

Cyclacel Pharmaceuticals, Inc.  
Form S-1  
December 26, 2012  
Table of Contents

As filed with the Securities and Exchange Commission on December 26, 2012

Registration No. 333-

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM S-1**

**REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF  
1933**

---

**CYCLACEL PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**91-1707622**  
IRS Employer  
Identification Number)

**200 Connell Drive, Suite 1500  
Berkeley Heights, NJ 07922  
(908) 517-7330**

(Address, including zip code, and telephone number, including area code, of  
registrant's principal executive offices)

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

**Spiro Rombotis**  
**Chief Executive Officer**  
**Cyclacel Pharmaceuticals, Inc.**  
**200 Connell Drive, Suite 1500**  
**Berkeley Heights, NJ 07922**  
**(908) 517-7330**

(Name, address, including zip code, and telephone number, including area code,  
of agent for service)

**With a copy to:**

**Martin Dunn, Esq.**

O Melveny & Meyers, LLP  
1625 Eye Street, NW  
Washington, D.C. 20006  
(202) 383 5300

**Joel I. Papernik, Esq.**

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.  
666 Third Avenue  
New York, New York 10017  
(212) 935-3000

**Approximate date of commencement of proposed sale to public: From time to time after the effective date of this registration statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(d) under the Securities Act, check the following box:

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. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

**CALCULATION OF REGISTRATION FEE**

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

<b>Title of Each Class of Security Being Registered</b>	<b>Amount Being Registered(1)</b>	<b>Proposed Maximum Offering Price Per Security</b>	<b>Proposed Maximum Aggregate Offering Price</b>	<b>Amount of Registration Fee</b>
Shares of common stock, \$.001 par value	1,689,317	\$ 6.19(2)	\$ 10,456,872.23	\$ 1,426.32

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the **Securities Act**), this Registration Statement shall also cover any additional shares of common stock which become issuable by reason of any stock dividend, stock split or other similar transaction effected without the receipt of consideration that results in an increase in the number of the outstanding shares of common stock of the registrant.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based upon the average of the high and low prices of the common stock on The NASDAQ Global Market on December 18, 2012. Under a common stock purchase agreement, Aspire Capital Fund, LLC has agreed to purchase up to \$20.0 million of shares of the Registrant's common stock.

**The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

Table of Contents

**The information in this prospectus is not complete and may be changed. The selling securityholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to Completion, dated December 26, 2012**

**PROSPECTUS**

**Relating to the Sale of up to  
1,689,317 Shares of Common Stock, \$0.001 Par Value**

**CYCLACEL PHARMACEUTICALS, INC.**

This prospectus relates to the sale of up to 1,689,317 shares of our common stock by Aspire Capital Fund, LLC. Aspire Capital is also referred to in this prospectus as the selling stockholder. The prices at which the selling stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive gross proceeds of up to \$20,000,000 from the sale of our common stock the selling stockholder, pursuant to a common stock purchase agreement entered into with the selling stockholder on December 14, 2012, once the registration statement, of which this prospectus is a part, is declared effective.

The selling stockholder is an underwriter within the meaning of the Securities Act of 1933, as amended. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling stockholder will be paid the selling stockholder.

Our common stock is listed on the NASDAQ Global Market under the symbol CYCC. On December 21, 2012, the last reported sale price for our common stock was \$5.71 per share.

**Investing in our securities involves significant risks. We strongly recommend that you read carefully the risks we describe in this Prospectus and the risk factors that are incorporated by reference in this Prospectus from our filings made with the Securities and Exchange Commission. See Risk Factors beginning on page 12 before deciding whether to invest in our common stock.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is December 26, 2012.

---

Table of Contents

TABLE OF CONTENTS

<b><u>PROSPECTUS SUMMARY</u></b>	1
<b><u>THE OFFERING</u></b>	10
<b><u>RISK FACTORS</u></b>	12
<b><u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u></b>	35
<b><u>USE OF PROCEEDS</u></b>	36
<b><u>MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u></b>	37
<b><u>DIVIDEND POLICY</u></b>	37
<b><u>DILUTION</u></b>	38
<b><u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	39
<b><u>BUSINESS</u></b>	58
<b><u>MANAGEMENT AND CORPORATE GOVERNANCE</u></b>	80
<b><u>CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS</u></b>	97
<b><u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT (2)</u></b>	98
<b><u>SELLING STOCKHOLDER</u></b>	100
<b><u>THE ASPIRE CAPITAL TRANSACTION</u></b>	101
<b><u>PLAN OF DISTRIBUTION</u></b>	105
<b><u>DESCRIPTION OF SECURITIES</u></b>	107
<b><u>MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS</u></b>	122
<b><u>LEGAL MATTERS</u></b>	125
<b><u>EXPERTS</u></b>	125
<b><u>WHERE YOU CAN FIND MORE INFORMATION</u></b>	125
<b><u>INDEX TO FINANCIAL STATEMENTS</u></b>	F-1
<b>PART II INFORMATION NOT REQUIRED IN PROSPECTUS</b>	

You should rely only on the information provided in this Prospectus or in any free writing Prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with different information. The information contained in this Prospectus is accurate only as of the date of this Prospectus, regardless of the time of delivery of this Prospectus or of any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

**Persons outside the United States who come into possession of this Prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this Prospectus outside of the United States.**

Table of Contents

**PROSPECTUS SUMMARY**

*Because this is only a summary, it does not contain all of the information that may be important to you. You should carefully read the more detailed information contained in this prospectus and the information incorporated by reference carefully before you invest. Our business involves significant risks. You should carefully consider the information under the heading "Risk Factors" beginning on page 12.*

As used in this prospectus, unless otherwise indicated, the terms **we**, **us**, **our company**, **the Company** and **Cyclacel** refer to Cyclacel Pharmaceuticals, Inc., a Delaware corporation.

**Our Company**

We are a biopharmaceutical business dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat cancer and other serious diseases. We are focused on delivering leading edge therapeutic management of cancer patients based on a clinical development pipeline, led by sapacitabine, of novel drug candidates. Our core area of expertise, and a foundation of the Company since our inception, is in cell cycle biology; the processes by which cells divide and multiply. We focus primarily on the development of orally available anticancer agents that target the cell cycle with the aim of slowing the progression or shrinking the size of tumors, and enhancing the quality of life and improving survival rates of cancer patients.

We are focusing our clinical development priorities on:

- Sapacitabine in acute myeloid leukemia, or AML, in elderly patients;
- Sapacitabine in myelodysplastic syndromes, or MDS, in older patients; and
- Sapacitabine in non-small cell lung cancer, or NSCLC.

We have a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA, 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; the SEAMLESS trial. SEAMLESS is a registration-directed, clinical trial of sapacitabine oral capsules is being conducted under the SPA and is a randomized study against an active control drug with the primary efficacy of overall survival.



## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

We have additional ongoing programs in clinical development which are currently pending the availability of clinical data. Once these data become available and are reviewed, we will determine the feasibility of pursuing further development and/or partnering of these assets including sapacitabine in combination with seliciclib, seliciclib in nasopharyngeal cancer, or NPC, and NSCLC and CYC065.

We were founded by Professor Sir David Lane, a recognized leader in the field of tumor suppressor biology who discovered the p53 protein, which operates as one of the body's own anticancer agents by regulating cell cycle targets. Our Chief Scientist, Professor David Glover, is a recognized leader in the biology of mitosis or cell division. Professor Glover discovered, among other cell cycle targets, the mitotic kinases, Polo and Aurora, enzymes that act in the mitosis phase of the cell cycle.

Although our resources are primarily directed towards advancing our anticancer drug candidate sapacitabine through in-house development activities we are also progressing, but with lower levels of investment than in previous years, our other novel drug series which are at earlier stages. Taken together, our pipeline covers all four phases of the cell cycle, which we believe will improve the chances of successfully developing and commercializing novel drugs that work on their own or in combination with approved conventional chemotherapies or with other targeted drugs to treat human cancers.

Table of Contents

*Sapacitabine*

Our lead candidate, sapacitabine, is an orally available prodrug of CNDAC, which is a novel nucleoside analog, or a compound with a structure similar to a nucleoside. A prodrug is a compound that has a therapeutic effect after it is metabolized within the body. CNDAC has a significantly longer residence time in the blood when it is produced in the body through metabolism of sapacitabine than when it is given directly.

