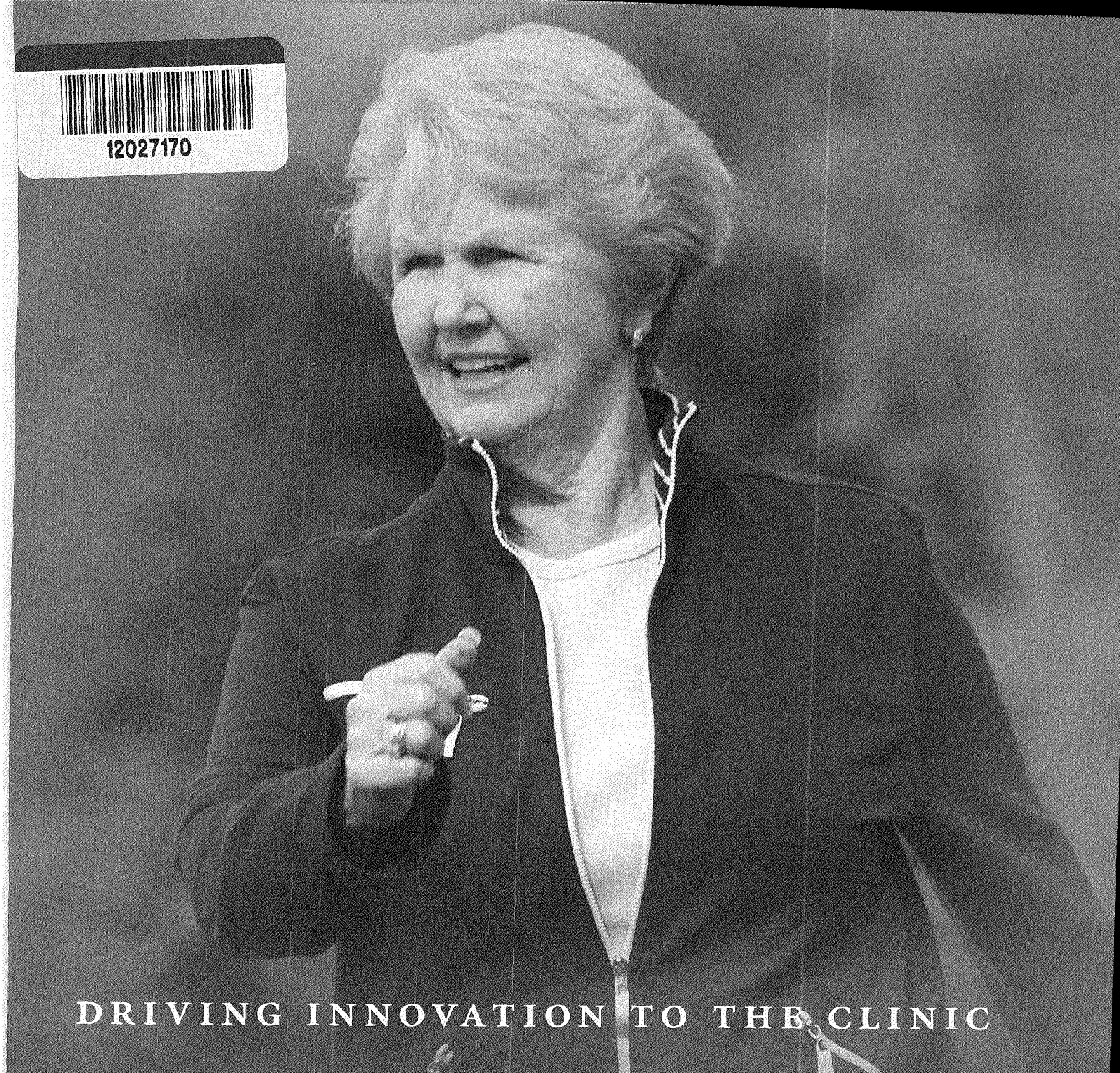
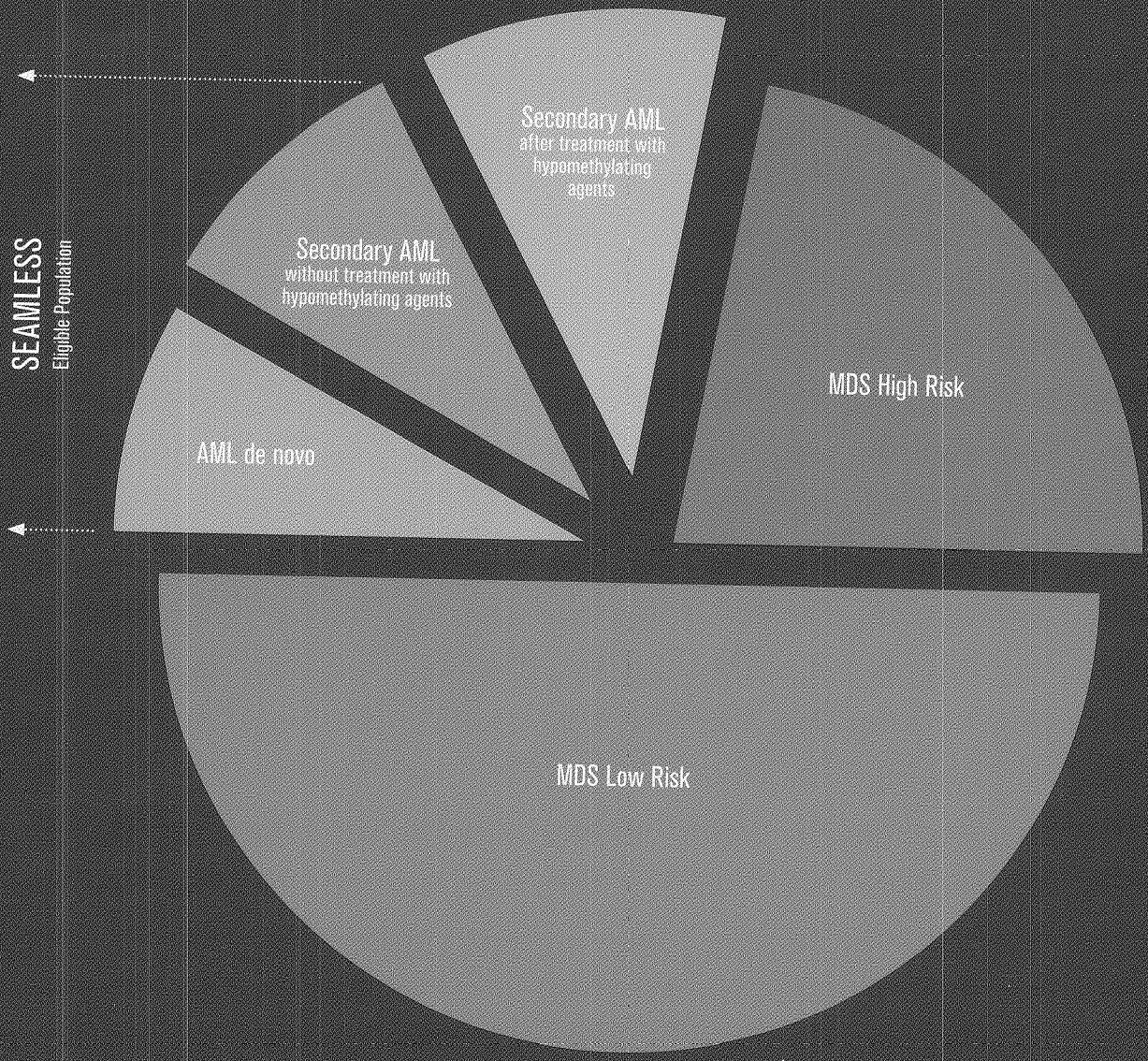


DRIVING INNOVATION TO THE CLINIC

CYCLACEL PHARMACEUTICALS, INC.
2011 ANNUAL REPORT

CYCLACEL®

AML/MDS: HETEROGENEOUS DISEASES



UNFIT FOR INTENSIVE CHEMOTHERAPY
CYTOGENETICS: FAVORABLE, INTERMEDIATE, UNFAVORABLE.

*Source: ACS SEER and Cyclacel-commissioned primary market research

DEAR FELLOW STOCKHOLDERS,

During 2011 Cyclacel became a "late-stage" biopharmaceutical company following the initiation of our first Phase 3, registration-directed, clinical trial for oral sapacitabine capsules, our lead agent. The study, called SEAMLESS, is being conducted under a Special Protocol Assessment (SPA) agreement that Cyclacel reached with the U.S. Food and Drug Administration (FDA). SEAMLESS is enrolling elderly patients with newly diagnosed acute myeloid leukemia (AML) who are not candidates for or have refused intensive induction therapy.

AML is a life-threatening disease representing a high unmet medical need. Older and elderly patients in particular have a poor prognosis, as the majority of these patients are not candidates for intensive induction chemotherapy because of poor tolerability to such therapy. They also have a high risk of relapse because of the lack of effective consolidation and maintenance therapy. These patients commonly have comorbidities and are often frail, because of their advanced age. As a result of these challenges, hematologists frequently recommend to such patients low intensity therapy regimens.

As indicated in a recently published FDA briefing document, available treatment options in the United States for elderly patients with AML unfit for induction chemotherapy are hypomethylating agents, intermediate intensity chemotherapy, low dose cytarabine and best supportive care. The above treatments involve intravenous therapies which, in order to be administered, require a hospital admission or a visit to a specialized doctor's office or home intravenous therapy for several days for each cycle of therapy. For elderly patients who are often too frail to frequently travel to the doctor's office or undergo home intravenous therapy, the route of administration of these treatments represents an additional hurdle. If sapacitabine reaches the market, it will be the first oral treatment for this elderly patient population with the important advantage that it can be taken by mouth at the patient's home.

SAPACITABINE

In 2011, we achieved a major objective for the Company as we opened SEAMLESS, our pivotal, Phase 3 study in patients aged 70 years or older with newly diagnosed AML who are not candidates for or have refused intensive induction chemotherapy. SEAMLESS is comparing as front-line treatment two low intensity regimens: a sequential regimen of sapacitabine administered in alternating cycles with decitabine versus decitabine alone. We chose decitabine, a hypomethylating agent, as active control as it is one of the treatment options recommended by the National Comprehensive Cancer Network's Clinical Practice Guidelines.

SEAMLESS is being conducted under a SPA agreement that we reached with the FDA. A SPA is a binding written agreement with the FDA that the design of the study's protocol, clinical endpoints and statistical analyses are acceptable to support regulatory approval.

SEAMLESS builds on the promising response rate and overall 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 and a Phase 1/2 pilot study examining the safety and efficacy of sapacitabine administered sequentially with decitabine.

The treatment regimen of sapacitabine administered in alternating cycles with decitabine was found to be safe and efficacious in the Phase 1/2 pilot study in patients aged 70 years or older conducted at The University of Texas MD Anderson Cancer Center, Rush University Medical Center and Roswell Park Cancer Institute. The pilot study results were reported in December 2011 at the American Society of Hematology Annual Meeting. Thirty-day mortality from all causes was 4% and 60-day mortality from all causes 12%. The overall response rate was 40%. No dose-limiting toxicities were observed. Median overall survival was 231 days and 44% of patients were still alive.

In a previously published study by investigators at The University of Texas MD Anderson Cancer Center the administration of intensive chemotherapy in AML patients aged 70 years or older was associated with median survival of only 4.6 months, a 4-week death rate of 26% and an 8-week death rate of 36%.

In early 2011, we opened the lead-in stage of SEAMLESS using a single-arm design to further confirm the safety and tolerability of the sequential regimen of sapacitabine alternating with decitabine in the multicenter setting.

In October, the independent Data Safety Monitoring Board (DSMB) of SEAMLESS reviewed available data from the pilot and lead-in studies and recommended that the study should enter the randomized stage as planned. The DSMB noted that no safety or efficacy concerns were identified. The DSMB review was mandated in the SPA agreement that Cyclacel entered into with the FDA with regard to the SEAMLESS study protocol.

In November, the FDA issued a SPA agreement letter to the Company reaffirming the validity of the SPA for the SEAMLESS study's two-arm randomized design. The study will enroll approximately 485 patients. The primary endpoint is overall survival. Secondary objectives are to compare the response rates in terms of complete remission (CR), complete remission with incomplete platelet recovery (CRp), partial response (PR), hematologic improvement (HI), stable disease (SD) and their corresponding durations, transfusion requirements, number of days in hospital, one-year survival and safety. A prespecified interim analysis for futility will be performed and reviewed by the DSMB when 212 events have occurred.

As 2011 drew to a close and enrollment in the randomized stage of SEAMLESS got underway, the study received a positive reception from several U.S. based centers, including virtually all of the hospitals that took part in the Phase 2 trials and new ones.

In addition to SEAMLESS and our AML investigations, we continued to study sapacitabine in patients with myelodysplastic syndromes (MDS). Shortly after the close of the year, we announced topline response data from an ongoing, multicenter, Phase 2 randomized trial of oral sapacitabine capsules in older patients with MDS after treatment failure of hypomethylating agents, such as azacitidine and/or decitabine. We look forward to reporting survival outcomes from this study once data matures. MDS represents a market many times the size of AML. Sapacitabine has the potential of being the first oral treatment option for underserved patients with MDS in whom the front line drugs were not active or have stopped working.

In December, we reported topline data from a Phase 2 trial of sapacitabine in patients with non-small cell lung cancer (NSCLC), who have failed one or more prior chemotherapy regimens. At the same time we also reported Phase 1 data of sapacitabine in combination with our seliciclib agent in heavily pretreated patients with advanced solid tumors, *including breast, ovarian, pancreatic and other* cancers. Partial responses and stable disease were observed in both studies. In the ongoing Phase 1 trial responding patients were found to be carriers of BRCA

mutations, a finding possibly related to the drug's mechanism of action and its effects on the homologous recombination DNA repair (HRR) pathway.

If confirmed in larger studies, these results may expand sapacitabine's potential as a treatment for solid tumors as well as hematological malignancies. Progress with our understanding of how sapacitabine's benefits can be maximized is reported in the next section of this annual report.

In addition to trials sponsored by Cyclacel, sapacitabine is currently being evaluated in two investigator-sponsored trials (ISTs). The U.K.'s Leukaemia Lymphoma Research and UK National Cancer Research Institute (NCRI) Working Group are conducting a Phase 2/3 multicenter, randomized IST comparing sapacitabine to low dose cytarabine in approximately 100 patients aged 60 years or older who are unfit for intensive chemotherapy with previously untreated AML or high risk MDS. Investigators at The University of Texas MD Anderson Cancer Center are conducting a Phase 2 IST of sapacitabine in combination with cyclophosphamide and rituximab in approximately 40 patients with previously treated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and 11q22-23 deletion. Deletion at chromosome 11q22-23 is associated with deletion of the Ataxia Telangiectasia Mutated (ATM) gene, an important element of the HRR pathway.

SELICICLIB

Topline data from the APPRAISE, Phase 2b, randomized discontinuation, double-blinded, placebo-controlled, study of oral seliciclib capsules, our CDK inhibitor, as a third or more line treatment in patients with NSCLC showed no difference in median progression free survival 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 respectively).

Published preclinical work indicated that K-Ras mutational status, cyclin D1 and cyclin E1 protein levels correlated strongly with tumor sensitivity towards seliciclib. In order to explore a possible biological basis for the difference in overall survival, we retrospectively collected and analyzed available biopsy samples from APPRAISE patients who granted informed consent. However, the number of samples obtained and analyzed was not sufficient to allow meaningful correlative analysis. A new, prospectively-designed study is required to test the hypothesis that these biomarkers can predict therapeutic effect of seliciclib (or CYC065, our next-generation CDK inhibitor) in patients with advanced stage NSCLC.

