policies, practices and procedures contribute to our success. The Compensation and Organization Development Committee also develops and implements policies, principles and procedures for the selection and performance review of the Company's executive officers (including our Chief Executive Officer), other officers, directors, employees, consultants, and advisors; interprets and administers our Amended and Restated 2006 Equity Incentive Plan.

*Nominating and Corporate Governance Committee.* Our Nominating and Corporate Governance Committee conducted its affairs during meetings of our Board of Directors, including a self-evaluation process which was undertaken by our Board of Directors, and did not meet separately. The Nominating and Corporate Governance Committee has two members, Sir John Banham (Chairman) and Mr. Daniel K. Spiegelman, both of whom qualify as independent under the definition promulgated by the NASDAQ and SEC. The functions of the Nominating and Corporate Governance Committee include making recommendations to the full Board of Directors as to particular nominees for election or appointment to the Board of Directors; making recommendations to the full Board of Directors as to the membership, structure and operations of the committees of the Board of Directors; reviewing and assessing the adequacy of our corporate governance guidelines, principles and practices and recommending changes to the full Board of Directors for approval; monitoring compliance with our Corporate Code of Conduct and Ethics; and reviewing and maintaining oversight of matters relating to the independence, operation and effectiveness of the Board of Directors and committee members.

The Nominating and Corporate Governance Committee may consider candidates recommended by stockholders as well as from other sources, such as other directors or officers, third party search firms or other appropriate sources for all potential candidates. The Nominating and Corporate Governance Committee may consider all factors it deems relevant, such as a candidate's personal integrity and sound judgment, business and professional skills and experience, independence, knowledge of the industry in which we operate, possible conflicts of interest, diversity, the extent to which the candidate would fill a present need on the Board of Directors, and concern for the long-term interests of the stockholders. In general, persons recommended by stockholders will be considered on the same basis as candidates from other sources. If a stockholder wishes to nominate a candidate to be considered for election as a director at our 2011 annual meeting of stockholders, such a recommendation should be submitted in writing to the Nominating and Corporate Governance Committee, c/o Paul McBarron, Secretary, Cyclacel Pharmaceuticals, Inc., 200 Connell Drive, Suite 1500, Berkeley Heights, New Jersey 07922. Any such written recommendation should include a minimum of the following: (a) all information relating to such person that would be required to be disclosed pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended, or the Exchange Act (including such person's consent to being named in the proxy statement as a nominee and to serving as a director, if elected); (b) the name(s) and address(es) of the stockholder(s) making the recommendation; and (c)(i) the name, age, business address and residence address of such nominee, (ii) the principal occupation or employment of such nominee, (iii) the class and number of shares of the Company which are beneficially owned by such person and (iv) any other information relating to such nominee that is required to be disclosed in solicitations of proxies for election of directors. Any such recommendation should be submitted in the time frame for stockholder proposals which are to be included in proxy materials for the annual meeting to be held in 2012.

We have no formal policy regarding board diversity. Our Nominating and Corporate Governance Committee and Board of Directors may therefore consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity, which is not only limited to race, gender or national origin. Our Nominating and Corporate Governance Committee and Board of Directors' priority in selecting members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members and professional and personal experiences and expertise relevant to our growth strategy.

#### Compliance with Section 16(a) of the Exchange

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our officers and directors, and persons who own more than 10% of a registered class of our equity securities to file reports of ownership and changes in ownership with the SEC. These persons are required by regulation to furnish us with copies of all Section 16(a) reports that they file. Based on our review of the copies of these reports received by us, or written representations from the reporting persons that no other reports were required, we believe that, during fiscal year 2010, all reports to be filed pursuant to Section 16(a) of the Exchange Act were filed on a timely basis, except that two reports, covering an aggregate of two transactions, were filed late by Austin W. Marx and David M. Greenhouse, filing jointly, and an initial report of ownership was filed late by Austin W. Marx and David M. Greenhouse, filing jointly.

#### Code of Conduct and Ethics

We have adopted a code of conduct and ethics that applies to all of our employees, including our chief executive officer and chief financial and accounting officers. The text of the code of conduct and ethics is posted on our website at [www.cyclacel.com](http://www.cyclacel.com), is filed as an exhibit to our Annual Report on Form 10-K, and will be made available to stockholders without charge, upon request, in writing to the Corporate Secretary at 200 Connell Drive, Suite 1500, Berkeley Heights, New Jersey 07922, Attention: Paul McBarron, Executive Vice President—Finance, Chief Financial Officer, Chief Operating Officer and Secretary. Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K within

four business days following the date of the amendment or waiver, unless website posting of such amendments or waivers is then permitted by the rules of NASDAQ.

**Item 11. Executive Compensation**  
**Summary Compensation Table**

The following table shows the compensation paid or accrued during the last two fiscal years ended December 31, 2009 and 2010 to (1) our President and Chief Executive Officer, (2) our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, and (3) our next most highly compensated executive officer, other than our President and Chief Executive Officer and our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, who earned more than \$100,000 during the year ended December 31, 2010.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)(1)	Stock Awards (\$)(2)	Option Awards (\$)(3)	All Other Compensation (\$)(4)	Total (\$)
Spiro Rombotis							
President and Chief Executive Officer	2010	476,100	59,500	—	92,250	32,506	660,356
	2009	460,000	138,000 <sup>(4)</sup>	—	—	32,188	630,188
Paul McBarron <sup>(5)</sup>							
Executive Vice President, Finance, Chief Operating Officer, Chief Financial Officer, and Secretary	2010	289,768	36,350	—	92,250	17,732	436,100
	2009	288,297	86,489 <sup>(4)</sup>	—	—	17,903	392,689
Judy Chiao, MD							
Vice President, Clinical Development and Regulatory Affairs	2010	312,570	75,000	—	76,875	19,624	484,069
	2009	302,000	72,480 <sup>(4)</sup>	—	—	20,552	395,032

(1) This column represents the dollar amount recognized for financial statement reporting purposes for the fair value of stock awards. The fair value, a non-cash expense, was estimated using the Black-Scholes option-pricing method in accordance with ASC Topic 718. See Note 13 to our Financial Statements reported in our Form 10-K/A for our fiscal year ended December 31, 2009 and Note 11 to our Financial Statements reported in our Form 10-K for our fiscal year ended December 31, 2010 for details as to the assumptions used to determine the fair value of the stock awards and stock options. See also our discussion of stock-based compensation under “Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates.”