Sapacitabine acts through a dual mechanism whereby the compound interferes with DNA synthesis and repair by causing single-strand DNA breaks and induces arrest of the cell division cycle at G2/M checkpoint. A number of nucleoside drugs, such as gemcitabine, or Gemzar®, from Eli Lilly, and cytarabine, also known as Ara-C, a generic drug, are in wide use as conventional chemotherapies. Both sapacitabine and its major metabolite, CNDAC, have demonstrated potent anti-tumor activity in both blood and solid tumors in preclinical studies. In a liver metastatic mouse model, sapacitabine was shown to be superior to gemcitabine and 5-FU, two widely used nucleoside analogs, in delaying the onset and growth of liver metastasis. We have retained worldwide rights to commercialize sapacitabine, except for Japan, for which Daiichi-Sankyo Co., Ltd, or Daiichi-Sankyo, has a right of first negotiation.

We are currently exploring sapacitabine in both hematological cancers and solid tumors. Over 500 patients have received sapacitabine in Phase 2 studies in AML, MDS, CTCL and NSCLC and Phase 1 studies in hematological malignancies and solid tumors. Sapacitabine, an orally-available nucleoside analogue, is currently being studied in SEAMLESS, an ongoing, Phase 3, registration-directed trial in elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for or have refused induction chemotherapy. SEAMLESS will be conducted under a SPA.

*Hematological Cancers*

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

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

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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

In December 2007, we initiated an open-label, multicenter, randomized Phase 2 clinical trial of oral sapacitabine in 60 elderly patients with AML aged 70 or older who are previously untreated or in first relapse. The Phase 2 study, led by Dr. Kantarjian, has a primary endpoint of 1-year survival rate of three dosing schedules of sapacitabine in elderly patients with previously untreated or first relapsed AML. Secondary objectives are to assess CR or CRp, partial remission, or PR, duration of CR or CRp, or major hematological improvement and their corresponding durations, transfusion requirements, number of hospitalized days and safety. The study uses a selection design with the objective of identifying a dosing schedule among three different arms, A. 200 mg twice daily for seven days every 3-4 weeks, B. 300 mg twice daily for seven days every 3-4 weeks, and C. 400 mg twice daily for three days per week for two weeks every 3-4 weeks, which produces a better 1-year survival rate in the event that all three dosing schedules are active. Each arm enrolled and treated 20 patients. Approximately 55% of patients had AML de novo and the rest had AML preceded by antecedent hematological disorder, or AHD, such as MDS, or myeloproliferative disease. Eighty percent of the patients were untreated and 20% in first relapse. We completed enrollment of 60 AML patients in this study in October 2008.

Table of Contents

In December 2009, at the 51st Annual Meeting of ASH we reported 1-year survival data. The primary endpoint of 1-year survival was 35% on Arm A, 30% on Arm C and 10% on Arm B. The median overall survival was 212 days on Arm C (range of 13 to over 654 days), 197 days on Arm A (range of 26 to over 610 days) and 100 days on Arm B (range of 6 to over 646 days). Overall response rate, or ORR, a secondary endpoint, was 45% on Arm A, 35% on Arm C and 25% on Arm B with CR rate of 25% on Arm C and 10% on Arms A and B. Thirty-day mortality was 10% on Arm C and Arm A and 20% on Arm B. Approximately 30% of all patients received sapacitabine for at least 6 cycles. Fifteen patients who survived one year or more received an average of 12 treatment cycles.

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

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

In November 2012, the results from the Phase 2 study were published in *The Lancet Oncology*, demonstrating the safety and efficacy of sapacitabine in this patient population. The Phase 2 study enrolled and treated between December 27, 2007 and April 21, 2009, a total of 105 patients aged 70 years or above with untreated or first relapse AML. The median age of patients was 77 years (range 70-91). The group was comprised of a randomized cohort of 60 patients and an expanded, non-randomly assigned cohort enrolling a further 45 patients. Of the 105 patients, 86 were previously untreated and 19 in first relapse. Approximately 50% of patients had AML de novo and 50% had AML preceded by antecedent hematological disorder (AHD), such as MDS or myeloproliferative disease, or treatment-related AML. All but one enrolled patients had intermediate or unfavorable cytogenetics. The randomized cohort of patients were randomly assigned to one of three dosing schedules: 200 mg twice a day for 7 days (group A); 300 mg twice a day for 7 days (group B); and 400 mg twice a day for 3 days each week for 2 weeks (group C). All schedules were given in 28 day cycles. The 3-day dosing schedule in group C was selected for further clinical development in elderly patients with untreated AML. This decision was based on the schedule's overall efficacy profile, which included a 1-year survival rate of 30%, median overall survival of 213 days and durable complete remissions (CRs) in 25% of patients. The median overall survival of patients from all groups who achieved CR was 525 days (95% C.I. 192-798). The most common grade 3-4 adverse events regardless of causality were anemia, neutropenia, thrombocytopenia, febrile neutropenia and pneumonia. Seven deaths were thought to be probably or possibly related to sapacitabine treatment. Approximately 31% of all patients received sapacitabine for at least 4 cycles.

Table of Contents

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

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

In June 2010, at the American Society of Clinical Oncology, or ASCO, meeting we reported interim response data for the ongoing Phase 2 clinical trial of sapacitabine in older patients with MDS. The study has recently completed enrollment of 61 patients aged 60 or older with MDS who were previously treated with azacitidine or decitabine or both. In this three-arm study, Arms B & C enrolled 20 patients each while Arm C enrolled 21 patients across the same three randomized dosing schedules of sapacitabine tested in the AML stratum of the study. All patients have received at least one hypomethylating agent and 15 patients (25%) have received two hypomethylating agents, i.e., azacitidine and decitabine. Approximately 51% of the 61 patients had baseline bone marrow blast counts above 10%. Based on interim data, the overall response rate is 24% on Arm A, the 7-day low dose schedule, 35% on Arm B, the 7-day high dose schedule, and 10% on Arm C, the 3-day high dose schedule. Two patients achieved complete remission and both were treated on Arm A. Thirty-day mortality from all-causes is 4.8% on Arm A, 0% on Arm B and 15% on Arm C. Approximately 34% of the patients received 4 or more cycles of sapacitabine.

In October 2012, at the The Eighth Annual Hematologic Malignancies 2012 Conference, we reported updated data from an ongoing, multicenter, Phase 2 randomized trial of sapacitabine in older patients with intermediate-2 or high-risk MDS after treatment failure of front-line hypomethylating agents, such as azacitidine (Vidaza®) and/or decitabine (Dacogen®). Median overall survival to date for all 63 patients in the Phase 2 study is 252 days or approximately 8 months. Median overall survival for 41 out of 63 patients with 10% or more blasts in their bone marrow is 274 days or approximately 9 months. Updated median survival for all three arms is 252 days (approximately 8 months). The median survival for each arm is 291 days (approximately 10 months) for Arm G, 274 days (approximately 9 months) for Arm H, and 227 days (approximately 8 months) for Arm I. Twenty-seven percent of all patients received 6 or more cycles. Twenty-two percent of patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival of each arm.

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

On September 13, 2010, we announced that we reached agreement with the FDA regarding the SPA, on the design of a pivotal Phase 3 trial, the SEAMLESS 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. SEAMLESS is being conducted under an SPA agreement that Cyclacel reached with the FDA. Patients who received hypomethylating agents for prior myelodysplastic syndromes or myeloproliferative diseases are excluded from SEAMLESS. Patients in the control arm of SEAMLESS will receive decitabine alone, while in the experimental arm of SEAMLESS, patients will receive intravenous decitabine at 20 mg/m<sup>2</sup> per day for five consecutive days of a 4-week cycle (odd cycles) alternating with sapacitabine at 300 mg orally twice per day for three days per week for two weeks of a 4-week cycle (even cycles). The primary efficacy endpoint is overall survival. A prespecified interim analysis for futility will be performed and reviewed by the Data Safety Monitoring Board. An SPA provides trial sponsors with an FDA agreement that the design and analysis of the trial adequately address objectives in support of a submission for a marketing application if the trial is performed according to the SPA. The SPA may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. However, an SPA does not provide any assurance that a marketing application would be approved by the FDA. Furthermore, Phase 3

clinical trials are time-consuming and expensive, and because we have limited resources, we may be required to collaborate with a third party or raise additional funds. However, there is no assurance that we will be able to do so.

Table of Contents

In December 2012, at the 54th Annual Meeting of ASH, the Company announced updated survival data from the pilot study and lead-in phase of SEAMLESS. Forty-six patients were treated with alternating cycles of sapacitabine and decitabine, which is the treatment regimen in the experimental arm of SEAMLESS. Median age is 77 years (range 70-90). Thirty-three patients (72%) are 75 years or older. Median overall survival is 238 days, or approximately 8 months. The number of patients still alive at 3 months was 38 (83%), at 6 months 30 (65%), at 12 months 16 (35%) and at 18 months 12 (26%). Sixteen patients (35%) survived 1 year or longer. Among 33 patients who are 75 years or older, median overall survival is 263 days, or approximately 9 months, and 1-year survival is 36%. Nineteen patients (41%) responded with 10 complete responses (CRs), 4 partial responses (PRs) and 5 major hematological improvements (HIs). Median time to response is 2 cycles, i.e., one cycle of decitabine and one cycle of sapacitabine (range 1-10). Twenty-seven patients (59%) received 5 or more cycles of treatment. Two dose-limiting toxicities (DLT) were observed (lung infection/sepsis, typhlitis). Thirty-day mortality from all causes was 4%. Sixty-day mortality from all causes was 13% with one death from typhlitis considered to be possibly related to decitabine by investigator assessment. The sequential combination of decitabine and sapacitabine is safe and active.