OTHER DEVELOPMENTS

During the year, investigators from Massachusetts General Hospital Cancer Center published preclinical data with CYC065 in the Proceedings of the National Academy of Sciences (PNAS). The data demonstrated that cyclin E and CDK2, which are targeted by CYC065, play a major role in making Human Epidermal growth factor Receptor 2 positive (HER2+) breast cancer resistant to trastuzumab (Herceptin®), a widely used medicine for breast cancer patients who test positive for HER2. The publication provides a rationale for exploring our orally available CDK inhibitors in this patient population. Future efforts to progress our Aurora kinase (including CYC116), CDK and Polo Kinase inhibitors will be undertaken when appropriate resources become available.

FINANCIAL CONDITION

During 2011, we raised approximately $10.4 million in gross proceeds through an underwritten offering and ended the year with approximately $24.4 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.

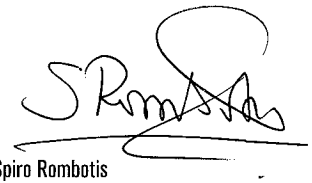
2012 OUTLOOK

Our major objectives for 2012 are to:

- Continue enrolment in the SEAMLESS pivotal Phase 3 study of sapacitabine in AML;
- Report updated Phase 2 sapacitabine data in AML preceded by MDS following previous treatment with hypomethylating agents for the preceding MDS;
- Report updated Phase 2 sapacitabine data in 2nd line MDS following previous treatment with hypomethylating agents;
- Report updated Phase 2 sapacitabine data in NSCLC;
- Report updated Phase 1 sapacitabine and seliciclib combination data in patients with solid tumors; and
- Report data from investigator-sponsored studies as they become available.

The Cyclacel team has been working long hours to deliver on our goals and objectives. Advancing sapacitabine into a randomized Phase 3 trial under a SPA granted by FDA is a seminal achievement for our team and underscores our commitment to realizing the potential of sapacitabine. This potential was enhanced during the year by the emergence of clinical data in MDS and solid tumors, including NSCLC. As we concentrate on enrolling the SEAMLESS Phase 3 study, we continue in parallel to evaluate alternative commercialization and partnering strategies for sapacitabine and monetizing our other assets.

Our employees have continued to perform in a challenging macroeconomic environment. Their loyalty to the company and adherence to the values we share at Cyclacel are the main reasons why in 2011 we succeeded in advancing our scientific, translational research and business objectives. We will continue to pursue our strategy in 2012 with the ultimate aim of making a difference in patients' lives. Thank you for your continued support.



Spiro Rombotis
President and Chief Executive Officer
March 31, 2012

MAXIMIZING THE EFFECTIVENESS OF SAPACITABINE

At Cyclacel, we are proud to have advanced sapacitabine, our lead investigational drug, into a Phase 3 clinical trial. Currently there are more than 800 drugs in clinical development for cancer indications, but only 5% - 8% of them will make it to market according to a recently published editorial. There are many reasons why success rates are so low including incomplete understanding of a drug's mechanism of action, poor insight into drug resistance and sensitivity, heterogeneous patient populations, lack of biomarkers to identify patients most likely to benefit, unclear regulatory requirements and in certain cases lack of agreement between investigators and regulators as to what constitutes clinical benefit. (Schilsky 2010)

During 2011, we gained significant insight on several factors, discussed by Schilsky, pertaining to sapacitabine and our understanding of how the drug works to attack cancer. These include which patients are most likely to respond to therapy and how to best define clinical benefit in trials. Alongside Cyclacel's translational research, investigators from The University of Texas MD Anderson Cancer Center in Houston led by William Plunkett, Ph.D., Professor and Deputy Chair, Department of Experimental Therapeutics, Division of Cancer Medicine (photo, top right) have helped elucidate these mechanisms and propose biomarkers that may correlate with patient response to the drug.

Sapacitabine is an orally bioavailable nucleoside analogue prodrug. After ingestion by mouth sapacitabine converts to an active metabolite, called CNDAC.[1] For many years, it has been known that other nucleoside analogues, such as cytarabine, fludarabine and gemcitabine, work by blocking DNA replication. These nucleoside analogues interfere with DNA replication and cause an arrest of cell cycle progression at the S-phase of the cell cycle. This may be why leukemia patients sometimes achieve a complete remission after their first cycle of chemotherapy with cytarabine as cancer cells die rapidly because their replication is blocked.

Sapacitabine, and its primary, active metabolite, CNDAC, exhibit a unique mechanism of action. Unlike structurally related nucleoside analogues which cause a stalling of the DNA replication process, sapacitabine/CNDAC cause single strand breaks (SSBs) after incorporation and subsequent DNA strand elongation. If unrepaired, these are subsequently converted to double strand breaks (DSBs) when cells progress through another cycle of DNA replication. This phenomenon may explain why certain elderly AML patients treated with sapacitabine frequently do not achieve complete remission in the first or second cycle but in later treatment cycles or after tumor cells have undergone a number of replications.

Over time the vulnerability of cancer cells to sapacitabine therapy is influenced by their ability to repair DSBs and thereby eventually block the drug's activity. There are two major pathways for repairing DSBs in mammalian cells: non-homologous end joining (NHEJ) and homologous recombination repair (HRR). A functioning HRR pathway is critical for repairing sapacitabine/CNDAC-induced DSBs.

A recent review by the MD Anderson group entitled "Sapacitabine for Cancer" discussed this mechanism in detail. The authors highlighted that unrepaired sapacitabine/CNDAC-induced SSBs are transformed into more lethal DSBs during subsequent rounds of tumor cell replication. The authors summarized findings that cancer cells with HRR pathway defects are dramatically more sensitive to sapacitabine/CNDAC than those with intact HRR. They also proposed that this sensitivity profile can help identify cancer patients most likely to benefit from sapacitabine. (Liu 2012)

SAPACITABINE & CNDAC HRR PATHWAY MECHANISM[3]

At Cyclacel's Analyst and Institutional Investor Meeting held in New York City on December 7, 2011, the HRR pathway was extensively discussed. Dr. Plunkett summarized his findings on sapacitabine's mechanism and proposed certain patient populations who would be particularly responsive to sapacitabine because of mutations in HRR pathway genes. He cited the examples of the 11q22-23 deletion (a chromosomal region that includes the ATM gene) in chronic lymphocytic leukemia (CLL) and BRCA1 or BRCA2 defects in breast, ovarian and non-small cell lung (NSCLC) cancers.

Based on Dr. Plunkett's findings, investigators at MD Anderson recently initiated an investigator-sponsored Phase 2 study of sapacitabine in combination with cyclophosphamide and rituximab in chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) with deletion 11q22-23. The biological hypothesis underpinning this trial is that such patients may be very sensitive to sapacitabine because around 36% have reduced ATM activity resulting in defective HRR.

Dr. Plunkett also reviewed evidence that sapacitabine/CNDAC-induced DSBs are repaired predominantly by HRR and showed that cells deficient in HRR components are greatly sensitized to sapacitabine/CNDAC. Dr. Plunkett had previously reported that cell lines lacking the BRCA2 protein were approximately 20-fold more sensitive to CNDAC. BRCA1 or BRCA2 activity has been found to be decreased in many tumors, including breast cancer, ovarian cancer, NSCLC and leukemias. Screening for BRCA-defects may help identify patients with potential for enhanced response to sapacitabine. Dr. Plunkett also reported that cells lacking other HRR pathway components, including Rad51D or XRCC3 are also sensitized to sapacitabine/CNDAC by 60- or 100-fold respectively. Similarly to

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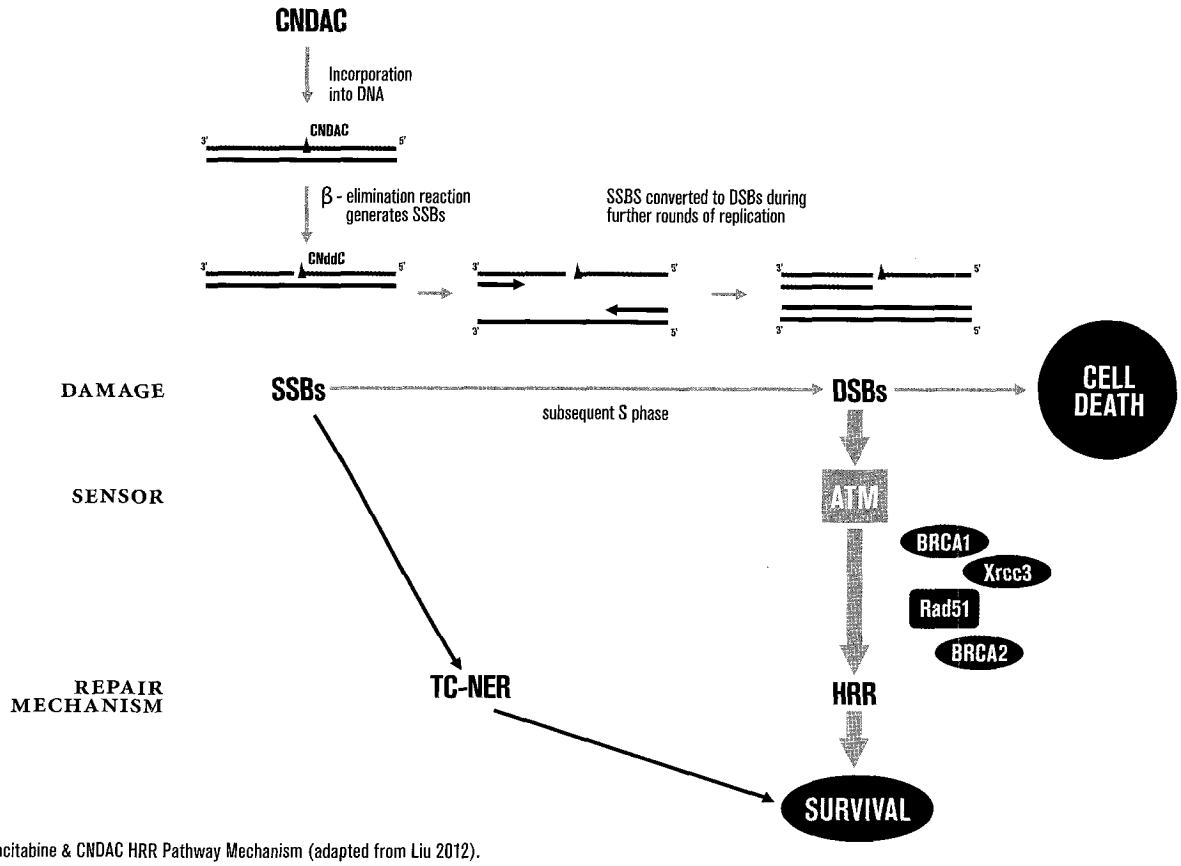

Figure 2: Sapacitabine & CNDAC HRR Pathway Mechanism (adapted from Liu 2012).

BRCA, Rad51D germline mutations have been reported to confer susceptibility to ovarian cancer.

In addition to Dr. Plunkett, three clinical investigators reported at the Analyst and Institutional Investor Meeting on their findings and experience with sapacitabine in trials of the drug in patients with AML, MDS and lung cancer. Karen Seiter, MD (New York Medical College) and David Claxton, MD (Penn State Hershey Cancer Institute) reported on their experience with sapacitabine in AML and MDS patients. Phil Bonomi, MD (Rush University Medical Center) discussed the role of sapacitabine in patients with non-small cell lung cancer. The three practicing clinicians welcomed Dr. Plunkett's new scientific findings and their implications for future targeted therapy protocols of sapacitabine both as a single agent and in combinations.

The aim of treatment strategies with sapacitabine in rational combinations with other agents would be to overcome resistance to current therapies and enhance synergy with other anticancer drugs that interact with DNA repair pathways, such as agents targeting PARP, CHK1, HDAC, etc.

The "Sapacitabine for Cancer" publication garnered broad attention by the medical community. In a recent editorial and expert opinion in the same journal, Dr. Franco Muggia of New York University, noted that this research serves as a reminder that much remains to be learned about the entire nucleoside analogue class of agents. He stated that the "diversity of mechanisms and action and clinical activities of nucleoside and nucleoside base analogs represents a 'wake-up' call". He also noted that "taken with this broad context, the renewed interest generated by sapacitabine may catalyze additional questions in these neglected areas of therapeutic research."(Muggia 2012)

The authors of the "Sapacitabine for Cancer" review are excited by the recent understanding of sapacitabine's novel mechanism and the potential of identifying highly responsive patients to sapacitabine treatment, such as those with ATM, BRCA or other HRR pathway defects.

At Cyclacel, we too are excited by the possibility of further developing sapacitabine's potential in a targeted manner to benefit patient groups that can be identified in advance with a companion diagnostic test.

References:

Liu, Xiaojun; Kantarjian, Hagop; Plunkett, William. "Sapacitabine for Cancer." Expert Opinion on Investigational Drugs 2012. Apr;21(4):541-55. Epub 2012 Feb 14.

Muggia, Franco; Diaz, Isabela; Peters, Godefridus. "Nucleoside and nucleobase analogs in cancer treatment: not only sapacitabine, but also gemcitabine." Expert Opinion on Investigational Drugs 2012. Apr;21(4):403-408. Epub 2012 Mar 9.

Schilsky, Richard L.; Allen, Jeff; Benner, Joshua; Sigal, Ellen; McClellan, Mark. "Commentary: Tackling the Challenges of Developing Targeted Therapies for Cancer." The Oncologist 2010. 15(5):484-7.

Seiter, Karen; Claxton, David; Bonomi, Philip; Plunkett, William. "Cyclacel Analyst & Institutional Investor Meeting." Unpublished Proceedings and Transcript. New York City, December 7, 2011.

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, 2011

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:

Title of each class	**Name of each exchange on which registered**
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, 2011 (based upon the closing sale price of $1.36 of such shares on The NASDAQ Global Market on June 30, 2011) was $63,382,642.

As of March 29, 2012, there were 59,001,738 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of the Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on or about May 23, 2012.

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PART I

Item 1. Business

The following Business Section contains forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain risks, uncertainties and other factors including the risk factors set forth in Part I, Item 1A of this Annual Report on Form 10-K. In this report, "Cyclacel," the "Company," "we," "us," and "our" refer to Cyclacel Pharmaceuticals, Inc.

General

Cyclacel are cell cycle pioneers with a vision to improve patients' healthcare with orally available innovative medicines. Our goal is to develop and commercialize small-molecule drugs that target the various phases of cell cycle control for the treatment of cancer and other serious diseases, particularly those of high unmet medical need.

Our 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

Purchase Agreement

On March 22, 2012, we entered into a purchase agreement with certain existing institutional stockholders and raised gross proceeds of $3,036,000 to fund certain litigation-related expenses on certain intellectual property and otherwise for general corporate purposes. Under the terms of the purchase agreement, the investors purchased 4,688,079 shares of the Company's common stock, par value $0.001 per share, or the Common Shares, at a per share purchase price of $0.6476, which is equal to the 10-day average closing price of the Company's common stock for the period ending on March 21, 2012, and obtained certain contractual economic rights, or the Economic Rights, generally related to the litigation, including rights to receive additional shares, or the Additional Shares, or warrants to purchase shares of common stock in certain circumstances. The Common Shares are subject to a lock-up for a period of one year from the date of issuance. The Economic Rights are transferable at any time to an affiliate of each respective investor, and are subject to a right of first refusal in favor of the Company with respect to each proposed sale, transfer or other disposition.

The purchase agreement also provides for certain registration rights with respect to the Common Shares, and if issued, the Additional Shares. We are required, upon demand of a majority-in-interest of the investors, to use our commercially reasonable efforts to file a registration statement for the resale of such securities, and to cause such registration statement to be declared effective no later than 90 days following the date of such investors' demand (or 180 days following such date, if the Securities and Exchange Commission determines to review the registration statement at issue). The investors are also entitled to piggyback registration rights, subject to cut-backs, as more fully set forth in the purchase agreement. We also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the registration statements.