(2) These amounts represent the aggregate grant date fair value for option awards for fiscal years 2009 and 2010, respectively, computed in accordance with FASB ASC Topic 718. The grant date fair value of performance awards is determined based on the probable outcome of such performance conditions as of the grant date. A discussion of the assumptions used in determining grant date fair value may be found in Note 11 to our Financial Statements, included in our Annual Report on Form 10-K for the year ended December 31, 2010.

- 3) Consists of the following for all executive officers: Payments for private medical and health insurance, life insurance and permanent health insurance; matching contributions made under the Company's UK Group Personal Pension Plan and the U.S. 401(k) Plan.
- 4) Bonuses earned in 2009 were paid during fiscal year 2010 and were not accrued in the Company's Financial Statements. Bonuses earned in 2010 were paid during fiscal year 2010 and were not accrued in the Company's Financial Statements.
- 5) Mr. McBarron's compensation was translated from British pound sterling to the U.S. dollar using the exchange rate of \$1.59280 as of December 31, 2009 and \$1.54679 as of December 31, 2010.

### **Narrative Disclosure to Summary Compensation Table**

The Compensation and Organization Development Committee of our Board of Directors makes decisions regarding the compensation of our President and Chief Executive Officer. The Compensation and Organization Development Committee is composed entirely of independent directors and meets in executive session to discuss and formulate its recommendation for the Chief Executive Officer's base salary and bonus. The Compensation and Organization Development Committee does not rely solely on any predetermined formula or a limited set of criteria in evaluating the Chief Executive Officer's performance for the year. The evaluation is based on the Chief Executive Officer's success in achieving his performance goals, which include financial, strategic and leadership objectives. The Chief Executive Officer also provides the Compensation and Organization Development Committee with a self review of his performance as part of the Company's review process.

The Compensation and Organization Development Committee also approves the annual compensation (including base salary, bonus, and stock-based compensation) for our other named executive officers based on:

- the executive's scope of responsibilities;
- an informed market assessment of competitive practices for similar roles within peer group companies;
- evaluations of performance for the year, as assessed by the Chief Executive Officer, supported by the Company's performance review process and the executive's self assessment; and
- recommendations by our Chief Executive Officer for each named executive officer with respect to base salary, cash bonus, and stock-based compensation.

The Compensation and Organization Development Committee is authorized to engage and retain independent third party compensation and legal advisors to obtain advice and assistance on all matters related to executive compensation and benefit plans. During 2008, the Compensation and Organization Development Committee selected and engaged a representative of Radford Surveys and Consulting, a business unit of AON, to be the independent compensation consultant to the Committee to assess our 2007 and 2008 executive compensation program. Using this extensive analysis, the Compensation and Organization Development Committee acted on the recommendations made to determine executive compensation and implement our compensation program structures for 2009 and 2010. Although no external compensation consultant was engaged during 2009 or 2010, the Compensation and Organization Development Committee did consult independent external compensation survey data as part of the decision making process relating to such periods.

The Company intends to engage periodically an external consultant to provide independent verification of market position and ensure the appropriateness of executive compensation.

No stock options were granted to our named executive officers during 2009. On December 10, 2010, our Board of Directors, at the recommendation of the Compensation and Organization Development Committee, made stock option grants under our Amended and Restated 2006 Equity Incentive Plan to our executive officers. The stock options were granted at an exercise price of \$1.59 per share, and are exercisable over a four-year period, such options vesting ratably on a monthly basis over 48 months.

During 2009, the Company granted 221,000 stock options to employees and directors of the Company with a weighted value exercise price of \$0.39 per share. During 2010, the Company granted 607,300 stock options to employees and directors of the Company with a weighted value exercise price of \$1.82 per share.

We currently have employment agreements with two of our named executive officers, Spiro Rombotis, our President and Chief Executive Officer, and Paul McBarron, our Executive Vice President—Finance, Chief Financial Officer, Chief Operating Officer and Secretary.

On March 20, 2008, we entered into a three-year employment agreement with Mr. Spiro Rombotis, effective January 1, 2008, which agreement was renewed on substantially the same terms, effective January 1, 2011, for an additional three years. This agreement provides for an initial annual base salary of \$490,383, which salary may be increased in the future. Mr. Rombotis's annual base salary was \$460,000 and \$476,100, respectively, for 2009 and 2010. Mr. Rombotis is also eligible for a yearly incentive cash bonus, based on a percentage of his then current base salary, if he meets certain corporate and individual performance criteria set by the Compensation and Organization Development Committee at the beginning of each year of employment, subject to the approval of our Board of Directors. The agreement had been amended effective December 31, 2008, to make certain payments to be made under the agreement compliant with Section 409A of the Internal Revenue Code of 1986, as amended, and similar regulations.