***Solid Tumors***

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

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

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

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

Table of Contents

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

In April 2007, we initiated a Phase 2 clinical trial in patients with advanced CTCL, a cancer of T-lymphocytes, or white blood cells, which causes disfiguring skin lesions and severe itching. The primary objective of the study is to evaluate tolerability and response rate of 50 mg and 100 mg regimens of sapacitabine both twice a day for three days per week for two weeks in a three week cycle in patients with progressive, recurrent, or persistent CTCL on or following two systemic therapies. The study uses a selection design to choose an optimal dose if both are active. Secondary objectives are to assess response duration, time to response, time to progression and relief of pruritus or itching. Non-hematological toxicities were mostly mild to moderate. The best response by investigator assessment was partial response in 3 patients out of 16 enrolled. We stopped the trial in order to re-direct our resources to sapacitabine clinical trials with a higher priority.

*Orphan Designation*

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

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, the opportunity to apply for grant funding from the U.S. 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*

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



Table of Contents

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

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

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

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

Four Phase 2 trials have been conducted in cancer patients to evaluate the tolerability and antitumor activities of seliciclib alone or in combination with standard chemotherapies used in the treatment of advanced NSCLC or breast cancer. Interim data from two Phase 2 open-label studies of a total of 52 patients with NSCLC, 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.



Table of Contents

*Phase 2 clinical trials in patients with NPC*

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

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

***CYC065***

CYC065 is a novel, orally available, cell cycle kinase inhibitor currently in IND-directed preclinical development. CYC065 targets similar CDK/cyclin complexes to those targeted by seliciclib, our first generation CDK inhibitor currently in Phase 2 studies. CYC065 retains the high CDK specificity of seliciclib, but with substantially higher anti-proliferative potency and improved pharmaceutical properties. CYC065 is a second generation aminopurine which selectively inhibits CDK2, CDK5 and CDK9. Strong preclinical anti-cancer efficacy data for CYC065 in multiple myeloma, chronic lymphocytic leukemia (CLL) and mixed lineage leukemia (MLL) have been presented at the 2010 Annual Meetings of the American Society of Hematology (ASH) 1 and the American Association of Cancer Research (AACR). 2 3 At the 2010 AACR CYC065 was also reported to be active in solid tumor models, including trastuzumab-resistant, cyclin E overexpressing breast cancer. These findings were subsequently published by Scaltriti, et al ( Cyclin E amplification/overexpression is a mechanism of trastuzumab resistance in HER2+ breast cancer patients , PNAS, 2011:108:3761-3766). In addition CYC065 was shown to have preclinical efficacy in proliferative kidney disease models (Cyclacel data on file). Cyclacel discovered CYC065 in collaboration with the Cancer Research UK Centre for Cancer Therapeutics at The Institute of Cancer Research. In November 2012, we received a grant of approximately \$1.9 million from the UK Government s Biomedical Catalyst to complete investigational new drug (IND)-directed preclinical development of CYC065.

***CYC116***

In June 2007, we initiated a multicenter Phase 1 pharmacologic clinical trial of CYC116, an orally-available inhibitor of Aurora kinase A and B and VEGFR2, in patients with advanced solid tumors. The multicenter Phase 1 trial, now completed, is designed to examine the safety and tolerability of CYC116 in patients with advanced solid tumors. The primary objective of the study is to determine the maximum tolerated dose. Secondary objectives are to evaluate pharmacokinetic and pharmacodynamic effects of the drug and document anti-tumor activity. Aurora kinases, or AK, are a family of serine/threonine protein kinases discovered by Professor David Glover, our Chief Scientist, that are only expressed in actively dividing cells and are crucial for the process of cell division or mitosis. These proteins, which have been found to be over-expressed in many types of cancer, have generated significant scientific and commercial interest as cancer drug targets. VEGFR2 is a receptor protein that plays a key regulatory role in the angiogenesis pathway, or blood vessel formation. VEGFR is targeted by recently

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

approved drugs such as bevacizumab and sorafenib indicated for the treatment of several solid cancers, such as breast, colorectal, kidney, liver and lung. We have retained worldwide rights to commercialize CYC116. Further work on CYC116 will be undertaken when appropriate levels of resource are available to direct to the program.

Table of Contents

***Other programs***

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

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

**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.

Table of Contents

**THE OFFERING**

<b>Common stock covered hereby:</b>	Up to 1,689,317 shares, including 233,440 shares currently outstanding
<b>Common stock outstanding as of December 18, 2012:</b>	8,452,954 shares
<b>Use of proceeds:</b>	Aspire Capital will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by Aspire Capital. However, we may receive up to \$20.0 million in proceeds from the sale of our common stock to Aspire Capital under the Common Stock Purchase Agreement described below, which we currently intend to use for working capital and general corporate purposes. See Use of Proceeds.
<b>Risk factors:</b>	The shares of common stock offered hereby involve a high degree of risk. See Risk Factors beginning on page 12.
<b>Dividend policy:</b>	We currently intend to retain any future earnings to fund the development and growth of our business. Therefore, we do not currently anticipate paying cash dividends on our common stock.
<b>Trading Symbol:</b>	Our common stock currently trades on the NASDAQ Global Market under the symbol CYCC.

On December 14, 2012, we entered into a common stock purchase agreement referred to in this prospectus as (the **Purchase Agreement**), with Aspire Capital Fund, LLC, an Illinois limited liability company (referred to in this prospectus as **Aspire Capital** or the **selling stockholder**), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over the approximately 24-month term of the Purchase Agreement, should we elect to sell shares to Aspire Capital. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 74,458 shares of our common stock, which we refer to as the Commitment Shares, as a commitment fee. Upon execution of the Purchase Agreement, we sold to Aspire Capital 158,982 shares of common stock, which we refer to as the Initial Purchase Shares, for an aggregate purchase price of \$1,000,000. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, which we refer to as the Registration Rights Agreement, pursuant to which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of December 18, 2012, there were 8,452,954 shares of our common stock outstanding (7,252,565 shares held by non-affiliates) excluding the 1,455,877 shares offered that may be issuable to Aspire Capital pursuant to the Purchase Agreement. If all of the 1,689,317 shares of our common stock offered hereby were issued and outstanding as of December 18, 2012, such shares would represent 17.1% of the total common stock outstanding, or 27% of the non-affiliate shares of common stock outstanding as of December 18, 2012. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Table of Contents

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering under the Securities Act 1,689,317 shares of our common stock, which includes the Commitment Shares and the Initial Purchase Shares that have already been issued to Aspire Capital. All 1,689,317 shares of common stock are being offered pursuant to this prospectus.

Under the Purchase Agreement, we have the right, but not the obligation, to sell more than the 1,689,317 shares of common stock offered in this prospectus. The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement shall be limited to 1,689,371 (the **Exchange Cap**), which represents 19.99% of our outstanding shares as of December 14, 2012, unless shareholder approval or an exception pursuant to the rules of the NASDAQ Global Market is obtained to issue more than 19.99%, to be in compliance with the applicable listing maintenance rules of the NASDAQ Global Market. This limitation shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Purchase Agreement is equal to or greater than \$6.29, the closing sale price of our common stock on December 14, 2012. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Global Market.

After the SEC has declared effective the registration statement of which this prospectus is a part, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a **Purchase Notice**), directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed \$500,000 per trading day, up to an additional \$19.0 million of our common stock in the aggregate at a per share price (the **Purchase Price**) calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 100,000 shares, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a **VWAP Purchase Notice**) directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on The NASDAQ Global Market on the next trading day (the **VWAP Purchase Date**), subject to a maximum number of shares we may determine (the **VWAP Purchase Share Volume Maximum**) and a minimum trading price (the **VWAP Minimum Price Threshold**) (as more specifically described below). The purchase price per Purchase Share pursuant to such VWAP Purchase Notice (the **VWAP Purchase Price**) is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that in no event will any shares of common stock be sold if the closing price of our common stock is less than \$1.00, or the Floor Price. This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. Additionally, the Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement if such shares proposed to be issued and sold, when aggregated with all other shares of the Company's common stock that Aspire Capital and its affiliates beneficially own, would result in Aspire Capital and its affiliates beneficially owning more than 19.99% of the Company's then issued and outstanding common stock.