NASDAQ Appeal

As previously reported, on September 16, 2011, we received a letter from the NASDAQ stating that for 30 consecutive business days the bid price of our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements set forth in Listing Rule 5450(a)(1), or the Rule, and that, pursuant to Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until March 14, 2012, to regain compliance with the minimum bid price requirement.

On March 15, 2012, we received a determination letter from NASDAQ notifying us that we had not regained compliance with the minimum closing bid price required by the continued listing requirements set forth in Listing Rule 5450(a)(1), or the Rule, during the 180 calendar days allowed to regain compliance pursuant to Listing Rule 5810(c)(3)(A), and that our security is subject to delisting from the NASDAQ Global Market, unless we timely request a hearing before a NASDAQ Listing Qualifications Panel, or the Panel. We have requested a hearing before the Panel to present our plan to regain compliance with the Rule, which request automatically stays the delisting of our securities pending the issuance of the Panel's decision. The hearing is scheduled for April 26, 2012.

Under NASDAQ's Listing Rules, the Panel may, at its discretion, determine to continue our listing pursuant to an exception to the Rule for a maximum of 180 calendar days from the date of the NASDAQ Staff's notification, or through September 10, 2012. However, there can be no assurances that the Panel will do so.

Notwithstanding our request for a hearing before the Panel, if such appeal is unsuccessful, we may still transfer our listing to The NASDAQ Capital Market if it meets the initial listing criteria set forth in NASDAQ Marketplace Rule 5505, except for the bid price requirement. In that case, we may have an additional period of 180 calendar days in which to comply with the minimum bid price requirement. We currently meet these initial listing criteria, except for the bid price requirement.

Drug Candidates

The cell cycle, the process by which cells progress and divide, lies at the heart of cancer. In normal cells, the cell cycle is controlled by a complex series of signaling pathways by which a cell grows, replicated its DNA and divides. This process also includes mechanisms to ensure errors are corrected, and if not, the cells commit suicide (apoptosis). In cancer, as a result of genetic mutations, this regulatory process malfunctions, resulting in uncontrolled cell proliferation.

We have generated several families of anticancer drugs that act on the cell cycle including sapacitabine and seliciclib. We believe that these drug candidates are differentiated in that they are orally-available and interact with unique target profiles and mechanisms and have the potential to treat multiple cancer indications. CNDAC is incorporated into DNA during replication or repair, triggering a β-elimination reaction & leading to the formation of single-strand breaks (SSBs), which can activate the G2 checkpoint and/or be repaired by TC-NER. During subsequent rounds of replication, SSBs are converted to double-strand breaks (DSBs); these can be repaired by the homologous recombination repair (HRR) pathway, or, if unrepaired, result in cell death.

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 novel dual mechanism whereby it interferes with DNA synthesis and repair by causing single-strand DNA breaks (SSBs) which can induce arrest of the cell division cycle at the G2/M checkpoint. During subsequent rounds of replication SSBs are converted to double-strand DNA breaks which may be repaired by the homologous recombination (HRR) pathway, or, if unrepaired, result in cell death. 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. The U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, have designated sapacitabine as an orphan drug for the treatment of both Acute Myeloid Leukemia, or AML, and Myelodysplastic Syndromes, or MDS. Sapacitabine is part of Cyclacel's pipeline of small molecule drugs designed to target and stop uncontrolled cell division.

We are currently evaluating sapacitabine in a Phase 3 study being conducted under a Special Protocol Assessment, or SPA, with the FDA for the front-line treatment of AML in the elderly. We are also exploring sapacitabine in Phase 2 studies for MDS, non-small cell lung cancer, or NSCLC, and chronic lymphocytic leukemia, or CLL and in a Phase 1 study in solid tumors in combination with our own drug candidate, seliciclib.

Our second drug candidate, seliciclib, is a novel, first-in-class, orally-available, cyclin dependent kinase, or 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 publications by independent investigators which show 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. Seliciclib has completed a Phase 2B randomized study in third-line NSCLC and is currently undergoing a study in solid tumors in combination with our own drug candidate, sapacitabine.

In addition to our lead development 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. CYC116, an orally-available inhibitor of Aurora kinase, or AK, A and B and Vascular Endothelial Growth Factor Receptor 2, or VEGFR2, has completed a multicenter Phase 1 trial. 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 with our most advanced drug candidate being CYC065. In our polo-like kinase or Plk inhibitor program, CYC800, 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.

We also have a number of earlier stage programs for which limited or no resources will be allocated in the foreseeable future. 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 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.

Lead Development Programs

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

Oncology Development Programs

We have generated several families of anticancer drugs that act on the cell cycle, including nucleoside analogues, CDK inhibitors, AK/VEGFR2 inhibitors and Plk inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitors, AK and/or VEGFR inhibitor drugs and Plk inhibitors, we believe that our drug candidates, are differentiated in that they are orally-available and demonstrate 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.

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.

Research and Development Pipeline

The following table summarizes our currently active clinical and preclinical programs.

Program	Indication	Development Status	Target	Cell Cycle Mechanism
Oncology				
Sapacitabine, CYC682	Elderly AML	Phase 3 registration study 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	NSCLC	Phase 2 trial on-going	DNA polymerase	G2 and S phase
Sapacitabine, CYC682	CLL	Phase 2 randomized trial. Investigator-initiated study	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
Seliciclib, CYC065	Cancer	Preclinical	CDK2, 5, 9	G1/S checkpoint and others
Plk1 Inhibitors	Cancer	Preclinical	Plk	G2/M checkpoint
Other therapeutic areas				
Cell Cycle Inhibitors	Autoimmune & Inflammatory Diseases	Phase 1 trial completed On hold. Not a company priority	CDK	G1/S checkpoint and others

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.

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 Sates. Patients currently receive hypomethylating agents as first-line treatment. There is no approved therapy for second-line treatment.

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.

Sapacitabine

Sapacitabine (previously known as CYC682) is an orally-available nucleoside analogue. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies. 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 novel dual mechanism whereby the compound interferes with DNA synthesis through the incorporation of CNDAC into DNA and repair by causing DNA single-strand breaks. This leads to the production of DNA double strand breaks (DSBs) and/or checkpoint activation at G2/M checkpoint. Unrepaired DSBs cause cell death. Repair of sapacitabine-induced DSBs is dependent on the Homologous Recombinant Repair pathway.

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. The SEAMLESS pivotal Phase 3 trial is on-going, which evaluates 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. 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.

Hematological Cancers

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

SEAMLESS is our pivotal Phase 3 trial for 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 an SPA agreement that Cyclacel reached with the FDA. 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 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 two treatment arms. In Arm A, sapacitabine is administered in alternating cycles with decitabine and in Arm C decitabine is administered alone. The primary efficacy endpoint is overall survival and the study is designed to demonstrate an improvement in overall survival. Approximately 242 patients per arm or a total of 485 patients from approximately 50 centers will be enrolled. SEAMLESS will be monitored by a Data Safety Monitoring Board, or DSMB. A prespecified interim analysis for futility will be performed and reviewed by the DSMB. In October 2011, the DSMB reviewed the lead-in arm of the study, which followed the same treatment regimen as Arm A, and recommended that the study should enter the randomized stage as planned and following this recommendation we have implemented an improvement in the SEAMLESS trial design converting it into the two-arm design described above from the original three-arm design. We received written confirmation from the FDA that, following the modification in the trial design, the previously agreed SPA agreement remains valid.

Results from an on-going, multicenter, Phase 1/2 clinical trial examining the safety and efficacy of oral sapacitabine administered sequentially with decitabine, the same treatment regimen as Arm A in SEAMLESS, was reported during a poster session at the 2011 American Society of Hematology, or ASH, Annual Meeting in San Diego, California. The study enrolled 25 patients aged 70 years or older, 76% of which were aged 75 years or older. Thirty-day mortality from all causes was 4% and 60-day mortality from all causes 12%. The overall response rate was 40%. We reported median overall survival at 231 days with 44% of patients still alive. No dose-limiting toxicities were observed in 25 patients. The median age in the group is 76 years (range 72-90). Nineteen patients were 75 years or older (76%). Common adverse events regardless of cause included anemia, asthenia, decreased appetite, diarrhea, constipation, dyspnea, limb edema, hypocalcemia, nausea, febrile neutropenia, neutropenia, lung infection, and thrombocytopenia, which were mostly moderate in intensity.

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 complete remission, or CR, 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 one 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 51st ASH Annual Meeting, we reported one year survival data.

The primary endpoint of one 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 three day dosing schedule in Arm C was selected for further clinical development in elderly patients with de novo AML based on a one 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 one 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

Sapacitabine is in 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 one 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 one year survival rate for each stratum in the event that all three dosing schedules are active.

In February 2012, we reported interim data from the Phase 2 study. The study randomized 61 patients aged 60 years or older with IPSS score 2 or higher risk MDS to receive sapacitabine every 4 weeks on one of the 3 dosing schedules: 200 mg twice daily for 7 days, 300 mg once daily for 7 days, or 100 mg once daily for 5 days per week for 2 weeks. Among 56 patients who have had at least 30 days of follow-up, the thirty-day mortality from all causes is 5.4%. Eight patients responded with 2 CR, 2 complete remissions with incomplete platelet count recovery (CRp) and 4 major hematological improvements of platelet counts or neutrophils. Responses occurred on all 3 dosing schedules. More than 50% of the patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival.

In December 2010, at the 52nd Annual Meeting of ASH, we reported interim data from three schedules of sapacitabine administered as single-agent treatment over a 4-week cycle in 61 patients with IPSS intermediate — 2 or higher risk MDS after treatment failure of hypomethylating agents, such as azacitidine and decitabine: 200 mg twice daily for 7 days, 300 mg twice daily for 7 days, or 400 mg twice daily for 3 days per week for 2 weeks. The primary endpoint of one year survival was achieved in 29%, 30% and 35% of the patients respectively among the 3 schedules tested. Median overall survival was 217, 232 and 236 days respectively. Two patients achieved a CR. The mortality rate from all causes within 30 days of randomization was 6.6%.

Solid Tumors

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

We are evaluating sapacitabine in 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, one year survival, overall survival and safety.

In December 2011, we provided an update on the study. Forty-eight patients were treated with two dosing schedules, either twice daily or once a day. In the twice daily schedule 15 patients were treated with escalating doses. The recommended Phase 2 dose was reached at 75 mg twice daily for 5 days per week for 2 weeks every 3 weeks. Among 12 patients treated at this recommended Phase 2 dose, 4 achieved stable disease. All 4 responders had at least 2 prior therapies and have been discontinued from the study. Responders received an average of 7 treatment cycles.

In the once daily schedule 33 patients were treated with escalating doses. Maximum tolerated dose has not been reached at the upper limit of the dosing range as per protocol. Patients are currently being entered into the 200 mg once daily dosing level for 5 days per week for 2 weeks every 3 weeks. Among 25 patients treated with daily doses ranging from 100 mg to 175 mg, two patients achieved PR and 10 stable disease. The two PR responders had 3 or 4 prior therapies, respectively, and one remains on study. Among the 10 stable disease responders, 9 had at least 2 prior therapies and 2 remain on study. Responders received an average of 10 treatment cycles.

Phase 1 clinical trial of sapacitabine and seliciclib in patients with advanced cancers

In the ongoing Phase 1, single-arm study of sapacitabine, a nucleoside analogue, and seliciclib, a CDK inhibitor, as an orally-administered combination regimen in patients with advanced solid tumors, 27 patients have been treated to date. The primary objective of the study is to determine the recommended Phase 2 dosing schedule of the sapacitabine and seliciclib combination, which has been achieved. Among 11 patients treated at the recommended Phase 2 doses, two patients with advanced pancreatic cancer and breast cancer, respectively, achieved PR and one patient with advanced ovarian cancer achieved stable disease. The number of treatment cycles administered ranges from 7 to 9 cycles. The breast and ovarian cancer patients remain on study. All three responders were reported by the investigator to be carriers of BRCA mutations. BRCA1 and BRCA2, or breast cancer susceptibility genes, are tumor suppressor genes that help ensure the stability of DNA, the cell's genetic material, and help prevent uncontrolled cell growth. Genetic testing for BRCA-status is routinely available. BRCA mutation has been linked to predisposition to breast and ovarian cancer. According to the US National Cancer Institute, during her life time a woman has a 60% chance of developing breast cancer and 15-40% chance of developing ovarian cancer if she inherits a harmful BRCA mutation. These risks are 5 times and over 10 times more likely than for women without the mutation, respectively.

Orphan Designation

European Union

During May 2008, we received designation from the European Medicines Agency, or EMA, for sapacitabine as an orphan medicine in two separate indications: AML and MDS. The EMA's Committee for Orphan Medicinal Products, or COMP, adopted a positive opinion on our 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, EMA scientific advice on protocol development, direct access to the centralized procedure for review of marketing authorizations, EMA 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 2 clinical trial in patients with NSCLC

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, suggests that seliciclib treatment neither aggravated the known toxicities of standard first and second-line chemotherapies nor appeared to cause unexpected toxicities, although these trials were not designed to provide statistically significant comparison.

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. APPRAISE was led by Chandra P. Belani, M.D. at Milton S. Hershey Medical Center, Penn State University. 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, or OS, 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.

Published pre-clinical work indicated that K-Ras mutational status, cyclin D1 and cyclin E1 protein levels correlated strongly with tumor sensitivity towards seliciclib. In order to explore this possible molecular rationale for the difference in OS, we retrospectively collected and analyzed available biopsy samples from APPRAISE patients who granted informed consent. As only 30 patient samples were available from the 152 APPRAISE patients who gave consent, results of the retrospective analysis were insufficient to allow meaningful correlation. A new prospectively designed study is required to test the hypothesis that these biomarkers can predict therapeutic effect of seliciclib in patients with advanced stage NSCLC.

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 OS, 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, which is dependent on clinical data from the lead-in phase and available resources to fund 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.

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 and completed 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. 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 if we have a sufficient level of resources 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 his 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 poly ADP ribose polymerase, or 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, or ICR, in London, The United Kingdom.

CYC800 (Plk)

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.

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.

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 glycyrrhetinic 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. Glycyrrhetinic 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

Our operating plan is to focus on the clinical development of sapacitabine, specifically the on-going SEAMLESS trial, with selective investment in the advancement of other clinical studies or our other drug candidates. We currently anticipate that our cash and cash equivalents of approximately $24.4 million at December 31, 2011 are sufficient to meet our anticipated short-term working capital needs and to fund our on-going sapacitabine clinical trials for at least the next twelve months. However, we cannot be certain that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in clinical development, should they succeed.

Focus on the cell cycle and cancer

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

- The novel, mechanism-targeted cell cycle drugs we are developing are designed to be highly selective in comparison to conventional chemotherapies, potentially inducing death in cancer cells while sparing most normal cells which may give rise to fewer side-effects.
- We believe that our sapacitabine is the only orally-available nucleoside analogue presently being tested in 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.

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 15 patent applications pending in the United States, 13 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 26 pending patent applications worldwide to which we have a license or an option to take a license.

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 our 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 and held valid, 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, substances, processes and techniques that we use in the course of our research and development and manufacturing operations.

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

On September 10, 2003, we 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 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 eleven other countries, with patents pending in a further three 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, $1.6 million was paid in April 2011 and further aggregate milestone payments totaling approximately $10.0 million could be payable subject to achievement of 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. Effective July 11, 2011, the license was amended to irrevocably waive a termination right Daiichi Sankyo possessed under a provision of the agreement that required the Company to obtain regulatory approval to sell sapacitabine in at least one country by September 2011, and releases the Company from all claims and liability of any kind arising under such provision. The amendment further provides that the royalty fee due from us to Daiichi Sankyo on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50%, depending on the level of net sales of sapacitabine realized. In general, however, 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.