On March 31, 2008, we entered into a three-year employment agreement with Mr. Paul McBarron effective January 1, 2008, which agreement was renewed on substantially the same terms, effective January 1, 2011, for an additional three years. This agreement provides for an initial annual base salary of £192,955, which salary may be increased in the future. Mr. McBarron's base salary was £181,000 and £187,278 for 2009 and 2010, respectively. Mr. McBarron is also eligible for a yearly incentive cash bonus, based on a percentage of his then current base salary, if he meets certain corporate and individual performance criteria set by the Compensation and Organization Development Committee at the beginning of each year of employment, subject to the approval of our Board of Directors.

## Outstanding Equity Awards At Fiscal Year-End

The following table shows grants of stock options and grants of unvested stock or unvested stock units outstanding on the last day of the fiscal year ended December 31, 2010, including non-performance based awards, to each of the executive officers named in the Summary Compensation Table. The Company does not have any unearned equity incentive awards.

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options # Exercisable	Number of Securities Underlying Unexercised Options # Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested #	Market Value of Shares or Units of Stock That Have Not Vested <sup>(1)</sup> \$
Spiro Rombotis	97,834	0	\$6.40	06/13/2016		
	160,000	0 <sup>(2)</sup>	\$6.95	12/20/2016		
	150,000	50,000 <sup>(3)</sup>	\$5.53	12/06/2017		
	29,171	45,829 <sup>(4)</sup>	\$0.44	11/18/2018		
	0	75,000 <sup>(5)</sup>	\$1.59	12/10/2020		
					23,954 <sup>(6)</sup>	35,212
Paul McBarron	63,680	0	\$6.40	06/13/2016		
	100,000	0 <sup>(7)</sup>	\$6.95	12/20/2016		
	75,000	25,000 <sup>(8)</sup>	\$5.53	12/06/2017		
	104,171	45,829 <sup>(9)</sup>	\$0.44	11/18/2018		
	0	75,000 <sup>(10)</sup>	\$1.59	12/10/2020		
					23,954 <sup>(11)</sup>	35,212
Judy Chiao	48,967	0	\$6.40	06/13/2016		
	80,000	0 <sup>(12)</sup>	\$6.95	12/20/2016		
	75,000	25,000 <sup>(13)</sup>	\$5.53	12/06/2017		
	52,085	22,915 <sup>(14)</sup>	\$0.44	11/18/2018		
	0	62,500 <sup>(15)</sup>	\$1.59	12/10/2020		
					11,977 <sup>(16)</sup>	17,606

(1) The market value of the shares is determined by multiplying the number of shares by \$1.47, the closing price of our common stock on the NASDAQ Global Market on December 31, 2010, the last day of our fiscal year.

(2) These options were granted on December 21, 2006, and are exercisable over a four-year period with one-fourth (1/4) of the options granted vesting on December 21, 2007, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 36 months.

(3) These options were granted on December 6, 2007, and are exercisable over a four-year period with one-fourth (1/4) of the options granted vesting on December 6, 2008, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 36 months.

- (4) These options were granted on November 18, 2008, and vest over a three-year period, with one-third (1/3) of the options granted vesting on November 18, 2009, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 24 months.
- (5) These options were granted on December 10, 2010, and vest over a four-year period, such options vesting ratably on a monthly basis over 48 months.
- (6) The restricted stock units were granted on November 18, 2008, and vest over a four-year period, with one-fourth (1/4) of the restricted stock units granted vesting on November 18, 2009, the first anniversary of the grant date, and the balance of the restricted stock units granted vesting ratably on a monthly basis over the following 36 months.
- (7) These options were granted on December 21, 2006, and are exercisable over a four-year period with one-fourth (1/4) of the options granted vesting on December 21, 2007, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 36 months.
- (8) These options were granted on December 6, 2007, and are exercisable over a four-year period with one-fourth (1/4) of the options granted vesting on December 6, 2008, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 36 months.
- (9) These options were granted on November 18, 2008, and vest over a three-year period, with one-third (1/3) of the options granted vesting on November 18, 2009, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 24 months.
- (10) These options were granted on December 10, 2010, and vest over a four-year period, such options vesting ratably on a monthly basis over 48 months.
- (11) These shares of common stock represent restricted stock and are subject to forfeiture; the restrictions shall lapse over a four-year period, as follows: the restrictions with respect to one-fourth (1/4) of the restricted stock granted shall lapse on November 18, 2009, the first anniversary of the grant date, and the restrictions with respect to the balance of the restricted stock granted shall lapse ratably on a monthly basis over the following 36 months.
- (12) These options were granted on December 21, 2006, and are exercisable over a four-year period with one-fourth (1/4) of the options granted vesting on December 21, 2007, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 36 months.
- (13) These options were granted on December 6, 2007, and are exercisable over a four-year period with one-fourth (1/4) of the options granted vesting on December 6, 2008, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 36 months.
- (14) These options were granted on November 18, 2008, and vest over a three-year period, with one-third (1/3) of the options granted vesting on November 18, 2009, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 24 months.
- (15) These options were granted on December 10, 2010, and vest over a four-year period, such options vesting ratably on a monthly basis over 48 months.
- (16) The restricted stock units were granted on November 18, 2008, and vest over a four-year period, with one-fourth (1/4) of the restricted stock units granted vesting on November 18, 2009, the first anniversary of the grant date, and the balance of the restricted stock units granted vesting ratably on a monthly basis over the following 36 months.

## **Nonqualified Deferred Compensation**

We do not have any non-qualified deferred compensation plans.

## **Potential Payments Upon Termination or Change-in-Control**

We have entered into agreements that require us to make payments and/or provide benefits to certain of our executive officers in the event of a termination of employment or change-in-control. Our Amended and Restated 2006 Equity Incentive Plan already provides for payments to named executive officers in connection with a termination or a change-in-control of the Company.