There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.





Table of Contents

**RISK FACTORS**

*Any investment in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, together with all of the other information included in this prospectus, before deciding whether to purchase shares of our common stock. 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. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our operating results could differ materially from those anticipated in these forward-looking statements as a result of certain risk factors, including the risks we face as described below and elsewhere in this prospectus.*

**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. In January 2011, we opened enrollment in the lead-in portion of the SEAMLESS trial and in October 2011, we opened enrollment in the randomized portion of the 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.

Table of Contents

*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 Independent Review Board ( IRB ) and other regulatory approvals to commence a clinical trial;
- slower than anticipated rates of patient recruitment and enrollment, or not 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 pharmacodynamics behaviors;
- approval and intro 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;

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

- 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.

Table of Contents

***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.



Table of Contents

*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 a 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. 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.



Table of Contents

*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. 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 a New Drug Application ( **NDA** ) from the FDA. We have not received an NDA approval from the FDA for any of our drug candidates.

Table of Contents

Obtaining an NDA approval is expensive and is a complex, lengthy and uncertain process. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an Investigational New Drug Application, 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.

***Following regulatory approval of any of our drug candidates, we will be 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 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 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.



Table of Contents

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. 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.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

Table of Contents

***The commercial success of our drug candidates 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. The degree of market acceptance of any of our approved drugs 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 for our drug candidate seliciclib 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. Thus, the termination of this license could harm our business.

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

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

Table of Contents

We may also be 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.



Table of Contents

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

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.

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

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.

Table of Contents

**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.

Table of Contents

***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 earned modest product revenues from the ALIGN business prior to terminating operations effective September 30, 2012, we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products.

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the 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 AML, MDS, NSCLC and CLL. 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, 2011 and September 30, 2012, our accumulated deficit was \$257.1 million and \$265.5 million, respectively. Our net loss was \$11.6 million and \$8.4 million for the nine months ended September 30, 2011 and 2012, respectively. Our net loss applicable to common stockholders from inception through September 30, 2012 was \$307.8 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 and commercialize any approved drugs. 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.

Table of Contents

*If we fail to comply with the continued listing requirements of the NASDAQ Global Market, our common stock 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.

*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

Table of Contents

- 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.





Table of Contents

**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.

Table of Contents

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

***Intellectual property rights of third parties may increase our costs or delay or prevent us from being able to commercialize our drug candidates.***

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. 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:

Table of Contents

- 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.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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

Table of Contents

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

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

Table of Contents

***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.***



## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

Table of Contents

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 September 30, 2012, 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 \$14.3 million 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.

Table of Contents

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.

***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.

Table of Contents

***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 \$247.10. 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.

Table of Contents

*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.

**Risks Related to this Offering**

*Our management team will have broad discretion over the use of the net proceeds from this offering.*

Our management will use its discretion to direct the net proceeds from this offering. We intend to use all of the net proceeds, together with cash on hand, for general corporate purposes. General corporate purposes may include working capital, capital expenditures, development costs, strategic investments or possible acquisitions. Our management's judgments may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

*The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.*

We are registering for sale the Commitment Shares that we have issued, the Initial Purchase Shares previously sold to Aspire Capital and an additional 1,455,877 shares that we may sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered in this offering will be sold by Aspire Capital over a period of up to approximately 24 months from the date of this prospectus. Under the Purchase Agreement, we have the right, but not the obligation, to sell more than the 1,689,317 shares of common stock offered in this prospectus, if we obtain shareholder approval or an exception pursuant to the rules of the NASDAQ Global Market is obtained to issue more than 19.99%, to be in compliance with the applicable listing maintenance rules of the NASDAQ Global Market. This limitation shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Purchase Agreement is equal to or greater than \$6.29, the closing sale price of our common stock on December 14, 2012. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Global Market. In addition, we must register under the Securities Act the sale by Aspire Capital of any additional shares we may elect to sell to Aspire Capital before we can put such additional shares to Aspire Capital under the Purchase Agreement. Further, the number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Purchase Agreement may cause the trading price of our common stock to decline.

In addition to the Initial Purchase Shares, Aspire Capital may ultimately purchase all, some or none of the remaining \$19.0 million of common stock that, together with the Commitment Shares, is the subject of this prospectus. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement under the



## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

registration statement, of which this prospectus is a part, may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital in this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

Table of Contents

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

The Securities and Exchange Commission encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This prospectus contains such forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be made directly in this prospectus, and they may also be made a part of this prospectus by reference to other documents filed with the Securities and Exchange Commission, which is known as incorporation by reference.

Words such as may, anticipate, estimate, expects, projects, intends, plans, believes and words and terms of similar substance used in any discussion of future operating or financial performance identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Forward-looking statements might include one or more of the following:

- anticipated results of financing activities;
- anticipated agreements with marketing partners;
- anticipated clinical trial timelines or results;
- anticipated research and product development results;
- projected regulatory timelines;
- descriptions of plans or objectives of management for future operations, products or services;
- forecasts of future economic performance; and
- descriptions or assumptions underlying or relating to any of the above items.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Please also see the discussion of risks and uncertainties under the heading "Risk Factors" beginning on page 12.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus or in any document incorporated by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to Cyclacel or to any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Table of Contents

**USE OF PROCEEDS**

The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to an aggregate of \$20.0 million in proceeds from the sale of our common stock to the selling stockholder under the Purchase Agreement. We will bear all reasonable expenses incident to the registration of the shares of our common stock under federal and state securities laws other than expenses incident to the delivery of the shares to be sold by Aspire Capital. Any transfer taxes payable on these shares and any commissions and discounts payable to underwriters, agents, brokers or dealers will be paid by Aspire Capital.

Assuming the sale by us of all \$20.0 million of shares of our common stock to Aspire Capital and estimated expenses of \$0.1 million, the total net proceeds to us, would be \$19.0 million, which we currently intend to use for general corporate purposes, including capital expenditures, the advancement of our drug candidates in clinical trials, such our SEAMLESS pivotal Phase 3 trial of oral sapacitabine, and to meet working capital needs. The amounts and timing of the expenditures will depend on numerous factors, such as the timing and progress of our clinical trials and research and development efforts, technological advances and the competitive environment for our drug candidates. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions. As of the date of this Prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from the sale of common stock to Aspire Capital. Accordingly, we will retain broad discretion over the use of these proceeds, if any.

Table of Contents**MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

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

	<b>High</b>		<b>Low</b>
<b>2012</b>			
Quarter ended March 31, 2012	\$ 5.60	\$	3.36
Quarter ended June 30, 2012	5.39		2.73
Quarter ended September 30, 2012	6.23		3.08
<b>2011</b>			
Quarter ended March 31, 2011	\$ 11.13	\$	8.40
Quarter ended June 30, 2011	\$ 12.88	\$	8.54
Quarter ended September 30, 2011	\$ 8.96	\$	2.73
Quarter ended December 31, 2011	\$ 6.16	\$	2.52
<b>2010</b>			
Quarter ended March 31, 2010	\$ 28.56	\$	7.00
Quarter ended June 30, 2010	\$ 20.79	\$	9.66
Quarter ended September 30, 2010	\$ 13.86	\$	9.80
Quarter ended December 31, 2010	\$ 13.65	\$	10.08

On December 18, 2012, we had approximately 70 registered holders of record of our common stock. On December 19, 2012, the closing sale price of our common stock as reported by NASDAQ was \$6.28 per share.

**DIVIDEND POLICY**

We have never declared any cash dividends with respect to our common stock. Future payment of dividends is within the discretion of our board of directors and will depend on our earnings, capital requirements, financial condition and other relevant factors. Although there are no material restrictions limiting, or that are likely to limit, our ability to pay dividends on our common stock, we presently intend to retain future earnings, if any, for use in our business and have no present intention to pay cash dividends on our common stock.

Table of Contents**DILUTION**

If you acquire shares of our common stock from the selling stockholder in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this offering. Our historical net tangible book value of common stock as of September 30, 2012 was \$13.2 million, or \$1.57 per share of common stock. Historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding.

After giving effect to (i) the issuance of the 74,458 Commitment Shares, (ii) the sale of the 158,982 Initial Purchase Shares, at a price of \$6.29 per share for an aggregate amount of \$1.0 million, and (iii) the sale of an additional 1,455,877 shares of common stock at \$1.00 per share, and after deducting estimated offering expenses payable by us, our pro forma net tangible book value as of September 30, 2012 would have been \$15.6 million, or \$1.54 per share of common stock. This represents an immediate decrease in pro forma net tangible book value of \$(0.03) per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of \$(0.54) per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share	\$	1.00
Historical net tangible book value per share as of September 30, 2012	\$	1.57
Decrease in net tangible book value per share attributable to this offering		(0.03)
Pro forma net tangible book value per share after this offering		1.54
Dilution per share to investors participating in this offering	\$	(0.54)

The shares sold in this offering, if any, in addition to the Commitment Shares and the Initial Purchase Shares may be sold from time to time at various prices.