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. We must also pay a portion of sublicensing revenues. 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 South 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, in Japan 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

As part of 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, Onconova and Sunesis. There are two other orally-available CDK inhibitors in Phase 2 clinical trials. PD-0332991 (Pfizer/Onyx), P-1446A-05 (Nicholas Piramal Ltd.) and PHA-848125 (Nerviano Medical Sciences) that target different subsets of CDK enzymes and have a different mechanism of action from seliciclib.There are a number of companies, including AstraZeneca, Astex Pharmaceuticals, 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 Amgen, Astex Pharmaceuticals, AstraZeneca, Entremed, Merck, jointly with Vertex, Nerviano Medical Sciences, Pfizer, Rigel, Sunesis and Takeda-Millennium have commenced Phase 1, 2 and 3 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, Merck, Nerviano Medical Sciences, 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.

Employees

As of March 30, 2012, we had 18 full-time 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.

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.

Available information

We file reports, proxy statements and other information with the Securities and Exchange Commission, or the SEC. Copies of our 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 Form 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 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 10-K 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.

We have grouped risks into several categories in order of their potential impact on our results of operations, financial condition, and cash flows.

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 AML.

On September 13, 2010, and as amended on October 11, 2011, 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 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.

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 and 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.

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 more years 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 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 if there is limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors for the use of agents used in our clinical trials, such as Dacogen® (decitabine) in SEAMLESS, 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.

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.

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 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. 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. 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. We depend upon a third party, Sinclair, to manufacture the commercial products sold by our ALIGN subsidiary and we cannot assure that Sinclair will be able to continue to supply the products.

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 clinical development, 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, clinical development, scientific, technical or sales and 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 clinical development, scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant clinical development, scientific and technical expertise, and this competition is likely to continue. The inability to attract and retain sufficient clinical development, scientific, technical and managerial personnel could limit or delay our product development efforts, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

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

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

Obtaining an NDA approval is expensive and is a complex, lengthy and uncertain process. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are the 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.

There is substantial time and expense invested in preparation and submission of an NDA or equivalents in other jurisdictions and 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. See "Competition" under *Item 1. Business* for further details.

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

If our drug candidates are approved, or approved in combination with another agent such as Dacogen® (decitabine) in SEAMLESS, by the FDA or by another regulatory authority, the resulting drugs, if any, must still gain market acceptance among physicians, healthcare providers and payors, patients and the medical community, as would our distribution partners' products, including Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. 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 drug candidates or distribution partners' products 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.

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 expires in 2015. Although we believe 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. Any attempts to terminate our distribution rights could have adverse consequences on the ALIGN business. This could restrict our ability to sell the ALIGN products.

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 or if the amount of the insurance coverage is insufficient to meet any liabilities resulting from any claims.

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.

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

In all the countries where we sell or may sell our products, governmental regulations exist to define standards for manufacturing, packaging, labeling and storing. All of our suppliers of raw materials and contract manufacturers must comply with these regulations. Failure to do so could result in supply interruptions. In the United States, the FDA requires that all suppliers of pharmaceutical bulk material and

all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA's cGMP regulations and guidelines. Failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications pre-approved by regulators for the content of the pharmaceutical product. If the operations of one or more of our manufacturers were to become unavailable for any reason, any required FDA review and approval of the operations of an alternative supplier could cause a delay in the manufacture of our products.

Our customer base is highly concentrated.

Our principal customers are a small number of wholesale drug distributors. Sales to three wholesale distributors represented 87% and 89% of our product sales in the United States for the years ended December 31, 2010 and 2011, respectively. 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, 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 three wholesalers, Cardinal Health, Inc., McKesson Corporation and Amerisource Bergen, 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. 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. Although 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, we may have quarter-over-quarter fluctuations in inventory and ordering patterns, which can cause our operating results for a particular quarter to be below expectations.

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 effective sales and marketing

initiatives in the United States. Although we launched the ALIGN products with a small specialty oncology sales force, we now sell and market our products via unique sales and marketing strategies in order to reduce costs. We contracted, trained and deployed additional telemarketing personnel to call on specialists who prescribe ALIGN products. We also utilize mailings, print advertising, sampling, trade show attendance and other unique marketing programs to reach our customer base. We may increase or decrease the size of our telemarketing 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. 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 may suffer, we may 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

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. We may have insufficient public equity available for issue to raise the required additional substantial funds to implement our operating plan and we may not be able to obtain the appropriate stockholder approvals necessary to increase our available public equity for issuance within a time that we may require additional funding. 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.

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.

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 European Union, 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. 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, 2010 and 2011, our accumulated deficit was $241.8 million and $257.1 million, respectively. Our net loss for the years ended December 31, 2009, 2010 and 2011 was $19.6 million, $16.0 million and $15.2 million, respectively. Our net loss applicable to common stockholders from inception through December 31, 2011 was $298.8 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.

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 effect 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. In September 2011, we received a NASDAQ Staff Deficiency Letter indicating that were not in compliance with the minimum bid price requirement for continued listing on the NASDAQ exchange because the bid price for the common stock had closed under $1.00 for 30 consecutive business days. On March 15, 2012, we were notified by the NASDAQ Staff that we did not comply with the minimum bid price set forth in NASDAQ Listing Rule 5450(a)(1) (the "Rule") and that our securities are subject to delisting from The NASDAQ Global Market unless we request a hearing before a NASDAQ Listing Qualifications Panel (the "Panel"). We have timely requested a hearing before the Panel to discuss potential ways, which could include enacting a reverse stock split, of complying with the minimum bid price requirement, which automatically stays the delisting of our securities pending the issuance of the Panel's decision after a hearing. Under NASDAQ's Listing Rules, the Panel may, at its discretion, determine to continue our listing pursuant to an exception to the Rule for a maximum of 180 days from the date of the Staff's notification or through September 10, 2012. However, there can be no assurances that the Panel will do so.

Notwithstanding our intention to request a hearing before the panel, we may, if an appeal is unsuccessful, transfer our listing to The NASDAQ Capital Market if we meet the initial listing requirements set forth in NASDAQ Marketplace Rule 5505, except for the bid price requirement, which requirements include, among other things, the following criteria: (i) our stockholders' equity must be at least $5,000,000; (ii) the market value of our publicly held shares must be at least $15,000,000; and (iii) the market value of our shares held by non-affiliates must be at least $1,000,000. In that case, we may have an additional 180 calendar day compliance period to regain compliance. The Company currently meets these initial listing criteria of the NASDAQ Capital Market, except for the bid price requirement.

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 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.

Funding constraints 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 operating 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, 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 (and may be eligible for a Hatch-Waxman term restoration of up to five years, which could extend the expiration date to 2027) and also patent applications claiming the combination of sapacitabine with hypomethylating agents, including decitabine, which is being tested as one of the arms of the SEAMLESS Phase 3 trial. 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 and applicants 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 us 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 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 and held valid, 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, substances, processes and techniques that we use in the course of our research and development and manufacturing processes. 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 effect on our business and stock price.

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 have concluded that our internal control over financial reporting was effective as of December 31, 2011.

We incur increased costs and management resources as a result of being a public company, and we 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 cost. 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, 2011, our internal control over financial reporting was effective. As our business grows and changes, there can be no assurances that we can maintain the effectiveness of our internal controls over financial reporting.

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

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. 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.

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, 2011, 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 $13,708,505 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 preferred stock or we may choose not to declare the dividends.

On January 6, 2012, the Board of Directors decided not to declare the quarterly cash dividend on the preferred stock with respect to the fourth quarter of 2011 that would have otherwise been payable on February 1, 2012. In addition, the Board of Directors also did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009, the first, second and third quarters of 2010, and the second and third quarters of 2011.

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

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. 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 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 May 2011, we extended for an additional five years, our current lease for our corporate headquarters in Berkeley Heights, New Jersey, for an additional five years. 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® (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® (romidepsin for injection) product.

A scheduling Order was entered February 2, 2012, at which time the court set the following significant dates: March 22, 2012 (amendment of pleadings/joinder of parties); March 14, 2013 (claim construction hearing); August 14, 2013 (summary judgment briefing); and June 2, 2014 (7 day jury trial start date). Discovery is currently ongoing.

Item 4. Mine Safety Disclosures

Not applicable.

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
2011		
Quarter ended March 31, 2011	$1.59	$1.20
Quarter ended June 30, 2011	$1.84	$1.22
Quarter ended September 30, 2011	$1.28	$0.39
Quarter ended December 31, 2011	$0.88	$0.36
2010		
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

Holders of Common Stock

On March 30, 2012, we had approximately 66 registered holders of record of our common stock. On March 29, 2012, the closing sale price of our common stock as reported by NASDAQ was $0.71 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 that may be 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.

The Board of Directors did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009, the first, second and third quarters of fiscal year 2010, the second, third and fourth quarters of 2011 and the first quarter of 2012. 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, 2009, 2010 and 2011 and for the period from August 13, 1996 (inception) to December 31, 2011 and the consolidated balance sheet data as of December 31, 2010 and 2011 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K.

The statement of operations data for the years ended 2007 and 2008 and the balance sheet data as of December 31, 2007, 2008 and 2009 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 August 13, 1996 (inception) to December 31,
	2007	2008	2009	2010	2011	2011
	(in thousands, except per share data)					
Consolidated Statements of Operations:						
Revenues:						
Collaboration and research and development revenue	$ 10	$ —	$ —	$ 100	$ —	$ 3,100
Product revenue	—	838	910	574	699	3,021
Grant revenue	119	39	1	12	—	3,648
Total revenues	129	877	911	686	699	9,769
Operating expenses:						
Cost of goods sold	—	429	545	418	360	1,752
Research and development	19,569	18,869	9,766	6,414	9,206	185,799
Selling, general and administrative	12,033	15,354	8,538	10,120	7,521	89,487
Goodwill and intangibles impairment	—	7,934	—	—	—	7,934
Other restructuring costs	1,554	489	366	—	—	2,634
Total operating expenses	33,156	43,075	19,215	16,952	17,087	287,606
Operating loss	(33,027)	(42,198)	(18,304)	(16,266)	(16,388)	(277,837)
Total other income (expense), net	6,933	63	(2,214)	(412)	580	5,844
Loss before taxes	(26,094)	(42,135)	(20,518)	(16,678)	(15,808)	(271,993)
Income tax benefit	2,041	1,749	948	657	565	18,444
Net loss	(24,053)	(40,386)	(19,570)	(16,021)	(15,243)	(253,549)
Dividend on preferred ordinary shares	—	—	—	—	—	(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)	(728)	(3,657)
Net loss applicable to common shareholders	$ (24,360)	$ (41,613)	$ (20,798)	$ (19,703)	$ (15,971)	$ (298,844)
Net loss per share – basic and diluted	$ (1.23)	$ (2.04)	$ (0.94)	$ (0.52)	$ (0.32)	
Weighted average common shares outstanding	19,873,911	20,433,129	22,196,840	37,844,695	50,301,144	

	As of December 31,				
	2007	2008	2009	2010	2011
			(in thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 30,987	$ 24,220	$ 11,493	$ 29,495	$ 24,449
Short-term investments	$ 27,766	$ 1,502	$ —	$ —	$ —
Working capital	$ 49,065	$ 20,387	$ 4,775	$ 24,516	$19,333
Total assets	$ 75,912	$ 30,957	$ 14,466	$ 31,459	$25,998
Long-term liabilities, net of current portion	$ (3,231)	$ (1,688)	$ —	$ —	$ —
Total stockholders' equity	$ 57,969	$ 20,642	$ 5,872	$ 24,924	$ 19,500

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, 2011 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

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 becomes available and is reviewed, we will determine the feasibility of pursuing further development and/or partnering these assets, including sapacitabine in combination with seliciclib and seliciclib in NSCLC and nasopharyngeal cancer, or NPC. 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 have generated 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/VEGFR 2 inhibitors and Plk 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. Our resources are primarily directed towards advancing our lead drug candidate sapacitabine through in-house development activities although we are also progressing our earlier stage novel drug series through working with external collaborators but with limited investment by us. Research and development expenditures for the year ended December 31, 2011 increased $2.8 million, or 44%, from $6.4 million for the year ended December 31, 2010 to $9.2 million for the year ended December 31, 2011. Research and development expenditures for the year ended December 31, 2010 were reduced by $3.4 million, or 35%, from $9.8 million for the year ended December 31, 2009, to $6.4 million for the year ended December 31, 2010.

We have worldwide rights to commercialize sapacitabine and seliciclib 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, 2011, 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, 2011, our accumulated deficit during the development stage was $257.1 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 of 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, 2011, totaling $9.8 million, of which $3.1 million is derived from fees under collaborative agreements, $3.7 million of grant revenue from various United Kingdom government grant awards, and $3.0 million from product sales. We have also recognized $18.4 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

Purchase Agreement

On March 22, 2012, we entered into a purchase agreement with certain existing institutional stockholders, raising $3.0 million of proceeds, net of certain fees and expenses. The proceeds from the financing will be used to fund ongoing litigation-related expenses on certain intellectual property and for general corporate purposes.

Under the terms of the purchase agreement, the investors purchased 4,688,079 shares of our common stock at a price of $0.6476, which is equal to the 10-day average closing price of our common stock for the period ending on Wednesday, March 21, 2012. In addition to the common stock, investors received contractual rights to receive in cash 10% of any future litigation settlement on certain intellectual property, subject to a cap, or alternatively, in lieu of a cash payment, either warrants to purchase common stock in certain situations or additional shares as part of any settlement in a possible related, alternative transaction. The shares issued at closing are subject to a lock-up period of one year from the date of issuance.

NASDAQ Appeal

As previously reported, on September 16, 2011, we received a letter from the NASDAQ stating that for 30 consecutive business days the bid price of our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements set forth in Listing Rule 5450(a)(1), or the Rule, and that, pursuant to Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until March 14, 2012, to regain compliance with the minimum bid price requirement.

On March 15, 2012, we received a determination letter from NASDAQ notifying us that we had not regained compliance with the minimum closing bid price required by the continued listing requirements set forth in Listing Rule 5450(a)(1), or the Rule, during the 180 calendar days allowed to regain compliance pursuant to Listing Rule 5810(c)(3)(A), and that our security is subject to delisting from the NASDAQ

Global Market, unless the we timely request a hearing before a NASDAQ Listing Qualifications Panel, or the Panel. We have requested a hearing before the Panel to present our plan to regain compliance with the Rule, which request automatically stays the delisting of our securities pending the issuance of the Panel's decision. The hearing is scheduled for April 26, 2012.

Under NASDAQ's Listing Rules, the Panel may, at its discretion, determine to continue our listing pursuant to an exception to the Rule for a maximum of 180 calendar days from the date of the NASDAQ Staff's notification, or through September 10, 2012. However, there can be no assurances that the Panel will do so.

Notwithstanding our request for a hearing before the Panel, if such appeal is unsuccessful, we may still transfer our listing to The NASDAQ Capital Market if it meets the initial listing criteria set forth in NASDAQ Marketplace Rule 5505, except for the bid price requirement. In that case, we may have an additional period of 180 calendar days in which to comply with the minimum bid price requirement. We currently meet these initial listing criteria, except for the bid price requirement.

Results of Operations

Years ended December 31, 2010 and 2011 compared to years ended December 31, 2009 and 2010, respectively.

Revenues

The following table summarizes the components of our revenues for the years ended December 31, 2009, 2010 and 2011:

	Years ended			$ Differences		% Differences	
	2009	2010	2011	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
	(in thousands)						
Collaboration and research and development revenue...	$ —	$ 100	$ —	$ 100	$ (100)	100%	(100)%
Product Revenue	910	574	699	(336)	125	(37)%	22%
Grant revenue.....	1	12	—	11	(12)	1,100%	(100)%
Total revenue.....	$ 911	$ 686	$ 699	$ (225)	$ 13	(25)%	2%

We recognized $0.1 million of collaboration and research and development revenue for the year ended December 31, 2010, derived from an agreement with a pharmaceutical company under which we provided one of our compounds for evaluation in the field of eye care. We had no collaboration and research and development revenue for the years ended December 31, 2009 and 2011.