The following summarizes the potential payments to each named executive officer for which we have entered into such an agreement, assuming that one of the events identified below occurs. The discussion assumes that the event occurred on December 31, 2010, the last business day of our fiscal year, at which time the closing price of our common stock as listed on the NASDAQ Global Market was \$1.47 per share. Our change-in-control arrangements with our executive officers are currently being reviewed and assessed by our Compensation and Organization Development Committee, in consultation with our Board of Directors. The reviewing process is on-going and has not yet been finalized.

### *Spiro Rombotis, President and Chief Executive Officer*

On March 20, 2008, we entered into a three-year employment agreement with Mr. Spiro Rombotis, effective January 1, 2008, which agreement was renewed on substantially the same terms, effective January 1, 2011, for an additional three years. Mr. Rombotis's current base salary is \$490,383, which may be increased in the future. Mr. Rombotis is also eligible for a yearly incentive cash bonus, based on a percentage of his then current base salary, if he meets certain corporate and individual performance criteria set by the Compensation and Organization Development Committee at the beginning of each year of employment, subject to the approval of our Board of Directors. The agreement also provides for reimbursement of reasonable and necessary expenses incurred by Mr. Rombotis in connection with the performance of his services. In addition, Mr. Rombotis is entitled to certain employment benefits.

The agreement also provides for certain severance arrangements for Mr. Rombotis. In the event that Mr. Rombotis's employment is terminated "without cause," other than termination for a "change of control" (each as defined in the Agreement), we will be required to pay Mr. Rombotis (i) all accrued but unpaid compensation up to the time of such termination; (ii) for a period of twelve months following such termination, severance payments in the form of continuation of his base salary as in effect immediately prior to such termination (the "Severance Payments"), including coverage of his medical care and life insurance pursuant to COBRA, on the same terms as applicable to other executive employees, unless Mr. Rombotis obtains substitute coverage; and (iii) a period of six months in which to exercise all vested options held by Mr. Rombotis. In the event that Mr. Rombotis' employment is terminated within six months following a "change in control" event, Mr. Rombotis will be entitled to (i) all accrued but unpaid compensation up to the time of such termination; (ii) Severance Payments for a period of 24 months; (iii) out-of-pocket expenses reasonably incurred by Mr. Rombotis in connection with his and his family's relocation to London; and (iv) 18 months' accelerated vesting of any options held by him. In the event of termination due to his death or disability, we will pay Mr. Rombotis (or his estate, as the case may be) (i) all accrued but unpaid compensation up to the time of such termination; (ii) Severance Payments for a period of twelve months; and (iii) he will be entitled to a period of twelve months in which all of his vested options can be exercised.

In addition, Mr. Rombotis also agreed to certain confidentiality and assignment of inventions obligations and will be subject to certain non-competition obligations for a period of one year following termination of his employment.

Mr. Rombotis's employment agreement was amended effective December 31, 2008, to make certain payments to be made under the agreement compliant with Section 409A of the Internal Revenue Code of 1986, as amended, and then amended again effective January 1, 2011 to extend its term for an additional three years.

*Paul McBarron, Executive Vice President—Finance, Chief Financial Officer, Chief Operating Officer and Secretary*

On March 31, 2008, we entered into a three-year employment agreement with Mr. Paul McBarron effective January 1, 2008, which agreement was renewed on substantially similar terms, effective January 1, 2011, for an additional three years. Mr. McBarron's current base salary is £192,955, which may be increased in the future. Mr. McBarron is also eligible for a yearly incentive cash bonus, based on a percentage of his then current base salary, if he meets certain corporate and individual performance criteria set by the Compensation and Organization Development Committee at the beginning of each year of employment, subject to the approval of our Board of Directors. The agreement also provides for reimbursement of reasonable and necessary expenses incurred by Mr. McBarron in connection with the performance of his services. In addition, Mr. McBarron is entitled to certain employment benefits.

The agreement also provides for certain severance arrangements for Mr. McBarron. In the event that Mr. McBarron's employment is terminated "without cause," other than termination for a "change of control" (each as defined in the Agreement), we will be required to pay Mr. McBarron (i) all accrued but unpaid compensation up to the time of such termination; (ii) Severance Payments for a period of twelve months following such termination; and (iii) a period of six months in which to exercise all vested options held by Mr. McBarron. In the event that Mr. McBarron's employment is terminated within six months following a "change in control" event, Mr. McBarron will be entitled (i) all accrued but unpaid compensation up to the time of such termination; (ii) Severance Payments for a period of 12 months; and (iii) 18 months' accelerated vesting of any options held by him and, in the event of termination due to his death or disability, we will pay Mr. McBarron (or his estate, as the case may be) (i) all accrued but unpaid compensation up to the time of such termination; (ii) Severance Payments for a period of twelve months; and (iii) he will be entitled to a period of twelve months in which all of his vested options can be exercised.

In addition, Mr. McBarron also agreed to certain confidentiality and assignment of inventions obligations and will be subject to certain non-competition obligations for a period of one year following termination of his employment.

*Dr. Judy Chiao, Vice President, Clinical Development and Regulatory Affairs*

On December 10, 2010, we entered into a Change in Control Agreement, or the CIC Agreement, with Dr. Chiao.