Each \$0.25 increase in the per share price at which we sell shares to Aspire Capital under the Purchase Agreement from the assumed offering price of \$1.00 per share would increase our pro forma net tangible book value by \$0.40 million, our pro forma net tangible book value per share by \$0.04 and dilution per share to new investors purchasing shares of common stock in this offering by \$0.21, assuming that the number of shares of common stock offered, as set forth on the cover page of this prospectus, remains the same and after deducting estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only.

The table and calculations set forth above are based on the number of shares of common stock outstanding as of September 30, 2012 and assumes no exercise of any outstanding options or warrants. To the extent that options or warrants are exercised, there will be further dilution to new investors.

The above information excludes the following shares as of December 18, 2012:

- 843,228 shares of common stock authorized and reserved for future issuance under our equity incentive plans;

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

- 520,536 shares of common stock issuable upon exercise of outstanding stock options; and
- 1,973,431 shares of common stock issuable upon exercise of outstanding warrants.

Table of Contents

**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 herein under the caption Risk factors section and elsewhere in this prospectus.*

*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.

Sapacitabine is being evaluated in the SEAMLESS Phase 3 trial being conducted under a Special Protocol Assessment agreement with the US Food and Drug Administration ( FDA ) for the front-line treatment of AML in the elderly and in Phase 2 studies for MDS, lung cancer and chronic lymphocytic leukaemia. Additionally, sapacitabine has been shown to have increased activity in cancer cells with BRCA- or Homologous Recombinant repair-deficient backgrounds, including ovarian cancer cell lines. In June, we reported new data at the American Society of Clinical Oncology Annual Meeting from an on-going multicenter Phase 2 randomized trial of oral sapacitabine capsules, in older patients with MDS after treatment failure of front-line hypomethylating agents, such as azacitidine (Vidaza®) and/or decitabine (Dacogen®). Median overall survival to date for all patients is 252 days or approximately 8.4 months. We will initiate regulatory discussions regarding an



appropriate registration plan in this setting after a dosing schedule is selected.

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 marketed directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. However, the distribution agreements for the promotion and sale of these products terminated effective September 30, 2012.

Table of Contents

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 nine months ended September 30, 2012 decreased \$2.4 million, or 34%, from \$7.0 million for the nine months ended September 30, 2011 to \$4.6 million for the nine months ended September 30, 2012. 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 decreased 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 September 30, 2012, we have devoted substantially all our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of September 30, 2011, our accumulated deficit during the development stage was \$265.5 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 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 September 30, 2012, totaling \$6.8 million, of which \$3.1 million is derived from fees under collaborative agreements and \$3.7 million of grant revenue from various United Kingdom government grant awards. We have also recognized \$19.2 million in research and development tax credits from inception through September 30, 2012, which are reported as income tax benefits on the consolidated statements of operations, from the United Kingdom's tax authority, H.M. Revenue & Customs. In addition, we have recognized revenue from discontinued operations from inception through September 30, 2012 of approximately \$3.6 million from sales of commercial products.

Table of Contents

**Recent Events**

Stock Purchase Agreement

On December 14, 2012, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC ( *Aspire* ). Upon execution of the Purchase Agreement, Aspire purchased 158,982 shares of common stock for an aggregate purchase price of \$1.0 million based the closing price of our common stock December 13, 2012, the date upon which the business terms were agreed. Under the terms of the Purchase Agreement, Aspire has committed to purchase up to an additional 1,454,877 shares from time to time as directed us over the next two years at prices derived from the market prices on or near the date of each sale. However, such commitment is limited to an additional \$19.0 million of share purchases. In consideration for entering into the Purchase Agreement, concurrent with the execution of the Purchase Agreement, we issued to 74,458 shares of our common stock to Aspire for no consideration.

Grant Award

In November 2012, we were awarded a grant of approximately \$1.9 million from the UK Government's Biomedical Catalyst to complete an Investigational New Drug ( *IND* ) directed preclinical development of CYC065, a novel orally available, second generation, CDK inhibitor.

Reverse Stock Split

On August 24, 2012, we effected a 1-for-7 reverse stock split of shares of common stock in order to increase the per share trading price of our shares of common stock to satisfy the \$1.00 minimum bid requirement for continued listing on the NASDAQ Global Market. We received notification from NASDAQ that as of September 11, 2012, we evidenced a closing bid of our common stock price in excess of the \$1.00 minimum requirement for at least 10 consecutive trading days. Accordingly, we have regained compliance with Listing Rule 5450(a)(1). All share and per share information presented gives effect to the reverse stock split, which occurred on August 24, 2012.

Termination and Settlement Agreement

On August 10, 2012, we entered into an agreement with Sinclair Pharmaceuticals Limited ( *Sinclair* ) to terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid. The agreement includes a minimum royalty arrangement based on future net revenues, under which Sinclair will pay us a minimum of approximately \$1.0 million in quarterly installments over the next three years ending on September 30, 2015. The operating results associated with the promotion and sale of Xclair®, Numoisyn® Liquid and Numoisyn® Lozenges are classified within income (loss) from discontinued operations, net of tax in the consolidated statements of operations for all periods presented, and the associated assets and liabilities are classified within current and long-term assets of discontinued operations and current liabilities of discontinued operations, as appropriate, in the consolidated balance sheets for all applicable periods presented.

Preferred Stock Dividend

On September 12, 2012, our Board of Directors decided not to declare a quarterly cash dividend on our 6% Convertible Exchangeable Preferred Stock ( Preferred Stock ) with respect to the third quarter of 2012 that would have otherwise been payable on November 1, 2012.

Table of Contents

**Results of Operations**

*Nine Months Ended September 30, 2011 and 2012*

**Results of Continuing Operations**

*Revenues*

The following table summarizes the components of our revenues for the nine months ended September 30, 2011 and 2012:

	2011	Nine months ended September 30, 2012 (\$000s)	Difference	Difference %
Grant revenue		64	64	
Total revenue		64	64	

We recognized approximately \$64,000 in grant revenue for the nine months ended September 30, 2012 in connection with an award from the European Union to study ovarian cancer therapies. We had no grant revenue for the nine months ended September 30, 2011.

We may also recognize, from time to time, revenue from collaboration and research and development and from grant awards. We had no collaboration and research and development revenue or grant revenue for each of the nine months periods ended September 30, 2011 and 2012.

*The future*

We expect to recognize approximately \$0.1 million in grant revenue over the next twelve to eighteen from the European and approximately \$1.9 million in grant revenue over the next two years from the UK Government's Biomedical Catalyst.

***Research and development expenses***

We expense all research and development expenses 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 expenditure for the nine months ended September 30, 2011 and 2012:

	2011	Nine months ended September 30,		Difference
		2012	Difference	
		(\$000s)		%
Sapacitabine	6,579	4,488	(2,091)	(32)
Other research and development costs	426	108	(318)	(75)
Total research and development expenses	7,005	4,596	(2,409)	(34)

Total research and development expenses represented 58% and 44% of our operating expenses for the nine months ended September 30, 2011 and 2012, respectively.

Research and development expenditures decreased by \$2.4 million to \$4.6 million for the nine month period ended September 30, 2012 from \$7.0 million for the nine month period ended September 30, 2011. The decrease was primarily due to \$1.6 million of contractual expenses recognized during the nine months ended September 30, 2011, resulting from an achievement of a milestone triggered by the opening of enrollment in the lead-in portion our SEAMLESS trial, pursuant to the Daiichi-Sankyo license under which we license certain patent rights for sapacitabine, a \$0.4 million decrease in outsourced research costs as a result of an out of period reversal of accrued pre-clinical costs, a \$0.4 million decrease in sapacitabine clinical supply costs, a \$0.1 million decrease in stock compensation charges, and a \$0.2 million decrease in employment costs and partially offset by a \$0.4 million increase in clinical trial costs.

Table of Contents*The future*

We expect to continue to concentrate our resources on the development of sapacitabine. We anticipate that overall research and development expenditures, excluding contractual milestone payments, for the year ended December 31, 2012 to be similar compared to the year ended December 31, 2011, as we continue enrollment on the randomized portion of the SEAMLESS pivotal Phase 3 trial.

**General and administrative expenses**

General and administrative expenses include costs for sales and marketing and administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the general and administrative expenses for the nine months ended September 30, 2011 and 2012:

	2011	Nine months ended September 30, 2012 (\$000s)	Difference	Difference %
Total general and administrative expenses	5,136	5,917	781	15%

Total general and administration expenses represented 42% and 56% of our operating expenses for the nine months ended September 30, 2011 and 2012, respectively.