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. During the years ended December 31, 2009, 2010 and 2011, we recognized $0.9 million, $0.6 million, and $0.7 million in revenues, respectively. The increase in product revenue for the year ended December 31, 2011 versus that in the prior year was mostly due to product returns approximating $0.2 million for the year ended December 31, 2010, related to expiring products with a two-year shelf-life previously sold into the marketplace.

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 December 31, 2009 and 2010, we had grant revenue of $1,000 and $12,000, respectively. We did not recognize any grant revenue for the year ended December 31, 2011, as our last grant was finalized in 2010 and no additional grants have been received since that time.

The future

We expect to continue to maintain the sales of ALIGN products with the support of a small sales and marketing infrastructure. We do not expect grant revenue to increase meaningfully over the next 12 months.

Cost of goods sold

	Years ended			$ Differences		% Differences	
	2009	2010	2011	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
			(in thousands)				
Cost of goods sold.....	$ 545	$ 418	$ 360	$ (127)	$ (58)	(23)%	(14)%

Cost of goods sold includes the cost of ALIGN products that have been delivered to our customers and for which revenues have been recognized. We recognized cost of goods sold of $0.5 million, $0.4 million and $0.4 million for the years ended December 31, 2009, 2010 and 2011, respectively. The reduction in the cost of sales for the year ended December 31, 2010, was mostly due to lower product revenues partially offset by $0.2 million of write-offs of expiring product during the year ended December 31, 2010. The reduction in cost of sales for the year ended December 31, 2011, was mostly the result of higher cost of goods recognized for the year ended December 31, 2010, due to write-offs of expiring product. Total cost of goods sold represented 60%, 73% and 52% of product revenue for the years ended December 31, 2009, 2010 and 2011, respectively. In the future, we expect to maintain a margin level in the range of what we incurred in 2011.

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, and sapacitabine in combination with seliciclib. 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. 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, 2009, 2010 and 2011:

	Years ended			$ Differences		% Differences	
	2009	2010	2011	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
				(in thousands)			
Sapacitabine	$ 7,001	$ 5,222	$ 8,710	$ (1,779)	$ 3,488	(25) %	67%
Seliciclib	(84)	53	106	137	53	163 %	100 %
Other costs related to research and development programs, management and exploratory research	2,849	1,139	390	(1,710)	(749)	(60) %	(66) %
Total research and development expenses	$ 9,766	$ 6,414	$ 9,206	$ (3,352)	$ 2,792	(34) %	44 %

Research and development expenses represented 51%, 38% and 54% of our operating expenses for the years ended December 31, 2009, 2010 and 2011, respectively. Included in research and development expenses is stock-based compensation of $0.3 million, $0.4 million and $0.2 million for the years ended December 31, 2009, 2010 and 2011, respectively.

Fiscal 2011 as compared to fiscal 2010

Research and development costs increased by 44%, or $2.8 million, from $6.4 million for the year ended December 31, 2010 to $9.2 million for the year ended December 31, 2011. The increase in costs of $2.8 million is primarily due to a $3.5 million increase in sapacitabine-related costs and a $0.7 million decrease in other research and development costs, respectively, as we continue to focus on the development of sapacitabine. The $3.5 million increase in sapacitabine expenditures was primarily due to $1.6 million of contractual expenses, resulting from an achievement of a milestone triggered by the opening of enrollment in our SEAMLESS trial, pursuant to the Daiichi Sankyo license under which we license certain patent rights for sapacitabine, a $0.9 million increase related to clinical trial supplies, and a $1.0 million increase in clinical trial expenses. Seliciclib costs increased by $53,000 from $53,000 for the year ended December 31, 2010 to $106,000 for the year ended December 31, 2011, primarily due to the cost of analyzing patient samples from the APPRAISE study. Other research and development costs decreased $0.7 million to $0.4 million for the year ended December 31, 2011 from $1.1 million for the year ended December 31, 2010, as we have concentrated financial resources on the development of sapacitabine and reduced investment in other compounds.

Fiscal 2010 as compared to fiscal 2009

Research and development costs decreased by 34%, or $3.4 million, from $9.8 million for the year ended December 31, 2009 to $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 $1.6 million due largely to capsule manufacture costs incurred in 2009 that were not necessary in 2010.

The future

We will continue to concentrate our resources on the development of sapacitabine. We anticipate that overall research and development expenditures in 2012 will increase as we continue enroll the randomized portion 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, 2009, 2010 and 2011:

	Years ended			$ Differences		% Differences	
	2009	2010	2011	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
			(in thousands)				
Total selling, general and administrative expenses	$8,538	$10,120	$7,521	$1,582	$(2,599)	19%	(26)%

Total selling, general and administrative expenses represented 44%, 60% and 44% of our operating expenses for the years ended December 31, 2009, 2010 and 2011, respectively.

Fiscal 2011 as compared to fiscal 2010

Selling, general and administrative expenses decreased by 26%, or $2.6 million, to $7.5 million for the year ended December 31, 2011, from $10.1 million for the year ended December 31, 2010. The decrease of $2.6 million in expenses was primarily attributable to a decrease in professional and consultancy costs of $1.7 million, a decrease in stock based compensation of $0.7 million, a decrease in salaries of $0.3 million, and a decrease in rent of $0.4 million as a result of the expiration of our lease on a facility in Bothell, Washington in December 2010. These amounts were partially offset by a $0.3 million increase in patent-related costs, and a $0.1 million increase in Board of Directors expenses, mostly due to the addition of two new board members during the year ended December 31, 2011.

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 $8.5 million for the year ended December 31, 2009. This was primarily due to increased consultancy and professional costs of $1.0 million, an increase in stock-based 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.

The future

We expect our selling, general and administrative expenditures in 2012 to remain at the same level or to be less than our expenditures in 2011.

Other restructuring costs

The following table summarizes the restructuring charges for years ended December 31, 2009, 2010 and 2011:

	Years ended			$ Differences		% Differences	
	2009	2010	2011	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
				(in thousands)			
Total restructuring charge.....	$ 366	$ —	$ —	$ (366)	$ —	(100) %	— %

Fiscal 2011 as compared to fiscal 2010

There was no restructuring charge for the years ended December 31, 2010 and 2011.

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 26 people as part of a revision of our operating plan to concentrate our resources on the advancement of our lead drug, sapacitabine.

The future

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, 2009, 2010 and 2011:

	Years ended			$ Differences		% Differences	
	2009	2010	2011	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
			(in thousands)				
Payment under guarantee	$ (1,652)	$ —	$ —	$ 1,652	$ —	100 %	— %
Change in valuation of derivative	—	—	(20)	—	(20)	— %	(100)%
Change in valuation of warrants liability	(299)	(338)	629	(39)	967	(13)%	286 %
Amendment to CEFF warrants	(44)	—	—	44	—	100 %	— %
Foreign Exchange gain/(loss)	(144)	(68)	(74)	76	(6)	53 %	(9)%
Interest income	102	37	45	(65)	8	(64)%	22%
Interest expense	(177)	(43)	—	134	43	76 %	100%
Total other income (expense), net	$(2,214)	$ (412)	$ 580	$ 1,802	$ 992	81 %	241%

Fiscal 2011 as compared to fiscal 2010

Total other income (expense), net, increased by $1.0 million, from an expense of $0.4 million for the year ended December 31, 2010, to income of $0.6 million for the year ended December 31, 2011, mainly due the $1.0 million increase in the change in the valuation of the warrant liability, mostly due to the decrease in our common share price from $1.47 at December 31, 2010 to $0.59 at December 31, 2011.

Change in valuation of derivative

The change in valuation of derivative relates to an agreement with Scottish Enterprise that would require us to make a payment of up to £4 million if our operations in Scotland fall below minimum staffing levels. This arrangement is accounted for as a liability and is measured at fair value. Changes in fair value are recognized in earnings. Due to the nature of the associated contingency and the likelihood of occurrence, we have concluded the fair value of this liability was approximately $20,000 at December 31, 2011. For the year ended December 31, 2011, we recognized a loss from the change in the valuation of derivative of approximately $20,000. There was no liability recorded at December 31, 2010 and no change in valuation of derivative for the year ended December 31, 2010.

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 exercise or expiration. For the year ended December 31, 2011, we recognized income from the change in the value of warrants of $0.6 million and for the year ended December 31, 2010, we recognized an expense of $0.3 million.

Foreign Exchange gain/(loss)

Foreign exchange gains/losses not related to intercompany loans are recorded in income (expense). Foreign exchange gain/(loss) was a $74,000 expense for the year ended December 31, 2011, compared to a $68,000 expense for the year ended December 31, 2010.

The intercompany loans outstanding are not expected to be repaid in the foreseeable future and the nature of the funding advanced is of a long-term investment nature. Therefore all unrealized foreign exchange gains or losses arising on the intercompany loans are recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable. Unfavorable unrealized foreign exchange movements related to intercompany loans recorded in other comprehensive income totaled $0.6 million and $2.1 million for the years ended December 31, 2011 and December 31, 2010, respectively.

Interest Income

Interest income increased by $8,000, from $37,000 for the year ended December 31, 2010, to $45,000 million for the year ended December 31, 2011. This is mostly attributed to a higher average daily balance of cash and cash equivalents during the year ended December 31, 2011, compared to the year ended December 31, 2010.

Interest Expense

Interest expense was $43,000 for year ended December 31, 2010. We did not record any interest expense for the year ended December 31, 2011. This reduction was due to the elimination of the accretion expense associated with the restructured Bothell lease, which expired in December 2010.

Fiscal 2010 as compared to fiscal 2009

Total other income (expense), net, decreased by $1.8 million from an expense of $2.2 million in 2009, to income of $0.4 million in 2010, mainly due the $1.7 million expense for the payment 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 exercise or expiration. For each of the years ended December 31, 2009 and 2010, we recognized an expense of $0.3 million in the change in the value of warrants.

Foreign Exchange gain / (loss)

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 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 for the year ended December 31, 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 $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.

The future

The valuation of the warrants liability and derivative 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. The valuation of derivative is dependent on a number of factors, including our stock price and management judgment of the probability of the occurrence of certain events that would give rise to a contingency. We do not expect the valuation of derivative to fluctuate significantly.

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, 2009, 2010 and 2011:

	Years ended			$ Differences		% Differences	
	2009	2010	2011	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
	(in thousands)						
Total income tax benefit	$ 948	$ 657	$ 565	$ (291)	$ (92)	(31)%	(14)%

Fiscal 2011 as compared to fiscal 2010

Research and development tax credits recoverable decreased by 14%, or $0.1 million, from $0.7 million for the year ended December 31,2010 to $0.6 million for the year ended December 31, 2011. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any

one year but is restricted to payroll taxes paid by us in the United Kingdom in that same year. The decrease is a consequence of the lower eligible payroll expenses in the United Kingdom.

Fiscal 2010 as compared to fiscal 2009

Research and development tax credits recoverable decreased by 31%, or $0.3 million, from $0.9 million for the year ended 2009, to $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 consequence of the lower eligible payroll expenses in the United Kingdom following the workforce reductions commenced in September 2008 and continued in 2009.

The future

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future but expect the income tax benefit to increase for the year ended December 31, 2012 due to changes in the United Kingdom tax rules.

Liquidity and Capital Resources

The following is a summary of our key liquidity measures as at December 31, 2010 and 2011:

	December 31, 2010	December 31, 2011	$ Difference	% Difference
		(in thousands)		
Cash and cash equivalents	$ 29,495	$ 24,449	$ (5,046)	(17)%
Working capital:				
Current assets	$ 31,051	$ 25,831	$ (5,220)	(17)%
Current liabilities	(6,535)	(6,498)	37	(1)%
Total working capital	$ 24,516	$ 19,333	$ (5,183)	(21)%

At December 31, 2011, we had cash and cash equivalents of $24.4 million as compared to $29.5 million at December 31, 2010. The decrease in cash and cash equivalents was primarily due to normal cash outflows required to operate our business, offset by net proceeds of $9.3 million from the July 2011 underwritten offering.

Current liabilities were $6.5 million at both December 31, 2010 and 2011. Accrued and other current liabilities increased $0.5 million, offset by a $0.6 million decrease in warrants and other derivatives.

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 the exercise of 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, 2011, we had a deficit accumulated during the development stage of $257.1 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. However, we do not currently have sufficient funds to complete commercialization of any of our drug candidates. 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 clinical pipeline 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, 2009, 2010 and 2011 is summarized as follows:

	Year ended December 31,		
	2009	2010	2011
		(in thousands)	
Net cash used in operating activities	$ (14,886)	$ (16,044)	$ (13,977)
Net cash provided by (used in) investing activities	$ 1,559	$ 33	$ (1)
Net cash provided by financing activities	$ 3,545	$ 33,396	$ 8,906

Operating activities

Net cash used in operating activities decreased by $2.0 million, from $16.0 million for the year ended December 31, 2010 to $14.0 million for the year ended December 31, 2011. Net cash used in operating activities during the year ended December 31, 2011 of $14.0 million resulted primarily from our net loss of $15.2 million, adjusted for material non-cash activities comprising of change in valuation of liability-classified warrants, depreciation, unrealized foreign exchange losses and stock based compensation expense amounting to $0.5 million and a net increase of $0.8 million due to a decrease in prepaid expenses and other current assets combined with a net increase in accounts payable and other current liabilities.

Net cash used in operating activities 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 December 31, 2010, of $16.0 million resulted primarily from our net loss of $16.0 million, adjusted for material non-cash activities comprising of 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 $2.6 million due to a decrease in prepaid expenses and other current assets combined with a net decrease in accounts payable and other current liabilities.

Investing activities

Net cash provided by (used in) investing activities decreased $34,000, from and inflow of $33,000 for the the year ended December 31, 2010 to an outflow of $1,000 for the year ended December 31, 2011. During the year ended December 31, 2009, cash provided by investing activities amounted to $1.6 million, primarily due to cash proceeds from the redemption of short term securities of $1.5 million.

Capital expenditures have remained low as the Company has continued to focus on the clinical development of sapacitabine. Capital expenditures were $15,000, $8,000, and $6,000 for the years ended December 31, 2009, 2010 and 2011, respectively.

Financing activities

Net cash provided by financing activities decreased by $24.5 million, from a source of $33.4 million for the year ended December 31, 2010, to a source of $8.9 million for the year ended December 31, 2011.

For the year ended December 31, 2011, the net cash provided by financing activities was lower than in the previous year primarily due to the completion of a private placement of $14.0 million in net proceeds during October 2010, the two registered direct offerings in January 2010 for net proceeds of $11.9 million, the issuance of 2.8 million shares of common stock for $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, as compared to the completion of an underwritten offering in July 2011 for net proceeds of $9.3 million and payment of a preferred stock dividend of $0.4 million.

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 $14.0 million in net proceeds during October 2010, the two registered direct offerings in January 2010 for net proceeds of $11.9 million, the issuance of

2.8 million shares of common stock for $4.9 million as part of the CEFF with Kingsbridge and the exercise of options and warrants totaling $2.6 million during 2010.

During the year ended December 31, 2009, we received net proceeds of $2.8 million from a registered direct financing and 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.

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, 2009, 2010 and 2011, 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. 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, 2011, 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 less 5% of the current wholesale acquisition price in accordance with our returns policy 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. We also record against revenue a provision for product returns which is calculated based on the historical return rate for each product. For 2010, we recorded $0.2 million of product returns due to a higher than anticipated amount of returns. Since the first quarter of 2010, our supplier has increased the product shelf-life of Xclair® Cream from two to three years to assist us in the management of the product supply chain. Numoisyn® Liquid and Numoisyn® Lozenges have product shelf lives of three and five years, respectively.

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, 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 Amended and Restated Equity Incentive Plan, which was amended and restated as of April 14, 2008. 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.

The fair 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. We recognized income of $0.5 million, an expense of $0.5 million and an expense of approximately $38,000 for the years ended December 31, 2009, 2010 and 2011, respectively, as a result of changes in forfeiture estimates.