In the event of a Change in Control (as defined below) of the Company, and Dr. Chiao's employment with the continuing or surviving company, or the Controlling Company, is terminated (including if Dr. Chiao voluntarily terminates her employment for Good Reason, as defined below) at any time within six months following the effective date of a Change in Control, unless such termination is For Cause, death, disability or Dr. Chiao voluntarily leaves without Good Reason (as each such term is defined below), Dr. Chiao will be entitled to receive the following benefits from the Controlling Company in lieu of any further salary and bonus payments to Dr. Chiao for certain periods subsequent to the date of termination in consideration for Dr. Chiao's execution and delivery of a general release in favor of the Controlling Company: (i) payment by the Controlling Company of a lump sum severance payment equal to Dr. Chiao's annual salary for a period of twelve months from the date of termination; (ii) payment by the Controlling Company of all unpaid, accrued vacation through the date of termination; (iii) all options to purchase shares of the Company's Common Stock held by Dr. Chiao shall be vested and exercisable for twelve months

following the effective date of the Change in Control; and (iv) the Controlling Company shall arrange coverage for Dr. Chiao and her dependents, as the case may be, under medical care and life insurance benefit plans substantially similar to those which Dr. Chiao and her dependents were entitled immediately prior to the effective date of the Change in Control for a period of up to twelve months after the effective date of the Change in Control, subject to certain exceptions as set forth in more detail in the CIC Agreement.

Under the terms of the CIC Agreement, a “Change in Control” shall be deemed to have taken place in the event of: (i) any consolidation or merger of the Company is consummated in which Company is not the continuing or surviving corporation or pursuant to any transaction in which shares of the Company’s capital stock are converted into cash, securities or other property, or any sale, lease, exchange or other transfer in one transaction or a series of transactions contemplated or arranged by any party as a single plan of all or substantially all of the assets of the Company, or the approval of a plan of complete liquidation or dissolution of the Company adopted by the stockholders of the Company; (ii) any person (as such term is used in Sections 13(d) and 14(d)(2) of the Exchange Act, shall, after the date of the CIC Agreement, become the beneficial owner (as defined in Rules 13d-3 and 13d-5 under the Exchange Act), directly or indirectly, of securities of the Company representing 35% or more of the voting power of all then outstanding securities of the Company having the right under ordinary circumstances to vote in an election of the board of directors; or (iii) individuals who, at the date of the CIC Agreement, constitute the entire Board and any new directors whose election by the Board, or whose nomination for election by the Company’s stockholders, shall have been approved by a vote of at least a majority of the directors then in office who either were directors as of such date or whose election or nomination for election shall have been so approved shall cease for any reason to constitute a majority of the members of the Board.

Dr. Chiao’s employment shall have been terminated “For Cause” if the Controlling Company shall have terminated Dr. Chiao as a result of: (A) improper conduct, consisting of any willful act or omission with the intent of obtaining, to the material detriment of the Controlling Company, any benefit to which Dr. Chiao would not otherwise be entitled; (B) gross negligence, consisting of wanton and reckless acts or omissions in the performance of Dr. Chiao’s duties to the material detriment of the Controlling Company; (C) addiction to drugs or chronic alcoholism; or (D) any conviction of, or plea of *nolo contendere* to, a crime (other than a traffic violation) under the laws of the United States or any political subdivision thereof, subject to certain requirements, as set forth in more detail in the CIC Agreement.

Dr. Chiao shall be deemed to have terminated her employment for “Good Reason” if the Controlling Company (A) materially reduces Dr. Chiao’s duties, responsibilities or authority commensurate with his or her position immediately prior to the effective date of the Change in Control; (B) reduces Dr. Chiao’s base salary in effect immediately prior to the effective date of the Change of Control; (C) requires Dr. Chiao to relocate to another office more than 50 miles of her office location immediately prior to the effective date of the Change of Control, subject to certain exceptions, as more fully set forth in detail in the CIC Agreement; or (D) fails to offer Dr. Chiao all material benefits offered to all other employees of the Controlling Company, and the Controlling Company fails to correct or cure the acts giving rise to the termination of Dr. Chiao’s employment for “Good Reason,” after receipt of Dr. Chiao’s notice of such acts.

*Potential payments to each named executive officer under our Amended and Restated 2006 Equity Incentive Plan in connection with a termination or a change-in-control of the Company*

The following summarizes the potential payments to each named executive officer under our Amended and Restated 2006 Equity Incentive Plan in connection with a termination or a change-in-control of the Company.

## ***Termination***

*Termination For Cause* - If an award recipient's service relationship with the Company terminates for "cause" (as defined in the Amended and Restated 2006 Equity Incentive Plan, or the 2006 Plan), then any unexercised award shall terminate immediately upon his or her termination of service.

*Termination Without Cause* - If an award recipient's service relationship with the Company terminates for any reason other than for "cause" (excluding death or disability), then the recipient generally may exercise the award, to the extent vested, within 30 days of such termination to the extent that the award is vested on the date of termination (but in no event later than the expiration of the term of the award as set forth in the award agreement). If the recipient dies within three months following such a termination, the award generally may be exercised, to the extent vested, within 180 days' of the recipient's death.

*Death* - If an award recipient's service relationship with the Company terminates due to his or her death, the award recipient's personal representative, estate, or the person who acquires the right to exercise the award by bequest or inheritance, as the case may be, generally may exercise the award, to the extent the award was vested on the date of termination, within one year from the date of the recipient's death.

*Disability* - If an award recipient's service relationship with the Company terminates due to his or her disability, the recipient, the recipient's personal representative, estate, or the person who acquires the right to exercise the award by bequest or inheritance, as the case may be, generally may exercise the award, to the extent the award was vested on the date of termination, within one year from the date of the recipient's termination, or if the recipient dies during such one-year period, within the later of one year from the date of the recipient's termination and 180 days from the recipient's death. In no event may an award be exercised later than the expiration of the term of the award as set forth in the award agreement.

## ***Change in Control***

Pursuant to the terms of the Amended and Restated 2006 Equity Incentive Plan, in the event of a change in control (as defined in the 2006 Plan), all outstanding options, SARs and other awards granted under the 2006 Plan will be either:

- assumed by the successor corporation or a parent or subsidiary of the successor corporation; or
- substituted with an equivalent award by the successor corporation or a parent or subsidiary of the successor corporation.