Our general and administrative expenditure increased by approximately \$0.8 million to \$5.9 million for the nine months ended September 30, 2012, from \$5.1 million for the nine months ended September 30, 2011. The increase in expenses was primarily attributable to a net increase in professional and consultancy costs of \$1.1 million and offset by a decrease in stock compensation costs of \$0.3 million.

*The future*

We expect general and administrative expenditures for the year ended December 31, 2012 to be higher than our expenditures for the year ended December 31, 2011 as a result of an expected increase in professional and consultancy costs.

**Other income (expense)**

The following table summarizes other income (expense) for the nine months ended September 30, 2011 and 2012:

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

	2011	Nine months ended September 30, 2012 (\$000s)	Difference	Difference %
Change in valuation of Economic Rights		27	27	
Change in valuation of other liabilities measured at fair value	643	51	(592)	(92)
Foreign exchange gains (losses)	(59)	237	296	502
Interest income	33	17	(16)	(48)
Other income		77	77	
Total other income (expense)	617	409	(208)	(34)

Total other income and expense, net, decreased by approximately \$0.2 million, from income of approximately \$0.6 million for the nine months ended September 30, 2011, to income of \$0.4 million for the nine months ended September 30, 2012. The increase was primarily because of the \$0.6 million decrease in change in valuation of other liabilities measured at fair value, partially offset by a \$0.3 million increase in foreign exchange gains (losses), mostly due to the increase in exchange rate of the British Pound Sterling relative to the U.S. Dollar., and an approximately \$62,000 gain on sale of equipment.



Table of Contents

The change in valuation of Economic Rights related to the sale of Economic Rights in connection with the purchase agreement completed in March 2012. These collective rights are classified as liabilities and are marked to market each reporting period. For the nine months ended September 30, 2012, we recognized a gain of approximately \$27,000 due to the change in the value of Economic Rights from the transaction date of March 22, 2012 to September 30, 2012.

The change in valuation of other liabilities measured at fair value relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007 and our liability under an agreement with the Scottish Enterprise, or SE, that would potentially require us to make a payment to SE should staffing levels in Scotland fall below prescribed minimum levels. The warrants and agreement are classified as liabilities. The value of the warrants is being marked to market each reporting period as a gain or loss. Such gains or losses will continue to be reported for the warrants until they are exercised or expired. Gains or losses on the SE Agreement will be reported until the agreement expires in July 2014. For the nine months ended September 30, 2011 and 2012, the change in the valuation of other liabilities measured at fair value was a gain of \$0.6 million and a gain of approximately \$51,000, respectively.

Foreign exchange gains (losses) increased by \$0.3 million to a gain of \$0.2 million for the nine months ended September 30, 2012 compared to a loss of approximately \$0.1 million for the nine months ended September 30, 2011. Foreign exchange gains (losses) are reported in the consolidated statement of operations as a separate line item within other income (expense).

We recognized \$62,000 in other income from the sale of laboratory equipment during the nine months ended September 30, 2012. We did not recognize any such income during the nine months ended September 30, 2011.

*The future*

The valuation of the Economic Rights, warrants liability, and SE Agreement will continue to be re-measured at the end of each reporting period. The change in valuation of the Economic Rights is dependent on a number of factors, including our stock price, and other management assumptions, including, the probability of success of the underlying litigation, amount of award or settlement, discount rate, royalty rate, and timing of cash flows, and may fluctuate significantly, which may have a significant impact on our statement of operations. The valuation of the warrant is dependent upon many factors, including our stock price, interest, and remaining term of the instrument and may fluctuate significantly, which may have a significant impact on our statement of operations. The valuation of the SE Agreement is dependent on a number of factors, including our stock price and the probability of the occurrence of certain events that would give rise to a payment. We do not expect the valuation of fair value of the SE Agreement 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.

*Income tax benefit*

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Credit is taken for research and development tax credits, which are claimed from the United Kingdom's revenue and customs authority, or HMRC, in respect of qualifying research and development costs incurred.

The following table summarizes research and development tax credits for the nine months ended September 30, 2011 and 2012:

	2011	Nine months ended September 30, 2012 (\$000s)	Difference	Difference %
Total income tax benefit	443	714	271	61

Table of Contents

Research and development tax credits recoverable increased by approximately \$0.3 million to \$0.7 million for the nine months ended September 30, 2012 relative to the nine-month period ended September 30, 2011. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year. In 2011 it was also restricted to the payroll taxes paid by us to HMRC in that year. However, in July 2012, legislation was passed to eliminate this restriction for the year ended December 31, 2012. As a result, an adjustment of approximately \$0.3 million was recorded for the nine months ended September 30, 2012.

*The future*

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so. In July 2012, legislation was passed, effective for the year ended December 31, 2012, that eliminates the restriction of the amount recoverable to the payroll taxes paid in a period. Historically, our qualifying research and development expenditure has exceeded payroll taxes and, as we expect this to continue, the amount of tax credits we will be able to recover will increase for the year ended December 31, 2012.

Results of Discontinued Operations*Income (loss) from discontinued operations, net of tax*

	2011	Nine months ended September 30, 2012 (\$000s)	Difference	Difference %
Discontinued operations	(504)	(288)	216	43
Gain on termination of distribution agreement		1,192	1,192	
Income (loss) from discontinued operations, net of tax of \$0 for all periods presented	(504)	904	1,408	279

We entered into a termination and settlement agreement to terminate, effective September 30, 2012, our license to distribute the ALIGN products, after which we will no longer generate product revenue. Income (loss) from discontinued operations increased \$1.4 million from a loss of \$0.5 million for the nine months ended September 30, 2011, to income of \$0.9 million for the nine months ended September 30, 2012. The increase is the result of a \$1.2 million gain on termination of the distribution agreements, which represents the \$0.9 million present value of the \$1.0 million we will receive over the next three years as part of a minimum royalty arrangement included in our termination agreement with Sinclair and the recognition of \$0.3 million associated with a \$0.3 million product returns provision liability for which an offsetting asset has been recorded based on our rights under the termination and settlement agreement.

*The future*

We have ceased operations associated with the ALIGN products effective September 30, 2012 and do not expect significant activity beyond the year ended December 31, 2012. We may earn additional income from discontinued operations over the next three years if certain sales targets are met by a successor distributor according to the termination agreement with Sinclair.



Table of Contents

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

**Results of Continuing Operations**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)%
Grant revenue	1	12		11	(12)	1,100%	(100)%
Total revenue	\$ 1	\$ 112	\$	\$ 111	\$ (112)	11,100%	(100)%

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.

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.

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;

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

- 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%
Selaciclib	(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%

Table of Contents

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.

General and administrative expenses

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 (in thousands)	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
General and administrative expenses	\$ 6,631	\$ 8,833	\$ 6,542	\$ 2,202	\$ (2,291)	33%	(26)%





Table of Contents

Total selling, general and administrative expenses represented 40%, 58% and 42% of our operating expenses for the years ended December 31, 2009, 2010 and 2011, respectively.

*Fiscal 2011 as compared to fiscal 2010*

General and administrative expenses decreased by 26%, or \$2.3 million, to \$6.5 million for the year ended December 31, 2011, from \$8.8 million for the year ended December 31, 2010. The decrease of \$2.3 million in expenses was primarily attributable to a decrease in professional and consultancy costs of \$1.4 million, a decrease in stock based compensation of \$0.7 million, a decrease in salaries of \$0.1 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 \$0.2 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*

General and administrative expenses increased by 33%, or \$2.2 million, to \$8.8 million for the year ended December 31, 2010, from \$6.6 million for the year ended December 31, 2009. This was primarily due to increased consultancy and professional costs of \$1.5 million, and an increase in stock-based compensation costs of \$0.9 million. This was partially offset by reductions in intellectual property costs of \$0.2 million.

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.

Table of ContentsOther 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 (in thousands)	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
Payment under guarantee	\$ (1,652)	\$	\$	\$ 1,652	\$	100%	%
Change in valuation of liabilities measured at fair value	(343)	(338)	629	5	967	1%	286%
Foreign Exchange gain/(loss)	(144)	(68)	(74)	76	(6)	53%	(9)%
Interest income	102	37	45	(65)	8	(64)%	22%
Interest expense	(170)	(43)		127	43	75%	100%
Total other income (expense), net	\$ (2,207)	\$ (412)	\$ 600	\$ 1,795	\$ 1,012	81%	246%

*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 \$10.29 at December 31, 2010 to \$4.13 at December 31, 2011.