Warrants Liability

February 2007 Financing

The accounting guidance on derivatives and hedging 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 this guidance, 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. 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 an expense of $0.3 million and income of $0.6 million to reflect the change in fair value for the years ended December 31, 2011 and December 31, 2010, respectively. 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.

Other Derivatives

Scottish Enterprise Agreement

The accounting guidance on distinguishing liabilities and equity requires freestanding financial instruments that meet certain criteria to be accounted for as liabilities and carried at fair value until exercised or expired, with any changes in fair value recorded in the results of operations. We entered into an agreement with Scottish Enterprise, or SE, in 2009, that would require us to pay SE £4 million (approximately $6.2 million at December 31, 2011) less the market value of the shares held by SE if

staffing levels in Scotland fall below minimum levels stipulated in the agreement. Due to the nature of the associated contingency and the likelihood of occurrence, we concluded the fair value of this liability was approximately $20,000 at December 30, 2011. The most significant inputs in estimating the fair value of this liability are the probabilities that staffing levels fall below the prescribed minimum levels and that we are unable or unwilling to replace such employees within the prescribed time period. As of December 31, 2011, we concluded the probability of the combination of these events occurring is minimal. We recorded an expense of $20,000 in the consolidated statement of operations for the year ended December 31, 2011.

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued guidance related to amendments to disclosures about fair value measurements in order to converge the fair value measurement and disclosure requirements under Accounting Principles Generally Accepted in the United States ("U.S. GAAP") and International Financial Reporting Standards ("IFRS"). The amendments change the wording used to describe the requirements for measuring fair value, changes certain fair value measurement principles and enhances disclosure requirements. This guidance is effective for annual periods beginning after December 15, 2011, applied prospectively. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In June 2011, the FASB issued guidance on the presentation of comprehensive income that will requires companies to present a single statement of comprehensive income or two separate but consecutive statements, a statement of operations and a statement of comprehensive income. The guidance eliminates the alternative to present comprehensive income within the statement of equity. The guidance does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The guidance should be applied retrospectively and is effective for annual periods beginning after December 15, 2011. In December 2011, the FASB issued additional guidance, which deferred indefinitely the requirement for companies to present reclassifications out of accumulated other comprehensive income by component in both the statement where net income is presented and the statement where comprehensive income is presented. We are currently evaluating the presentational changes to our consolidated financial statements required by this guidance.

In December 2011, the FASB and International Accounting Standards Board ("IASB") issued joint requirements related to balance sheet disclosures related to offsetting assets and liabilities. Entities are required to disclose information about offsetting and related arrangements to enable users of financial statements to understand the effect of those arrangements on its financial position. The guidance is effective for annual periods beginning on or after January 1, 2013. An entity should provide the disclosures required by those amendments retrospectively for all comparative periods presented. We do not expect the adoption of this guidance to have a material impact on the Company's 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 equity price risk.

Foreign Currency Risk

We are exposed to foreign currency rate fluctuations related to the operation of our subsidiary in the United Kingdom. At the end of each reporting period, income and expenses of the subsidiary are remeasured into U.S. dollars using the average currency rate in effect for the period and assets and liabilities are remeasured into U.S. dollars using either historical rates or the exchange rate in effect at the end of the period.

Intercompany loans with this subsidiary are denominated in U.S. dollars. However, these loans are not expected to be repaid in the foreseeable future and the nature of the funding advanced is of a long-term investment nature. Therefore all unrealized foreign exchange gains or losses arising on the intercompany loans are recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable. Unfavorable unrealized foreign exchange movements related to intercompany loans recorded in other comprehensive income totaled $0.6 million and $2.1 million for the years ended December 31, 2011 and December 31, 2010, respectively.

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, 2011 and 2010.

Common Stock Price Risk

In February 2007, we issued common stock and warrants and 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, 2010 and 2011, was a loss of $0.3 million and a gain of $0.6 million, respectively. Fair value of the derivative instruments will be affected by estimates of various factors that may affect the respective instrument, including our stock price, the risk free rate of return and expected volatility in the fair value of our stock price. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

Item 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 sheet of Cyclacel Pharmaceuticals, Inc. (a development stage company) as of December 31, 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended and the period from August 13, 1996 (inception) to December 31, 2011. 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 audit. The financial statements as of December 31, 2010, and for the period August 13, 1996 (inception) to December 31, 2010, were audited by other auditors whose report dated March 31, 2011 expressed an unqualified opinion on those statements. The financial statements for the period August 13, 1996 (inception) to December 31, 2010, include total revenues and net loss applicable to common shareholders of $9,070,000 and $282,873,000, respectively. Our opinion on the statements of operations, stockholders' equity, and cash flows for the period August 13, 1996 (inception) to December 31, 2011, insofar as it relates to the amounts for prior periods through December 31, 2010, is based solely on the report of other auditors.

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 audit and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, 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, 2011, and the consolidated results of its operations and its cash flows for the year then ended and for the period from August 13, 1996 (inception) to December 31, 2011, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey
March 30, 2012

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

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 sheet of Cyclacel Pharmaceuticals, Inc. (a development stage company) as of December 31, 2010 and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two 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 the consolidated results of its operations and its cash flows for each of the two 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.

/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)

	December 31, 2010	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,495	$ 24,449
Inventory	174	182
Prepaid expenses and other current assets	1,382	1,200
Total current assets	31,051	25,831
Property, plant and equipment (net)	408	167
Total assets	$ 31,459	$ 25,998
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,723	$ 1,763
Accrued and other current liabilities	4,132	4,664
Warrants and other derivatives	680	71
Total current liabilities	6,535	6,498
Total liabilities	6,535	6,498
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2010 and 2011, respectively; 1,213,142 shares issued and outstanding at December 31, 2010 and 2011. Aggregate preference in liquidation of $13,344,562 and $13,708,505 at December 31, 2010 and December 31, 2011, respectively.	1	1
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2010 and 2011, respectively; 46,564,914 and 54,220,458 shares issued and outstanding at December 31, 2010 and 2011, respectively	47	54
Additional paid-in capital	266,666	276,452
Accumulated other comprehensive income	31	57
Deficit accumulated during the development stage	(241,821)	(257,064)
Total stockholders' equity	24,924	19,500
Total liabilities and stockholders' equity	$ 31,459	$ 25,998

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, 2009	Year ended December 31, 2010	Year ended December 31, 2011	Period from August 13, 1996 (inception) to December 31, 2011
Revenues:				
Collaboration and research and development revenue	$ —	$ 100	$ —	$ 3,100
Product Revenue	910	574	699	3,021
Grant revenue	1	12	—	3,648
Total revenues	911	686	699	9,769
Operating expenses:				
Cost of goods sold	545	418	360	1,752
Research and development	9,766	6,414	9,206	185,799
Selling, general and administrative	8,538	10,120	7,521	89,487
Goodwill and intangibles impairment	—	—	—	7,934
Other restructuring costs	366	—	—	2,634
Total operating expenses	19,215	16,952	17,087	287,606
Operating loss	(18,304)	(16,266)	(16,388)	(277,837)
Other income (expense):				
Costs associated with aborted 2004 IPO	—	—	—	(3,550)
Payment under guarantee	(1,652)	—	—	(1,652)
Change in valuation of derivative	—	—	(20)	(328)
Change in valuation of warrants liability	(299)	(338)	629	6,699
Warrant re-pricing	(44)	—	—	(44)
Foreign exchange losses	(144)	(68)	(74)	(4,329)
Interest income	102	37	45	13,725
Interest expense	(177)	(43)	—	(4,677)
Total other (expense) income, net	(2,214)	(412)	580	5,844
Loss before taxes	(20,518)	(16,678)	(15,808)	(271,993)
Income tax benefit	948	657	565	18,444
Net loss	(19,570)	(16,021)	(15,243)	(253,549)
Dividend on preferred ordinary shares	—	—	—	(38,123)
Deemed dividend on convertible exchangeable preferred shares	—	(3,515)	—	(3,515)
Dividend on convertible exchangeable preferred shares	(1,228)	(167)	(728)	(3,657)
Net loss applicable to common shareholders	$ (20,798)	$ (19,703)	$ (15,971)	$ (298,844)
Net loss per share – basic and diluted	$ (0.94)	$ (0.52)	$ (0.32)	
Weighted average common shares outstanding	22,196,840	37,844,695	50,301,144	

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	Accumulated other comprehensive income/(loss)	Deferred compensation	Deficit accumulated during development stage	Total
	No.	$000	No.	$000	$000	$000	$000	$000	$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	2,046,813	2	16,157,953	16	194,714	(2,537)	—	(138,276)	53,919

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
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	2,046,813	2	20,433,129	20	222,906	(2,630)	—	(162,329)	57,969
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	2,046,813	2	20,433,129	20	223,377	(42)	—	(202,715)	20,642

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	2,046,813	2	25,743,363	26	228,109	20	—	(222,285)	5,872

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	1,213,142	1	46,564,914	47	266,666	31	—	(241,821)	24,924

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	—	—	7,617,646	7	9,265	—	—	—	9,272
Issue of common stock upon draw down of Committed Equity Finance Facility	—	—	—	—	—	—	—	—	—
Warrant exercise	—	—	—	—		—	—	—	—
Issue of common stock on private placement, net of expenses	—	—	—	—	—	—	—	—	—
Stock-based awards exercised	—	—	37,898	—	3	—	—	—	3
Preferred stock conversions	—	—	—	—		—	—	—	—
Stock-based compensation	—	—	—	—	882	—	—	—	882
Preferred stock dividends	—	—	—	—	(364)	—	—	—	(364)
Comprehensive loss:									
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	(622)	—	—	(622)
Translation adjustment	—	—	—	—	—	648	—	—	648
Loss for the year	—	—	—	—	—	—	—	(15,243)	(15,243)
Comprehensive loss for the year	—	—	—	—	—	—	—	—	(15,217)
Balance at December 31, 2011	1,213,142	1	54,220,458	54	276,452	57	—	(257,064)	19,500

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, 2009	Year ended December 31, 2010	Year ended December 31, 2011	Period from August 13, 1996 (inception) to December 31, 2011
	$000	$000	$000	$000
Operating activities:				
Net loss	(19,570)	(16,021)	(15,243)	(253,549)
Adjustments to reconcile net loss to net cash used in operating activities:				
Accretion of interest on notes payable, net of amortization of debt premium	2	—	—	100
Amortization of investment premiums, net	20	—	—	(2,297)
Change in valuation of derivative	—	—	20	328
Change in valuation of warrants	299	338	(629)	(6,699)
Warrant re-pricing	44	—	—	44
Depreciation	668	457	241	12,555
Amortization of intangible assets	—	—	—	886
Fixed asset impairment	221	—	—	221
Unrealized foreign exchange (gains) losses	—	—	—	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	83	(13)	1	100
Goodwill and intangibles impairment	—	—	—	7,934
Stock-based compensation	810	1,746	882	19,023
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	1,716	516	174	(58)
Accounts payable and other current liabilities	821	(3,067)	577	(5,313)
Net cash used in operating activities	(14,886)	(16,044)	(13,977)	(213,119)

CYCLACEL PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS (cont'd)

	Year ended December 31, 2009	Year ended December 31, 2010	Year ended December 31, 2011	Period from August 13, 1996 (inception) to December 31, 2011
	$000	$000	$000	$000
Investing activities:				
Purchase of ALIGN	—	—	—	(3,763)
Purchase of property, plant and equipment	(15)	(8)	(6)	(8,837)
Proceeds from sale of property, plant and equipment	91	41	5	163
Purchase of short-term investments on deposit, net of maturities	—	—	—	(156,657)
Cash proceeds from redemption of short term securities	1,483	—	—	162,729
Net cash provided by (used in) investing activities	1,559	33	(1)	(6,365)
Financing activities:				
Payments of capital lease obligations	—	—	—	(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	9,267	91,671
Proceeds from the exercise of stock options and warrants, net of issuance costs	7	—	3	173
Payment of preferred stock dividend	(307)	—	(364)	(1,898)
Repayment of government loan	—	—	—	(455)
Government loan received	—	—	—	414
Loan received from Cyclacel Group plc	—	—	—	9,103
Proceeds of committable loan notes issued from shareholders	—	—	—	8,883
Loans received from shareholders	—	—	—	1,645
Cash and cash equivalents assumed on stock purchase of Xcyte	—	—	—	17,915
Costs associated with stock purchase	—	—	—	(1,951)
Net cash provided by financing activities	3,545	33,396	8,906	243,459
Effect of exchange rate changes on cash and cash equivalents	(2,945)	617	26	474
Net (decrease) increase in cash and cash equivalents	(12,727)	18,002	(5,046)	24,449
Cash and cash equivalents, beginning of period.	24,220	11,493	29,495	—
Cash and cash equivalents, end of period	11,493	29,495	24,449	24,449

	Year ended December 31, 2009	Year ended December 31, 2010	Year ended December 31, 2011	Period from August 13, 1996 (inception) to December 31, 2011
	$000	$000	$000	$000
Supplemental cash flow information:				
Cash received during the period for:				
Interest	59	11	31	11,746
Taxes	1,523	1,082	685	18,207
Cash paid during the period for:				
Interest	(78)	(155)	—	(1,914)
Schedule of non-cash transactions:				
Acquisitions of equipment purchased through capital leases	—	—	—	3,470
Issuance of common shares in connection with license agreements	—	—	—	592
Issuance of Ordinary shares on conversion of bridging loan	—	—	—	1,638
Issuance of Preferred Ordinary 'C' shares on conversion of secured convertible loan notes and accrued interest	—	—	—	8,893
Issuance of Ordinary shares in lieu of cash bonus	—	—	—	164
Issuance of other long term 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.

We have ongoing clinical programs in development awaiting further data. Once data becomes available and is reviewed, we will determine the feasibility of pursuing further development and/or partnering these assets, including sapacitabine in combination with seliciclib and seliciclib in NSCLC and nasopharyngeal cancer, or NPC. In addition, we market 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, 2010 and 2011, and for each of the three years in the period ended December 31, 2011 and for the period from August 13, 1996 (inception) to December 31, 2011, have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. 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 U.S. 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. Critical estimates include product returns reserve percentages and inputs used to determine stock-based compensation expense and fair value of financial instruments, such as warrants and other derivatives. 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, 2009, 2010 and 2011, approximately 86%, 87% and 89%, 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, 2009, 2010 and 2011, these three wholesalers accounted for 98%, 99% and 97%, 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, or is unable to obtain the necessary financing to complete development and approval, 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 purchase 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.

Trade accounts receivable are included in prepaid expenses and other current assets on the consolidated balance sheet and were $0.1 million at both December 31, 2010 and 2011. All trade accounts receivable were deemed collectible as of December 31, 2010 and 2011.

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, 2010 and 2011, 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, 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 years ended December 31, 2010 and December 31, 2011. 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, common stock warrants and other derivatives. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate their respective fair values due to the nature of the accounts, notably their short maturities. Warrants and other derivatives are measured at fair value using applicable inputs as described in *Note 5, Fair Value*.

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. The Company sold fixed assets totaling approximately $6,000 during the year ended December 31, 2011.

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.

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 less 5% of the current wholesale acquisition price in accordance with our returns policy 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. The Company also estimates its provision for returned products based on historical returns for each product and this provision is charged against revenues. 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 of Xclair® cream from two to three years to assist in the management of the product supply chain. Numoisyn® Liquid and Numoisyn® Lozenges have product shelf lives of three and five years, respectively.

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 the Company's clinical trials are performed with the assistance of 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 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 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 accounts for uncertain positions taken in its tax return in accordance with 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.