However, in the event that the successor corporation refuses to assume or substitute an award:

- awards consisting of options, SARs and rights to purchase restricted stock will become fully vested and immediately exercisable, including awards that would not otherwise have become vested or exercisable; and
- all other awards will become fully earned and eligible to receive a payout.

For the purposes of the Amended and Restated 2006 Equity Incentive Plan, a participant's award will be considered assumed if, following the change in control, the assumed award confers, for each share of the Company's common stock subject to the award immediately prior to the change in control, the right to receive the consideration (whether stock, cash, or other securities or property) received in the change in control for each share of common stock held on the effective date of the transaction; provided, however, that if the consideration received in the change of control is not solely common stock of the successor corporation or its parent, the committee administering the plan may, with the consent of the successor corporation, provide for

the consideration per share to be received upon the exercise of the award, to be solely common stock of the successor corporation or its parent equal in fair market value to the per share consideration received by holders of the Company's common stock in the change of control.

Under the 2006 Plan, a change of control is the occurrence of one of the following events:

- a person, partnership, joint venture, corporation or other entity, or two or more of any of the foregoing acting as a group (or any "person" within the meaning of Sections 13(d)(3) and 14(d) of the 1934 Act), other than the Company, a Subsidiary, or an employee benefit plan (or related trust) of the Company or a Subsidiary, become(s) the "beneficial owner" (as defined in Rule 13d-3 under the 1934 Act) of 30% or more of the then-outstanding voting stock of the Company;
- during any period of two consecutive years, individuals who at the beginning of such period constitute the Board of Directors (together with any new director whose election by the Board of Directors or whose nomination for election by the Company's stockholders, was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of such period or whose election or nomination for election was previously so approved) cease for any reason to constitute a majority of the directors then in office;
- all or substantially all of the business of the Company is disposed of pursuant to a merger, consolidation or other transaction in which the Company is not the surviving corporation or the Company combines with another Company and is the surviving corporation (unless the stockholders of the Company immediately following such merger, consolidation, combination, or other transaction beneficially own, directly or indirectly, more than 50% of the aggregate voting stock or other ownership interests of (x) the entity or entities, if any, that succeed to the business of the Company or (y) the combined company);
- the Company is a party to a merger, consolidation, sale of assets or other reorganization, or a proxy contest, as a consequence of which the Board of Directors in office immediately prior to such transaction or event constitutes less than a majority of the Board of Directors thereafter; or
- the stockholders of the Company approve a sale of all or substantially all of the assets of the Company or a liquidation or dissolution of the Company.

## Director Compensation

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2010 to each of our non-employee directors:

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(1)</sup>	Total (\$)
David U'Prichard, Ph.D.	66,000	89,500 <sup>(2)</sup>	155,500
Sir John Banham	37,000	44,750 <sup>(3)</sup>	81,750
Nicholas Bacopoulos, Ph.D.	29,000	44,750 <sup>(4)</sup>	73,750
Christopher S. Henney, Ph.D., D.Sc.	56,000	89,500 <sup>(5)</sup>	145,500
Daniel K. Spiegelman	43,000	62,650 <sup>(6)</sup>	105,650

- (1) These amounts represent the grant date fair value of stock awards granted to each director in 2010 computed in accordance with FASB ASC Topic 718. The grant date fair value of performance awards is determined based on the probable outcome of such performance conditions as of the grant date. A discussion of the assumptions used in determining grant date fair value may be found in Note 11 to our Financial Statements, included in our Annual Report on Form 10-K for the year ended 2010, as amended.
- (2) Fair value of the options granted on March 29, 2010 was \$1.79 per share. 250,000 options remain outstanding as of December 31, 2010.
- (3) Fair value of the options granted on March 29, 2010 was \$1.79 per share. 125,000 options remain outstanding as of December 31, 2010.
- (4) Fair value of the options granted on March 29, 2010 was \$1.79 per share. 75,000 options remain outstanding as of December 31, 2010.
- (5) Fair value of the options granted on March 29, 2010 was \$1.79 per share. 271,000 options remain outstanding as of December 31, 2010.
- (6) Fair value of the options granted on March 29, 2010 was \$1.79 per share. 156,500 options remain outstanding as of December 31, 2010.

## Director Compensation Program

Non-employee directors are compensated for their services as members of the Board of Directors and any committee of the Board of Directors, each in the amount of an annual cash retainer of \$20,000. The Chairman of the Compensation and Organization Development Committee and the Nominating and Corporate Governance Committee are each entitled to an additional annual cash retainer of \$7,000. The Chairman of the Audit Committee is entitled to an additional annual cash retainer of \$10,000. The Chairman of our Board of Directors receives a \$54,000 annual cash retainer for his services, and the Vice Chairman receives a \$34,000 annual cash retainer for his services.

In addition to the annual cash retainers, the non-employee members of our Board of Directors are entitled to \$2,000 for each Board of Directors meeting attended in person and \$1,000 for each Board of Directors meeting attended telephonically. The non-employee directors are also reimbursed for certain customary business expenses in connection with attending Board of Directors and committee meetings.

In addition to the cash compensation outlined above, the Chairman and Vice Chairman of the Board of Directors are each entitled to receive annually an option to purchase 50,000 shares of our common stock. Each of the other non-employee directors is entitled to receive annually an option to purchase 25,000 shares of our

common stock; the Chairman of the Audit Committee is entitled to receive annually an option to purchase 10,000 shares of our common stock.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters**

The following table sets forth certain information with respect to the beneficial ownership of our Common Stock as of March 22, 2011 for (a) the executive officers named in the Summary Compensation Table on page 141 of this report, (b) each of our directors, (c) all of our current directors and executive officers as a group, and (d) each stockholder known by us to own beneficially more than 5% of each class of our Common Stock, relying solely upon the amounts and percentages disclosed in their public filings.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of March 22, 2011 pursuant to the exercise or conversion of options or warrants to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of stock shown to be beneficially owned by them based on information provided to us by these stockholders.