*Change in valuation of liabilities measured at fair value*

The change in valuation of other liabilities measured at fair value relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007 and our liability under an agreement with the Scottish Enterprise, or SE, that would potentially require us to make a payment to SE should staffing levels in Scotland fall below prescribed minimum levels. The warrants and agreement are classified as liabilities. The value of the warrants is being marked to market each reporting period as a gain or loss. Such gains or losses will continue to be reported for the warrants until they are exercised or expired. Gains or losses on the SE Agreement will be reported until the agreement expires in July 2014. For the year ended December 31, 2011, we recognized income from the change in the valuation of liabilities measured at fair value 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.

Table of Contents

*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 an expense 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 liabilities measured at fair value*

The change in valuation of liabilities measured at fair value 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.

Table of Contents*Interest Expense*

Interest expense decreased by \$127,000, from \$170,000 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.

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.

**Results of Discontinued Operations**

*Loss from discontinued operations, net of tax*

	Years ended			\$ Differences		% Differences	
	2009	2010	2011	2009 to 2010	2010 to 2011	2009 to 2010	2010 to 2011
Loss from discontinued operations, net of tax	\$ (1,549)	\$ (1,131)	\$ (640)	\$ 418	\$ 491	27%	43%



Table of Contents

We entered into a termination and settlement agreement to terminate, effective September 30, 2012, our license to distribute the ALIGN products, after which we will no longer generate product revenue. Therefore, the operating results associated with the ALIGN products are classified within loss from discontinued operations, net of tax in the consolidated statements of operations for the years ended December 31, 2009, 2010 and 2011.

*Fiscal 2011 as compared to fiscal 2010*

Loss from discontinued operations, net of tax decreased \$0.5 million from a loss of \$1.1 million for the year ended December 31, 2010, to a loss of \$0.6 million for the year ended December 31, 2011. The decrease was primarily due to a \$0.3 million decrease in selling, general and administrative expenses, a \$0.1 million increase in product revenues and a \$0.1 million decrease in cost of sales.

*Fiscal 2010 as compared to fiscal 2009*

Loss from discontinued operations, net of tax decreased \$0.4 million from a loss of \$1.5 million for the year ended December 31, 2009, to a loss of \$1.1 million for the year ended December 31, 2010. The decrease was primarily due to a \$0.6 million decrease in general and administrative expenses, a \$0.3 million decrease in product revenues and a \$0.1 million decrease in cost of sales.

**Liquidity and Capital Resources**

The following is a summary of our key liquidity measures as of December 31, 2010, December 31, 2011 and September 30, 2011:

	December 31, 2010		December 31, 2011		September 30, 2012		% Difference
			(in thousands)				
Cash and cash equivalents	\$ 29,495	\$	24,449	\$	17,837		(17)%
<b>Working capital:</b>							
Current assets	\$ 31,051	\$	25,831	\$	19,953		(17)%
Current liabilities	(6,535)	(6,498)	(7,297)				(1)%
Total working capital	\$ 24,516	\$	19,333	\$	12,656		(21)%

At September 30, 2012, we had cash and cash equivalents of \$17.8 million compared to \$24.4 million at December 31, 2011. The decrease in balance was primarily due to normal cash outflows required to operate our business, offset by \$2.9 million in proceeds, net of certain expenses, received from a sale of common stock and Economic Rights completed in March 2012. 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.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Current liabilities were \$7.3 million at September 30, 2012 and \$6.5 million at both December 31, 2010 and 2011. The \$0.8 million increase from December 30, 2011 to September 30, 2012 was primarily due to the \$1.1 million economic rights liability recorded as the result of a financing agreement entered into in March 2012. Between December 31, 2010 and 2011, accounts payable, accrued and other current liabilities increased \$0.5 million, offset by a \$0.6 million decrease in warrants and other derivatives.

Table of Contents

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 September 30, 2011, we had a deficit accumulated during the development stage of \$265.5 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.

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

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2011 and 2012, is summarized as follows:

	2011	Nine months ended September 30, (\$000s)	2012
Net cash used in operating activities	(10,718)		(9,584)
Net cash (used in) provided by investing activities	(6)		50
Net cash provided by financing activities	8,897		2,934

Cash flows generated from discontinued operations have been combined with the cash flows from continuing operations within each of the Operating, Investing and Financing activities sections.

*Operating activities*

Net cash used in operating activities decreased slightly from \$10.7 million for the nine months ended September 30, 2011 to \$9.6 million for the nine months ended September 30, 2012. The \$1.1 million decrease is primarily due to the \$1.6 million of contractual expenses paid during the nine months ended September 30, 2011, resulting from an achievement of a milestone triggered by the opening of enrollment in the lead-in portion our SEAMLESS trial, pursuant to the Daiichi-Sankyo license under which we license certain patent rights for sapacitabine, a \$0.7 million increase in payments for professional fees and a \$0.2 million decrease in employment costs. Net cash used in operating activities from discontinued operations was \$0.6 million and \$0.2 million for the nine months ended September 30, 2011 and 2012, respectively.

*Investing activities*

Net cash (used in) provided by investing activities increased from approximately \$6,000 used in investing activities for the nine months ended September 30, 2011 to approximately \$50,000 provided by investing activities for the nine months ended September 30, 2012, primarily as a result of the sale of laboratory equipment.

Table of Contents*Financing activities*

Net cash provided by financing activities for the nine months ended September 30, 2011 was \$8.9 million, mostly from \$9.3 million in financing proceeds, net of certain expenses, and offset by the payment of a \$0.4 million dividend to the holders of our Preferred Stock. Net cash provided by financing activities was \$2.9 million for the nine months ended September 30, 2012 as a result of approximately \$2.9 million proceeds, net of certain expenses, from the sale of stock and Economic Rights.

*Annual Cash Flows*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:

	2009	Year ended December 31, 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

Cash flows generated from discontinued operations have been combined with the cash flows from continuing operations within each of the Operating, Investing and Financing activities sections.

*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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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. Net cash used in operating activities from discontinued operations was \$1.6 million and \$0.6 million for the years ended December 31, 2010 and 2011, respectively.

### *Investing activities*

Net cash provided by (used in) investing activities decreased \$34,000, from an inflow of \$33,000 for 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.

Table of Contents

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 0.4 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 0.4 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 179,289 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, and 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 have generated a limited amount of product revenues from ALIGN product sales but these product revenues ceased on September 30, 2012. However, we will receive \$1.0 million in quarterly installments over the next three years as part of a minimum royalty arrangement included in our termination agreement with Sinclair and cash flows provided by (used in) investing activities in our condensed consolidated statements of cash flows.

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;



Table of Contents

- 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 and September 30, 2012, 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. 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 factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. We believe the judgments and estimates required by the following accounting policies to be critical in the preparation of our consolidated financial statements.

***Stock-based Compensation***

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

Table of Contents

***Economic Rights***

The Economic Rights are accounted for as a derivative financial instrument and measured at fair value. Changes in fair value are recognized in earnings. The fair value of the Economic Rights has been estimated using a decision-tree analysis method. This is an income-based method that incorporates the expected benefits, costs and probabilities of contingent outcomes under varying scenarios. Each scenario within the decision-tree is discounted to the present value using the company's credit adjusted risk-free rate and ascribed a weighted probability to determine the fair value. Changes in any of these assumptions could result in material adjustments to the expense recognized for changes in the valuation of the Economic Rights.

The Company has concluded the fair value of this liability was approximately \$1.1 million as of September 30, 2012. We recognized gain of approximately \$27,000 on our consolidated statement of operations for the nine month periods ended September 30, 2012, respectively, as a result of changes in value of the Economic Rights during those periods.

***Other Liabilities Measured at Fair Value***

***Warrants Liability***

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 income of approximately \$0.6 million and \$51,000 for the nine months ended September 30, 2011 and 2012, respectively. 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. The fair value of the warrants liability as of September 30, 2012 is nil due to the high exercise price of the warrants relative to the Company's stock price at September 30, 2012 and the expected term of 1.38 years.

***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 SE in 2009 that would require us to pay SE £4 million (approximately \$6.5 million and \$6.2 million at September 30, 2012 and December 31, 2011, respectively) 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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

fair value of this liability was approximately \$20,000 at September 30, 2012 and December 31, 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 September 30, 2012 and December 31, 2011, we concluded the probability of the combination of these events occurring is minimal. We record changes in fair value in the consolidated statement of operations. There were no changes to the fair value for the nine month periods ended September 30, 2012 and 2011. We recorded an expense of \$20,000 in the consolidated statement of operations for the year ended December 31, 2011.

Table of Contents

**BUSINESS/**

**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.

**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, replicates 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.

Table of Contents

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.





Table of Contents***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.