	Year ended December 31, 2009	Year ended December 31, 2010	Year ended December 31, 2011
Stock options	3,349,876	3,489,932	3,515,741
Restricted Stock and Restricted Stock Units	91,145	59,885	266,625
Convertible preferred stock	870,980	516,228	516,228
Common stock issuable to Kingsbridge	328,602	—	—
Options issued in connection with the October 2010 financing	—	6,242,398	—
Common stock warrants	7,044,363	10,005,192	13,814,015
Total shares excluded from calculation	11,684,966	20,313,635	18,112,609

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 5 – 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, as amended on May 21, 2007, and subsequently amended and restated on April 14, 2008. The Company has granted various types of awards under the 2006 Plan, which are described more fully in Note 11 - "Stock-Based Compensation Arrangements". The Company accounts for these awards 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 December 2011, the Financial Accounting Standards Board ("FASB") FASB issued Accounting Standards Update ("ASU") 2011-11 which amends the guidance in Accounting Standards Codification ("ASC") 210, Balance Sheet (ASC 210). The ASU requires an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. The ASU is effective for annual periods beginning on or after January 1, 2013. An entity should provide the disclosures required by those amendments retrospectively for all comparative periods presented. We do not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

In June 2011, the FASB issued Accounting Standards ASU 2011-05 to amend the guidance on the presentation of comprehensive income in ASC 220. ASU 2011-05 requires companies to present a single statement of comprehensive income or two separate but consecutive statements, a statement of operations and a statement of comprehensive income. ASU 2011-05 eliminates the alternative to present comprehensive income within the statement of equity. ASU 2011-05 does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The ASU should be applied retrospectively and is effective for annual periods beginning after December 15, 2011. In December 2011, the FASB issued ASU 2011-12, which deferred the changes in ASU 2011-05 that relate to the presentation of reclassifications out of accumulated other comprehensive income. We do not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, which amends the guidance on fair value measurement in ASC 820 to converge the fair value measurement and disclosure requirements under GAAP and International Financial Reporting Standards ("IFRS") fair value measurement and disclosure requirements. The amendments change the wording used to describe the requirements for measuring fair value, changes certain fair value measurement principles and enhances disclosure requirements. This guidance is effective for annual periods beginning after December 15, 2011, applied prospectively. We do not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

3 Significant Contracts

Distribution, Licensing and Research Agreements

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

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. The up-front fee and certain past reimbursements have been paid and, as a result of the SEAMLESS trial entering Phase 3 during the first quarter of 2011, a milestone payment of $1.6 million was paid in April 2011. A further $10.0 million in aggregate milestone payments could be payable subject to achievement of all the specific contractual milestones and the Company's decision to continue with these projects. 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. Effective July 11, 2011, the license agreement was amended to irrevocably waive a termination right Daiichi Sankyo possessed under a provision of the agreement that required the Company to obtain regulatory approval to sell sapacitabine in at least one country by September 2011, and releases the Company from all claims and liability of any kind arising under such provision. The amendment further provides that the royalty due from the Company to Daiichi Sankyo on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.

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 $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 $0.2 million.

4 Cash and Cash Equivalents

The following is a summary of cash and cash equivalents at December 31, 2010 and 2011:

	December 31,	
	2010	2011
	$000	$000
Cash	429	4,555
Investments with original maturity of less than three months at the time of purchase	29,066	19,894
Total cash and cash equivalents	29,495	24,449

5 Fair Value

Fair value measurements

As defined in ASC 820, *Fair Value Measurements and Disclosures* ("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 financial assets and liabilities that are measured on a recurring basis were determined using the following inputs as of December 31, 2011:

	Fair Value Measurements Using Fair Value Hierarchy			
	Level 1	Level 2	Level 3	Total
	$000	$000	$000	$000
Cash equivalents	19,894	—	—	19,894
Warrants liability	—	—	51	51
Other derivatives	—	—	20	20
Total	19,894		71	19,965

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. 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 $0.7 million and $51,000 at December 31, 2010 and 2011, respectively. The Company used the Black-Scholes option-pricing model with the following assumptions to value the warrants:

	December 31,	
	2010	2011
Exercise price	$8.44	$8.44
Expected term	3.13 Yrs	2.13 Yrs
Risk free interest rate	1.02%	0.25%
Expected volatility	121%	106%
Expected dividend yield over expected term	—	—

During the year ended December 31, 2011, the Company recognized the change in the value of warrants of $0.6 million as income on the consolidated statement of operations. During each of the years ended December 31, 2010 and 2009, the Company recognized an expense of $0.3 million from the change in the value of warrants.

Other Derivatives

Scottish Enterprise Agreement

On June 22, 2009, the Company amended the Agreement with Scottish Enterprise ("SE") (the "Amendment"), 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 Agreement provided for repayment of up to £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 million (approximately $0.8 million) was paid and the remaining amount of £0.5 million (approximately $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 may be obligated to pay up to £4 million to SE, which will be calculated as a maximum of £4 million (approximately $6.2 million at December 31, 2011) less the market value of the shares held by SE at the time staffing levels in Scotland fall below the prescribed minimum levels. If the Company were to have reduced staffing levels below the prescribed levels as of December 31, 2011, the amount potentially payable to SE would have been approximately £3.8 million (approximately $5.9 million) based on the Company's share price of $0.59 at December 31, 2011.

This arrangement is accounted for as a liability under ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and is measured at fair value. Changes in fair value are recognized in earnings. Due to the nature of the associated contingency and the likelihood of occurrence, the Company has concluded the fair value of this liability was approximately $20,000 at December 30, 2011. The most significant inputs in estimating the fair value of this liability are the probabilities that staffing levels fall below the prescribed minimum and that the Company is unable or unwilling to replace such employees within the prescribed time

period. As of December 31, 2011, the Company has concluded that the probability of the combination of these events occurring is minimal. Changes in the value of derivatives are recorded in the consolidated statement of operations.

The following table reconciles the beginning and ending balance of fair value measurement using Level 3 inputs for the year ended December 31, 2011:

	Level 3
	$000
Balance as of December 31, 2010	680
Change in valuation of warrants liability	(629)
Change in valuation of derivative	20
Balance as of December 31, 2011	71

6 Prepaid Expenses and Other Current Assets

The following is a summary of prepaid expenses and other current assets at December 31, 2010 and 2011:

	December 31,	
	2010	2011
	$000	$000
Research and development tax credit receivable	660	541
Prepayments	317	321
Other current assets	405	338
	1,382	1,200

7 Property, Plant and Equipment

Property, plant and equipment consisted of the following:

		December 31,	
	Useful lives in years from date of acquisition	2010	2011
		$000	$000
Leasehold improvements	5 to 15 yrs	844	844
Research and laboratory equipment	3 to 5 yrs	6,281	6,251
Office equipment and furniture	3 to 5 yrs	1,267	1,273
		8,392	8,368
Less: accumulated depreciation and amortization		(7,984)	(8,201)
		408	167

The depreciation and amortization of property, plant and equipment amounted to $0.7 million, $0.5 million and $0.2 million for the years ended December 31, 2009, 2010 and 2011, respectively.

Depreciation and amortization expense for the period from inception or August 13, 1996 through December 31, 2011 was $12.6 million. At December 31, 2010 and 2011 there were no assets held under capital lease arrangements.

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 12 – "Restructuring"). For the year ended December 31, 2009, the Company recorded an asset impairment of $0.2 million in respect of these assets as accelerated depreciation in accordance with ASC 360, which is shown within research and development expense on the consolidated statement of operations. There were no impairments of property, plant and equipment during the years ended December 31, 2010 and 2011.

8 Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following:

	December 31,	
	2010	2011
	$000	$000
Accrued research and development	2,793	3,471
Other current liabilities	1,339	1,193
	4,132	4,664

9 Commitments and Contingencies

General

Please refer to Note 3 – "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 leases as at December 31, 2011:

	Operating lease obligations
	$000
2012	565
2013	565
2014	565
2015	554
2016	549
Thereafter	3,502
Total	6,300

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, 2009, and 2010 and $0.6 million for the year ended December 31, 2011.

In October 2000, the Company entered into a twenty-five year lease for its research and development facility in Dundee, Scotland. In May 2011, the Company extended its lease for office space at its headquarters in Berkeley Heights, New Jersey, for an additional five years.

Please refer to Note 5 – "Fair Value" for further discussion of certain of the Company's commitments and contingencies.

Purchase Obligations

At December 31, 2011, the Company had obligations in relation to the purchase of manufactured products within the ALIGN business of $0.2 million.

Preferred Dividends

Pursuant to the certificate of designation governing the terms of the Company's outstanding 6% Convertible Exchangeable 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 expenditures, the Board of Directors did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009, the first three quarters of fiscal year 2010, and the last three quarters of fiscal year 2011. On February 1, 2011 and on May 1, 2011, the Company paid a quarterly cash dividend in the amount of $0.15 per share on the preferred stock. Accrued and unpaid dividends in arrears on preferred stock were $1.6 million, or $1.30 per share of preferred stock, as of December 31, 2011.

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 the Company's 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 has 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.

A Scheduling Order was entered February 2, 2012, at which time the court set the following significant dates: March 22, 2012 (amendment of pleadings/joinder of parties); March 14, 2013 (claim construction hearing); August 14, 2013 (summary judgment briefing); and June 2, 2014 (7 day jury trial start date). Discovery is currently ongoing.

10 Stockholders' Equity

Preferred stock

As of December 31, 2011, 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. 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, 2011, 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, 2011. The shares of previously-converted 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 holders of Preferred Stock as of August 2, 2010 and two directors were nominated and elected at the annual meeting held on May 24, 2011.

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

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, 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. No such exchanges have taken place to date.

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 2011. The table below provides details of the aggregate activities in 2010:

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

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 $3.5 million for the year ended December 31, 2010.

Common Stock

July 2011 Underwritten Offering

On July 7, 2011, the Company closed an underwritten offering for an aggregate of 7,617,646 units, at an offering price of $1.36 per unit, for gross proceeds of approximately $10.4 million. Each unit consists of (i) one share of common stock and (ii) a five-year warrant to purchase 0.5 of a share of common stock at an exercise price of $1.36 per share, exercisable beginning six months after the date of issuance. The shares of common stock and warrants were immediately separable. As of December 31, 2011, all warrants issued to the investors in connection with this financing were outstanding and have been classified as equity. The transaction date fair value of the warrants of approximately $3.5 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate – 1.74%, expected volatility - 99%, expected dividend yield - 0%, and a remaining contractual life of 5.00 years. Net proceeds of approximately $9.3 million, after underwriting discounts and commissions and other fees and expenses of approximately $1.1 million, were allocated based on relative transaction date fair values in the following manner: $6.8 million ($0.89 per share) and $2.5 million ($0.66 per warrant) to common shares and warrants, respectively.

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, 2011, all options and warrants issued to the investors are outstanding and 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 had 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 or by July 6, 2011. As of December 31, 2011, none of the additional units had been exercised and, as of July 6, 2011, the right to acquire the additional units lapsed. 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.

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, 2011, 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, 2011, 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, 2011, 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, 2011, 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.

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 unit consisted of (i) one share of the Company's 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 Series II Warrants with proceeds of $43,266. There were no exercises during the year ended December 31, 2011.

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, 2011, the remaining Series II Warrants outstanding and 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 Committed Equity Financing Facility, or 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.

During the year ended 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. During the the year ended December 31, 2009, the Company sold an aggregate of 1,255,024 shares of its common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of $1.0 million.

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, 2010 and 2011, the fair value of the warrants determined utilizing the Black-Scholes option pricing model was approximately $0.7 million and $0.1 million, respectively. The fair value at December 31, 2011 reflects the decrease in the Company's common stock price to $0.59 per share at December 31, 2011 as compared to the common stock price of $1.47 per share at December 31, 2010. For the year ended December 31, 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. For the year ended December 31, 2011, the Company recognized the change in the value of warrants of approximately $0.6 million as a gain on the consolidated statement of operations.

The following table summarizes information about warrants outstanding at December 31, 2011:

Issued in Connection With	Expiration Date	Common Shares Issuable	Weighted Average Exercise Price
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
July 2011 stock issuance	2016	3,808,823	$ 1.36
Total		13,814,015	$ 3.28

Exercise of Stock Options

During 2010, there were 174,311 stock option exercises totaling approximately $0.1 million. During 2011, 6,638 shares of common stock were issued from the exercise of stock options resulting in proceeds of approximately $3,000.

11 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. Annual awards granted in December 2010 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 2009, 2010 and 2011 as shown in the following table:

	Year ended December 31, 2009	Year ended December 31, 2010	Year ended December 31, 2011
	$000	$000	$000
Research and development	271	351	171
Selling, general and administrative	539	1,395	711
Stock-based compensation costs before income taxes	810	1,746	882

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's 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 2011, the Company granted approximately 0.2 million options to employees and directors with a grant date fair value of approximately $0.2 million, of which approximately $24,000 has been recorded as compensation cost in the consolidated statement of operations for the year ended December 31, 2011. During 2010, the Company granted approximately 0.6 million options to employees and directors with a grant date fair value of approximately $0.6 million, of which approximately $50,000 was expensed in 2010. 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 $28,000 was expenses in 2009. The weighted average grant-date fair value of options granted during 2011, 2010, and 2009 was $1.15, $1.40 and $0.39 respectively.

As of December 31, 2011, the total remaining unrecognized compensation cost related to the non-vested stock options amounted to approximately $0.5 million, which will be amortized over the weighted-average remaining requisite service period of 2.88 years.

During the years ended December 31, 2009, 2010 and 2011, the Company did not settle any equity instruments with cash.

The Company received $3,000 from the exercise of 6,638 stock options during 2011. The total intrinsic value of options exercised during 2011 was approximately $1,000. 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 options during 2009. The total intrinsic value of options exercised during 2009 was approximately $11,000.

Outstanding Options

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

Cyclacel Pharmaceuticals, Inc.	Number of options outstanding	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value
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
Granted	199,500	$ 1.52		
Exercised	(6,638)	$ 0.41		
Cancelled/forfeited	(167,053)	$ 5.79		
Options outstanding at December 31, 2011.....	3,515,741	$ 3.73	6.44	$ 140
Unvested at December 31, 2011	631,655	$ 1.73	8.75	$ 3
Vested and exercisable at December 31, 2011 .	2,884,086	$ 4.17	5.93	$ 136

The following table summarizes information about options outstanding at December 31, 2011:

Exercise price ($)	Number outstanding	Weighted Average remaining contractual life	Number exercisable
0.29 – 1.98	1,519,913	7.77	1,013,387
2.15 – 4.95	377,878	7.15	256,989
5.26 – 5.81	508,213	5.82	503,973
6.30 – 6.95	891,237	4.57	891,237
7.80 – 15.00	218,500	4.93	218,500
	3,515,741		2,884,086

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, 2009	Year ended December 31, 2010	Year ended December 31, 2011
Expected term (years)	0.75 – 5 Yrs	5 – 6 Yrs	5 – 6 Yrs
Risk free interest rate	0.325 – .84%	1.64 – 2.96%	1.47 – 2.29%
Volatility	65 – 169%	90 – 102%	93 – 99%
Dividends	0.00%	0.00%	0.00%
Resulting weighted average grant date fair value	$0.39	$1.40	$1.15

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 Company considers many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. During the years ended December 31, 2009, 2010 and 2011, the Company recognized income of $0.5 million, an expense of $0.5 million and an expense of approximately $38,000, respectively, as a result of revised forfeiture rates.

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 $3,000 from the exercise of 6,638 options during 2011. The Company received approximately $0.1 million from the exercise of 174,311 options during 2010. 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 incurred tax losses in 2010 and 2011, the Company was not able to benefit from the deduction for exercised stock options in the current reporting period.