Percentage of ownership is based on 46,598,688 shares of Common Stock outstanding as of March 22, 2011.

The address for each of the directors and named executive officers is c/o Cyclacel Pharmaceuticals, Inc., 200 Connell Drive Suite 1500, Berkeley Heights, New Jersey 07922. Addresses of other beneficial owners are noted in the table.

	<b>Number of Shares of Common Stock Beneficially Owned<sup>(1)</sup></b>	<b>Percentage of Common Stock Owned</b>
<i>Directors and Executive Officers</i>		
Dr. Nicholas Bacopoulos <sup>(2)</sup> .....	40,703	*
Sir John Banham <sup>(3)</sup> .....	131,299	*
Dr. Judy Chiao <sup>(4)</sup> .....	355,524	*
Dr. Christopher Henney <sup>(5)</sup> .....	217,071	*
Paul McBarron <sup>(6)</sup> .....	556,930	1.19%
Spiro Rombotis <sup>(7)</sup> .....	1,042,562	2.21%
Daniel K. Spiegelman <sup>(8)</sup> .....	115,605	*
Dr. David U'Prichard <sup>(9)</sup> .....	214,210	*
Executive officers and directors as a group (8 persons) <sup>(10)</sup> .....	<u>2,673,904</u>	5.53%
<i>5% or more stockholders</i>		
Austin W. Marx and David M. Greenhouse <sup>(11)</sup> 527 Madison Avenue, Suite 2600, New York, NY 10022	9,911,148	18.91%

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\* Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Beneficial ownership also includes shares of common stock subject to options, warrants and preferred stock currently exercisable or convertible, or exercisable or convertible within 60 days of March 22, 2011. Except as indicated by footnote, to our knowledge, all persons named in the table above have sole voting and investment power with respect to all shares of common stock shown as beneficially owned.

(2) Includes options to purchase 38,203 shares of Common Stock that are exercisable within 60 days of March 22, 2011.

(3) Includes options to purchase 94,452 shares of Common Stock that are exercisable within 60 days of March 22, 2011.

(4) Includes options to purchase 282,356 shares of Common Stock that are exercisable within 60 days of March 22, 2011. Also includes 10,414 restricted stock units.

(5) Includes options to purchase 209,904 shares of Common Stock that are exercisable within 60 days of March 22, 2011.

(6) Includes options to purchase 380,876 shares of Common Stock that are exercisable within 60 days of March 22, 2011.

(7) Includes options to purchase 484,404 shares of Common Stock that are exercisable within 60 days of March 22, 2011. Also includes 20,828 restricted stock units. Of the shares of Common Stock reported, 1,000 shares are held indirectly by Mr. Rombotis through his IRA account.

(8) Includes options to purchase 115,605 shares of Common Stock that are exercisable within 60 days of March 22, 2011.

(9) Includes options to purchase 188,904 shares of Common Stock that are exercisable within 60 days of March 22, 2011.

(10) See footnotes (2)-(9). Also includes options to purchase 108,781 shares of Common Stock held by Robert Sosnowski, our Vice President, Sales & Marketing, which are exercisable within 60 days of March 22, 2011.

(11) Based on a Schedule 13G filed on February 11, 2011 with the SEC by Austin W. Marx ("Marx") and David M. Greenhouse ("Greenhouse"). Marx and Greenhouse share sole voting and investment power over 4,106,900 shares of common stock, 2,724,073 warrants to purchase shares of common stock, 176,200 warrants (not currently exercisable) and options to purchase 2,053,450 units (each unit consists of one share of common stock and warrant to purchase 0.5 of common stock). This amount includes 547,600 shares of common stock, 381,965 warrants to purchase shares of common stock, 26,400 warrants (not currently exercisable) and options to purchase 273,800 units (each unit consists of one share of common stock and warrant to purchase 0.5 of common stock) owned by Special Situations Private Equity Fund, L.P., 684,500 shares of common stock, warrants to purchase 342,250 shares of common stock and options to purchase 342,250 units (each unit consists of one share of common stock and warrant to purchase 0.5 of common stock) are owned by Special Cayman Fund, L.P., 2,053,400 shares of common stock, 1,459,360 warrants to purchase shares of common stock, 114,000 warrants (not currently exercisable) and options to purchase 1,026,700 units (each unit consists of one share of common stock and warrant to purchase 0.5 of common stock) owned by Special Situations Fund III QP, L.P. and 821,400 shares of common stock, 540,498 warrants to purchase shares of common stock, 35,800 warrants (not currently exercisable) and options to purchase 410,700 units (each unit consists of one share of common stock and warrant to purchase 0.5 of common stock) owned by Special Situations Life Sciences Fund, L.P. Marx and Greenhouse are the controlling principals of AWM Investment Company, Inc., the general partner of and investment adviser to Special Situations Cayman Fund, L.P. AWM also serves as the general partner of MGP Advisers Limited Partnership, the general partner of Special Situations Fund III QP, L.P. Marx and Greenhouse are members of

MG Advisers L.L.C., the general partner of Special Situations Private Equity Fund, L.P. Marxe and Greenhouse are also members of LS Advisers L.L.C., the general partner of Special Situations Life Sciences Fund, L.P. AMW serves as the investment adviser to Special Situations Private Equity Fund, L.P., Special Situations Fund III QP, L.P. and Special Situations Life Sciences Fund, L.P.

### Equity Compensation Plan Information

The following table provides certain aggregate information with respect to all of our equity compensation plans in effect as of December 31, 2010:

<u>Plan Category</u>	(a)	(b)	(c)
	No. of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in <u>column (a)</u> )
Total equity compensation plans approved by security holders (1)	3,549,817	\$3.90	1,363,894
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 18, 2011, under the 2006 Plan is 5,200,000.

### Item 13. Certain Relationships and Related Transactions, and Director Independence

Our Audit Committee reviews and approves in advance all related-party transactions. There have been no transactions during our last two fiscal years with our directors and officers and beneficial owners of more than 5% of our voting securities and their affiliates.

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

The following table presents fees for professional audit services rendered by E&Y for the audit of Cyclacel's annual financial statements for the years ended December 31, 2009 and 2010, and fees billed for other services rendered by E&Y during those periods.

	<u>2009</u>	<u>2010</u>
Audit fees: <sup>(1)</sup>	\$417,237	\$500,272
Audit related fees:	—	—
Tax fees: <sup>(2)</sup>	71,127	31,850
All other fees:	—	—
Total	\$488,364	\$532,122

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(1) Audit fees represent fees of E&Y for the audit of the Company's annual consolidated financial statements; reviews of the Company's quarterly results of operations and reports on Form 10-Q; the audit of management's assessment of the effectiveness of the Company's internal control over financial reporting and the audit of internal control over financial reporting; and the services that an independent auditor would customarily provide in connection with subsidiary audits, other regulatory filings, and similar engagements for each fiscal year shown, such as attest services, consents, and assistance with review of documents filed with the SEC.

(2) Tax fees represent tax compliance and return preparation and tax planning and advice.

*Policy on Audit Committee Pre-Approval of Audit and Permissible Non-audit Services of Independent Auditors.* Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation, and overseeing the work of the independent auditor. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent auditor.

Prior to engagement of the independent auditor for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. **Audit** services include audit work performed in the preparation of financial statements, as well as work that generally only the independent auditor can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

2. **Audit-Related** services are for assurance and related services that are traditionally performed by the independent auditor, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. **Tax** services include all services performed by the independent auditor's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. **Other Fees** are those associated with services not captured in the other categories. The Company generally does not request such services from the independent auditor.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires the independent auditor and management to report actual fees versus the

budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent auditor for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging the independent auditor.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

## 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 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 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 October 4, 2010, 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).
- 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 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).
- 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† Employment Agreement by and between Cyclacel Pharmaceuticals, Inc. and Spiro Rombotis, dated as of January 1, 2011.
- 10.14† Employment Agreement by and between Cyclacel Pharmaceuticals, Inc. and Paul McBarron, dated as of January 1, 2011.
- 10.15† Form of Change in Control Agreement by and between Cyclacel Pharmaceuticals, Inc. and Dr. Judy Chiao, dated as of December 10, 2010 (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 14, 2010, and incorporated herein by reference).
- 10.16 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).

- 10.17 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).
- 10.18 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).
- 10.19 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).
- 10.20 Purchase Agreement, dated as of October 4, 2010, by and between Cyclacel Pharmaceuticals, Inc. and each Investor named therein (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on October 5, 2010, and incorporated herein by reference).
- 10.21 Form of Registration Rights Agreement by and among the Company and the Investors named therein (previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on October 5, 2010, and incorporated herein by reference).
- 10.22 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).
- 10.23 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.

## 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 31, 2011

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 Spiro Rombotis	President & Chief Executive Officer (Principal Executive Officer) and Director	March 31, 2011
/s/ Paul McBarron Paul McBarron	Chief Operating Officer & Executive Vice President, Finance (Principal Financial and Accounting Officer) and Director	March 31, 2011
/s/ Dr. David U'Prichard Dr. David U'Prichard	Chairman	March 31, 2011
/s/ Dr. Christopher Henney Dr. Christopher Henney	Vice Chairman	March 31, 2011
/s/Dr. Nicholas Bacopoulos Dr. Nicholas Bacopoulos	Director	March 31, 2011
/s/ Sir John Banham Sir John Banham	Director	March 31, 2011
/s/ Daniel Spiegelman Daniel Spiegelman	Director	March 31, 2011

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-143786) pertaining to the 2006 Equity Incentive Plan of Cyclacel Pharmaceuticals, Inc. of our report dated March 31, 2011, with respect to the consolidated financial statements of Cyclacel Pharmaceuticals, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2010.

/s/ ERNST & YOUNG LLP

London, England  
March 31, 2011

## Exhibit 31.1

### CERTIFICATIONS PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Spiro Rombotis, certify that:

1. I have reviewed this report on Form 10-K for the year ended December 31, 2010 of Cyclacel Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within that entity, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 31, 2011

/s/ Spiro Rombotis

Spiro Rombotis

President & Chief Executive Officer  
(Principal Executive Officer)

## Exhibit 31.2

### CERTIFICATIONS PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul McBarron, certify that:

1. I have reviewed this report on Form 10-K for the year ended December 31, 2010 of Cyclacel Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within that entity, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 31, 2011

/s/ Paul McBarron

Paul McBarron

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

**Exhibit 32.1**

**CERTIFICATIONS PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

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

- (i) the Annual Report on Form10-K of the Company for the year ended December 31, 2010 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2011

/s/ Spiro Rombotis  
Spiro Rombotis  
President & Chief Executive Officer

**Exhibit 32.2**

**CERTIFICATIONS PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

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

- (i) the Annual Report on Form10-K of the Company for the year ended December 31, 2010 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2011

/s/ Paul McBarron

Paul McBarron

Chief Operating Officer, Chief Financial Officer  
and Executive Vice President, Finance