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. In accordance with 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 50,000 shares of 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 was accounted for at fair value at the date of grant and an expense is recognized during the vesting term. As of December 31, 2011, the total remaining unrecognized compensation cost related to the non-vested restricted stock amounted to approximately $3,000, which will be amortized over the weighted-average remaining requisite service period of 0.88 years. Summarized information for restricted stock activity for the years ended December 31, 2010 and 2011 is as follows:

	Restricted Stock	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2009	36,458	$0.44
Vested	(12,504)	$0.44
Non-vested at December 31, 2010	23,954	$0.44
Vested	(12,504)	$0.44
Non-vested at December 31, 2011	11,450	$0.44

Restricted Stock Units

The Company issued 91,700 and 238,000 restricted stock units, each of which entitles the holders to receive a share of the Company's common stock, to senior executives of the Company in November 2008 and December 2011, respectively. The 2008 grants vest over four years and the 2011 grants vest over three years. 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 over the vesting term. As of December 31, 2011, the total remaining unrecognized compensation cost related to the non-vested restricted stock amounted to $0.1 million, which will be amortized over the weighted-average remaining requisite service period of 2.78 years. Summarized information for restricted stock units activity for the years ended December 31, 2010 and 2011 is as follows:

	Restricted Stock Units	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2009	54,687	$0.44
Vested	(18,756)	$0.44
Non-vested at December 31, 2010	35,931	$0.44
Granted	238,000	$0.83
Vested	(18,756)	$0.44
Non-vested at December 31, 2011	255,175	$0.80

12 Restructuring

The Company revised its operating plan during 2008 in order to concentrate 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 was completed in 2009 and reduced the workforce across all locations by 51 people. 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.

In addition, the Company inherited provisions for termination benefits, lease restructuring, asset impairment and sales tax assessment from its acquisition of Xcyte in 2006. 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:

	Lease restructuring charges	Sales tax assessment	Total
	$000	$000	$000
Balance at December 31, 2009	1,062	—	1,062
Cash payments	(1,104)	—	(1,104)
Adjustments for lease-related deferred expenses and liabilities	42	—	42
Balance at December 31, 2010	—	—	—

13 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, 2009 and 2010 and $0.1 million for the year ended December 31, 2011.

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 2011 and to have those funds contributed to the 401(k) Plan. For each of the years ended December 31, 2009, 2010 and 2011, the Company made contributions of approximately $0.1 million to the 401(k) Plan.

14 Taxes

In the accompanying Consolidated Statements of Operations, "Loss before taxes" includes the following components for the years ended December 31, 2009, 2010 and 2011:

	Year ended December 31, 2009	Year ended December 31, 2010	Year ended December 31, 2011
	$000	$000	$000
Domestic	(3,013)	(4,664)	264
Foreign	(17,505)	(12,014)	(16,072)
Total loss before taxes	(20,518)	(16,678)	(15,808)

The benefit for income taxes consists of the following:

	Year ended December 31, 2009	Year ended December 31, 2010	Year ended December 31, 2011
	$000	$000	$000
Current – domestic	(12)	(10)	—
Current – foreign	960	667	565
Current – total	948	657	565

The Company has made a taxable loss in each of the operating periods since incorporation. The income tax credits of $0.9 million, $0.7 million and $0.6 million for the years ended December 31, 2009, 2010 and 2011, respectively, represent U.K. research and development ("R&D") tax credits receivable against such expenditures in the United Kingdom that are refundable.

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, 2009	Year ended December 31, 2010	Year ended December 31, 2011
	$000	$000	$000
Loss before income taxes	(20,518)	(16,678)	(15,808)
Income tax expense computed at statutory federal tax rate	(6,976)	(5,672)	(5,375)
State income tax (net of federal benefit)	8	7	—
Disallowed expenses and non-taxable income	(773)	(490)	(141)
Loss surrendered to generate R&D credit	2,322	1,605	1,372
Additional research and development tax relief	(1,185)	(793)	(2,260)
Change in valuation allowance	4,605	3,984	3,170
Research and development tax credit rate difference	237	132	—
Foreign items, including change is tax rates	814	570	2,669
	(948)	(657)	(565)

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

	December 31,	
	2010	2011
	$000	$000
Net operating loss carryforwards	43,056	43,870
Depreciation, amortization and impairment of property and equipment	1,925	1,772
Stock Options	1,228	1,372
Accrued Expenses	3,778	3,435
Other	89	96
Translation adjustment	(2,452)	249
Deferred Tax Assets	47,624	50,794
Valuation allowance for deferred tax assets	(47,624)	(50,794)
Net deferred taxes	—	—

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

The Company's management evaluated the positive and negative evidence bearing upon the realizability of its deferred assets, and has determined that, at present, the Company may not be able to recognize the benefits of the deferred tax assets under the more likely than not criteria. Accordingly, a valuation allowance of approximately $50.8 million has been established at December 31, 2011. The benefit of deductions from the exercise of stock options is included in the net operating loss ("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.

In certain circumstances, as specified in the Tax Reform Act of 1986, due to ownership changes, the Company's ability to utilize its NOL 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,	
	2010	2011
	$000	$000
Accumulated tax losses	132,521	148,274

As of December 31, 2010 and 2011, the Company had federal and foreign NOLs of $147.7 million and $166.9 million, respectively. The Company has federal NOLs that will start to expire in 2027 and state NOLs that will start expiring in 2023.

Utilization of the NOLs 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 has 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. Management has evaluated all significant tax positions at December 31, 2010 and 2011 and concluded that there are no material uncertain tax positions. The Company would recognize both 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.

Tax years 2009, 2010 and 2011 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.

15 Geographic Information

Geographic information for the years ended December 31, 2009, 2010 and 2011 is as follows:

	Year ended December 31, 2009	Year ended December 31, 2010	Year ended December 31, 2011
	$000	$000	$000
Revenue			
United States	910	574	699
United Kingdom	1	112	—
	911	686	699
Net loss			
United States	(3,007)	(4,662)	(75)
United Kingdom	(16,563)	(11,359)	(15,168)
	(19,570)	(16,021)	(15,243)

	December 31,	
	2010	2011
	$000	$000
Total Assets		
United States	30,055	20,715
United Kingdom	1,404	5,283
	31,459	25,998
Long Lived Assets, net		
United States	161	45
United Kingdom	247	122
	408	167

16 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, 2011	June 30, 2011	September 30, 2011	December 31, 2011
	$000, except per share amounts			
Revenues	192	168	164	175
Loss before taxes	(4,779)	(3,678)	(3,571)	(3,780)
Net loss applicable to common shareholders	(4,770)	(3,734)	(3,627)	(3,840)
Net loss per share – basic and diluted (1)	$(0.10)	$(0.08)	$(0.07)	$(0.07)

	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)

(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.

17 Subsequent Events

Purchase Agreement

On March 22, 2012, the Company entered into a purchase agreement with certain existing institutional stockholders, raising $3.0 million of proceeds, net of certain fees and expenses. The proceeds from the financing will be used to fund ongoing litigation-related expenses on certain intellectual property and for general corporate purposes.

Under the terms of the purchase agreement, the investors purchased 4,688,079 shares of the Company's common stock at a price of $0.6476, which is equal to the 10-day average closing price of the Company's common stock for the period ending on Wednesday, March 21, 2012. In addition to the common stock, investors received contractual rights to receive in cash 10% of any future litigation settlement on certain intellectual property, subject to a cap, or alternatively, in lieu of a cash payment, either warrants to purchase common stock in certain situations or additional shares as part of any settlement in a possible related, alternative transaction. The shares issued at closing are subject to a lock-up period of one year from the date of issuance.

NASDAQ Appeal

On March 15, 2012, the Company received a determination letter from NASDAQ notifying the Company that it had not regained compliance with the minimum closing bid price requirements set forth in Listing Rule 5450(a)(1) (the "Rule") during the 180 calendar days allowed to regain compliance and that the Company's security is subject to delisting from the NASDAQ Global Market, unless the Company requests a hearing before a NASDAQ Listing Qualifications Panel (the "Panel") by no later than March 22, 2012 to appeal the NASDAQ Staff's determination. The Company has requested a hearing before the Panel to present its plan to regain compliance with the Rule, which request automatically stays the delisting of the Company's securities pending the issuance of the Panel's decision. The hearing is scheduled for April 26, 2012.

Under NASDAQ's Listing Rules, the Panel may, at its discretion, determine to continue the Company's listing pursuant to an exception to the Rule for a maximum of 180 calendar days from the date of the NASDAQ Staff's notification, or through September 10, 2012. However, there can be no assurances that the Panel will do so.

Notwithstanding the Company's request for a hearing before the Panel, if such appeal is unsuccessful, the Company may still transfer its listing to the NASDAQ Capital Market if it meets the initial listing criteria set forth in NASDAQ Marketplace Rule 5505, except for the bid price requirement. In that case, it may have an additional period of 180 calendar days in which to comply with the minimum bid price requirement. The Company currently meets these initial listing criteria, except for the bid price requirement.

Preferred Stock Dividend

On January 6, 2012, the Company's Board of Directors decided not to declare a quarterly cash dividend on the Company's 6% Convertible Exchangeable Preferred Stock ("Preferred Stock") with respect to the fourth quarter of 2011 that would have otherwise been payable on February 1, 2012.

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, 2011.

Pursuant to this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2011, the end of the period covered by this report, our disclosure controls and procedures were effective.

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

We have concluded that the consolidated financial statements in this Annual Report on Form 10-K 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 U.S. 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, 2011, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our internal control over financial reporting, including the remediation of the material weakness 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 describe in detail below under "Remediation of Material Weakness in Internal Control Over Financial Reporting". Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2011, our internal control over financial reporting was effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

This annual report does not include an attestation report of the Company's registered independent 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) Remediation of Material Weakness in Internal Control Over Financial Reporting

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.

To remediate this material weakness in internal controls, management has strengthened the financial reporting function through the hiring of qualified and experienced US-based 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. The revised internal controls have been in place for the full year ended December 31, 2011 and were considered in management's review of the effectiveness of our internal control over financial reporting and deemed to be operating effectively as of December 31, 2011.

(d) Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal control over financial reporting, identified in connection with the evaluation of such internal control, that occurred during the fourth fiscal quarter ended December 31, 2011 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

The information required by item 10 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2011 fiscal year pursuant to Regulation 14A for its 2012 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by item 11 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2011 fiscal year pursuant to Regulation 14A for its 2012 Annual Meeting of Stockholders.

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

The information required by item 12 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2011 fiscal year pursuant to Regulation 14A for its 2012 Annual Meeting of Stockholders.

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

The information required by item 13 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2011 fiscal year pursuant to Regulation 14A for its 2012 Annual Meeting of Stockholders.

Item 14. Principal Accountant Fees and Services

The information required by item 14 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2011 fiscal year pursuant to Regulation 14A for its 2012 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

(1) See "Index to Consolidated Financial Statements and Financial Statement Schedules" at Item 8 of this Annual Report on Form 10-K.

(2) Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

(3) The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

(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).
1.4	Underwriting Agreement, dated as of June 30, 2011, by and among the Company, Leerink Swan LLC and Lazard Capital Markets LLC (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on July 1, 2011, and incorporated herein by this 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 Cyclacel Pharmaceuticals, Inc. (Previously filed as Exhibit 3.2 to the Registrant's Annual Report on Form 10-K, File No. 000-50626, originally filed with the SEC on March 31, 2011 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 4.1the 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).

4.12 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 July 1, 2011, 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 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, 2011 (previously filed as Exhibit 10.13 to the Registrant's Annual Report on Form 10-K, File No. 000-50626, originally filed with the SEC on March 31, 2011 and incorporated herein by reference).

10.11† Employment Agreement by and between Cyclacel Pharmaceuticals, Inc. and Paul McBarron, dated as of January 1, 2011 (previously filed as Exhibit 10.14 to the Registrant's Annual Report on Form 10-K, File No. 000-50626, originally filed with the SEC on March 31, 2011 and incorporated herein by reference).

10.12† 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).

10.13 Amendment No. 1 to Common Stock Purchase Agreement, dated as of November 24, 2009, by and between the Company and Kingsbridge Capital Limited (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on November 25, 2009, and incorporated herein by reference).

10.14 Form of Subscription Agreement between the Company and certain investors (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on July 24,

2009, and incorporated herein by reference).

10.15 Form of Subscription Agreement between the Company and certain investors (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 11, 2010, and incorporated herein by reference).

10.16 Form of Subscription Agreement between the Company and certain investors (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 21, 2010, and incorporated herein by reference).

10.17 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).

10.18 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).

1019 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).

10.20 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).

10.21# License Agreement by and between Sankyo Co., Ltd. and Cyclacel Limited, dated September 10, 2003, and letter amendments dated April 1, 2004 and April 28, 2004 (previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, File No. 000-50626, for the quarterly period ended June 30, 2011, originally filed with the SEC on August 12, 2011, and incorporated herein by reference).

10.22# Amendment No. 4 to License Agreement between Daiichi Sankyo Company, Limited and Cyclacel Limited, dated July 11, 2011(previously filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, File No. 000-50626, for the quarterly period ended June 30, 2011, originally filed with the SEC on August 12, 2011, and incorporated herein by reference).

21 * Subsidiaries of Cyclacel Pharmaceuticals, Inc.

23.1* Consent of Independent Registered Public Accounting Firm.

23.1* Consent of Independent Registered Public Accounting Firm.

23.2* 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).

101*** The following materials from Cyclacel Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Income, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

† Indicates management compensatory plan, contract or arrangement.

Confidential treatment has been granted with respect to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities and Exchange Act of 1934, as amended.

* Filed herewith.

** Furnished herewith.

*** XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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 30, 2012

By: /s/ Paul McBarron
Paul McBarron
Chief Operating Officer, Chief Financial Officer &
Executive Vice President, Finance
(Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Spiro Rombotis Spiro Rombotis	President & Chief Executive Officer (Principal Executive Officer) and Director	March 30, 2012
/s/ Paul McBarron Paul McBarron	Chief Operating Officer, Chief Financial Officer & Executive Vice President, Finance (Principal Financial and Accounting Officer) and Director	March 30, 2012
/s/ Dr. David U'Prichard Dr. David U'Prichard	Chairman	March 30, 2012
/s/ Dr. Christopher Henney Dr. Christopher Henney	Vice Chairman	March 30, 2012
/s/Dr. Nicholas Bacopoulos Dr. Nicholas Bacopoulos	Director	March 30, 2012
/s/ Sir John Banham Sir John Banham	Director	March 30, 2012
/s/Gregory Hradsky Gregory Hradsky	Director	March 30, 2012
/s/Lloys Sems Lloyd Sems	Director	March 30, 2012
/s/ Daniel Spiegelman Daniel Spiegelman	Director	March 30, 2012

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 balance sheet of Cyclacel Pharmaceuticals, Inc as of December 31, 2010 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2010 and the period from August 13, 1996 to December 31, 2010, which report appears in its Annual Report (Form 10-K) for the year ended December 31, 2011.

/S/ ERNST & YOUNG LLP

London, England
March 30, 2012

Exhibit 23.2

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 30, 2012, with respect to the consolidated balance sheet as of December 31, 2011, and the related consolidated statements of operations, stockholders' equity and cash flows for the year then ended and the period from August 13 1996 (inception) to December 31, 2011 of Cyclacel Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2011.

/S/ ERNST & YOUNG LLP

Metro Park, New Jersey
March 30, 2012

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, 2011 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 subsidiaries, is made known to us by others within those entities, 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 control over financial reporting.

Date: March 30, 2012

/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, 2011 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 subsidiaries, is made known to us by others within those entities, 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 control over financial reporting.

Date: March 30, 2012

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

Exhibit 32.1

CERTIFICATION UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (of subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), 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, 2011 (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 30, 2012

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

Exhibit 32.2

CERTIFICATION UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (of subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), 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, 2011 (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 30, 2012

/s/ Paul McBarron
Paul McBarron
Chief Operating Officer, Chief Financial Officer
and Executive Vice President, Finance

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DIRECTORY

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F: +1 866 271 3466

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F: +44 1382 206 067

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TRANSFER AGENTS

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6201 15th Avenue, 2nd Floor
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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

Gregory T. Hradsky

Lloyd Sems

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, 2011. 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.

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.

ANNUAL MEETING

Cyclacel stockholders are invited to attend our annual meeting, which will be held at 9:30 a.m. Eastern on May 23, 2012 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

WWW.CYCLACEL.COM