<b>Program</b>	<b>Indication</b>	<b>Development Status</b>	<b>Target</b>	<b>Cell Cycle Mechanism</b>
<i>Oncology</i>				
Sapacitabine, CYC682	Elderly AML	Phase 3 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

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Plk1 Inhibitors	Cancer	Preclinical	Plk	G2/M checkpoint
<i>Other therapeutic areas</i>				
Cell Cycle Inhibitors	Autoimmune & Inflammatory Diseases	Phase 1 trial completed On hold. Not a company priority	CDK	G1/S checkpoint and others

Table of Contents

***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 States. 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. Over 500 patients have received sapacitabine in Phase 2 studies in AML, MDS, CTCL and NSCLC and Phase 1 studies in hematological malignancies and solid tumors. Sapacitabine, an orally-available nucleoside analogue, is currently being studied in SEAMLESS, an ongoing, Phase 3, registration-directed trial in elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for or have refused induction chemotherapy. SEAMLESS will be conducted under a SPA.

Table of Contents

*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.

In December 2012, at the 54th Annual Meeting of ASH, the Company announced updated survival data from the pilot study and lead-in phase of SEAMLESS. Forty-six patients were treated with alternating cycles of sapacitabine and decitabine, which is the treatment regimen in the experimental arm of SEAMLESS. Median age is 77 years (range 70-90). Thirty-three patients (72%) are 75 years or older. Median overall survival is 238 days, or approximately 8 months. The number of patients still alive at 3 months was 38 (83%), at 6 months 30 (65%), at 12 months 16 (35%) and at 18 months 12 (26%). Sixteen patients (35%) survived 1 year or longer. Among 33 patients who are 75 years or older, median overall survival is 263 days, or approximately 9 months, and 1-year survival is 36%. Nineteen patients (41%) responded with 10 complete responses (CRs), 4 partial responses (PRs) and 5 major hematological improvements (HIs). Median time to response is 2 cycles, i.e., one cycle of decitabine and one cycle of sapacitabine (range 1-10). Twenty-seven patients (59%) received 5 or more cycles of treatment. Two dose-limiting toxicities (DLT) were observed (lung infection/sepsis, typhlitis). Thirty-day mortality from all causes was 4%. Sixty-day mortality from all causes was 13% with one death from typhlitis considered to be possibly related to decitabine by investigator assessment. The sequential combination of decitabine and sapacitabine is safe and active.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

### *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.

Table of Contents

In December 2009, at the 51st Annual Meeting of ASH we reported 1-year survival data. The primary endpoint of 1-year survival was 35% on Arm A, 30% on Arm C and 10% on Arm B. The median overall survival was 212 days on Arm C (range of 13 to over 654 days), 197 days on Arm A (range of 26 to over 610 days) and 100 days on Arm B (range of 6 to over 646 days). Overall response rate, or ORR, a secondary endpoint, was 45% on Arm A, 35% on Arm C and 25% on Arm B with CR rate of 25% on Arm C and 10% on Arms A and B. Thirty-day mortality was 10% on Arm C and Arm A and 20% on Arm B. Approximately 30% of all patients received sapacitabine for at least 6 cycles. Fifteen patients who survived one year or more received an average of 12 treatment cycles. Exploratory subgroup analysis suggests that (i) Arm C may be more effective for de novo AML and (ii) Arm A may be more effective for AML preceded by AHD, such as MDS. The 3-day dosing schedule in Arm C was selected for further clinical development in elderly patients with de novo AML based on a 1-year survival rate of 30%, ORR of 35% with durable CRs. The 7-day dosing schedule in Arm A was selected for further clinical development in elderly patients with AML preceded by AHD based on a 1-year survival rate of 35%, ORR of 45% with durable hematological improvement.

In November 2012, the results from the Phase 2 study were published in The Lancet Oncology, demonstrating the safety and efficacy of sapacitabine in this patient population. The Phase 2 study enrolled and treated between December 27, 2007 and April 21, 2009, a total of 105 patients aged 70 years or above with untreated or first relapse AML. The median age of patients was 77 years (range 70-91). The group was comprised of a randomized cohort of 60 patients and an expanded, non-randomly assigned cohort enrolling a further 45 patients. Of the 105 patients, 86 were previously untreated and 19 in first relapse. Approximately 50% of patients had AML de novo and 50% had AML preceded by antecedent hematological disorder (AHD), such as MDS or myeloproliferative disease, or treatment-related AML. All but one enrolled patients had intermediate or unfavorable cytogenetics. The randomized cohort of patients were randomly assigned to one of three dosing schedules: 200 mg twice a day for 7 days (group A); 300 mg twice a day for 7 days (group B); and 400 mg twice a day for 3 days each week for 2 weeks (group C). All schedules were given in 28 day cycles. The 3-day dosing schedule in group C was selected for further clinical development in elderly patients with untreated AML. This decision was based on the schedule's overall efficacy profile, which included a 1-year survival rate of 30%, median overall survival of 213 days and durable complete remissions (CRs) in 25% of patients. The median overall survival of patients from all groups who achieved CR was 525 days (95% C.I. 192-798). The most common grade 3-4 adverse events regardless of causality were anemia, neutropenia, thrombocytopenia, febrile neutropenia and pneumonia. Seven deaths were thought to be probably or possibly related to sapacitabine treatment. Approximately 31% of all patients received sapacitabine for at least 4 cycles.

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

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

Table of Contents

In June 2010, at the American Society of Clinical Oncology, or ASCO, meeting we reported interim response data for the ongoing Phase 2 clinical trial of sapacitabine in older patients with MDS. The study has recently completed enrollment of 61 patients aged 60 or older with MDS who were previously treated with azacitidine or decitabine or both. In this three-arm study, Arms B & C enrolled 20 patients each while Arm A enrolled 21 patients across the same three randomized dosing schedules of sapacitabine tested in the AML stratum of the study. All patients have received at least one hypomethylating agent and 15 patients (25%) have received two hypomethylating agents, i.e., azacitidine and decitabine. Approximately 51% of the 61 patients had baseline bone marrow blast counts above 10%. Based on interim data, the overall response rate is 24% on Arm A, the 7-day low dose schedule, 35% on Arm B, the 7-day high dose schedule, and 10% on Arm C, the 3-day high dose schedule. Two patients achieved complete remission and both were treated on Arm A. Thirty-day mortality from all-causes is 4.8% on Arm A, 0% on Arm B and 15% on Arm C. Approximately 34% of the patients received 4 or more cycles of sapacitabine.

In October 2012, at the The Eighth Annual Hematologic Malignancies 2012 Conference, we reported updated data from an ongoing, multicenter, Phase 2 randomized trial of sapacitabine in older patients with intermediate-2 or high-risk MDS after treatment failure of front-line hypomethylating agents, such as azacitidine (Vidaza®) and/or decitabine (Dacogen®). Median overall survival to date for all 63 patients in the Phase 2 study is 252 days or approximately 8 months. Median overall survival for 41 out of 63 patients with 10% or more blasts in their bone marrow is 274 days or approximately 9 months. Updated median survival for all three arms is 252 days (approximately 8 months). The median survival for each arm is 291 days (approximately 10 months) for Arm G, 274 days (approximately 9 months) for Arm H, and 227 days (approximately 8 months) for Arm I. Twenty-seven percent of all patients received 6 or more cycles. Twenty-two percent of patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival of each arm.

Table of Contents

*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.



Table of Contents

*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***

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

Table of Contents

*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.

Table of Contents

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.

***CYC065***

CYC065 is a novel, orally available, cell cycle kinase inhibitor currently in IND-directed preclinical development. CYC065 targets similar CDK/cyclin complexes to those targeted by seliciclib, Cyclacel's first generation CDK inhibitor currently in Phase 2 studies. CYC065 retains the high CDK specificity of seliciclib, but with substantially higher anti-proliferative potency and improved pharmaceutical properties. CYC065 is a second generation aminopurine which selectively inhibits CDK2, CDK5 and CDK9. Strong preclinical anti-cancer efficacy data for CYC065 in multiple myeloma, chronic lymphocytic leukemia (CLL) and mixed lineage leukemia (MLL) have been presented at the 2010 Annual Meetings of the American Society of Hematology (ASH) 1 and the American Association of Cancer Research (AACR). 2 3 At the 2010 AACR CYC065 was also reported to be active in solid tumor models, including trastuzumab-resistant, cyclin E overexpressing breast cancer. These findings were subsequently published by Scaltriti, et al ( Cyclin E amplification/overexpression is a mechanism of trastuzumab resistance in HER2+ breast cancer patients , PNAS, 2011:108:3761-3766). In addition CYC065 was shown to have preclinical efficacy in proliferative kidney disease models (Cyclacel data on file). Cyclacel discovered CYC065 in collaboration with the Cancer Research UK Centre for Cancer Therapeutics at The Institute of Cancer Research.

***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.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

Table of Contents

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.

**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:

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

- 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.

Table of Contents

*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.

Table of Contents

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.

Table of Contents

**Licenses**

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

***Sapacitabine***

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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

diseases, dermatological diseases, infectious diseases, inflammatory diseases, and proliferative diseases, including cancer. Non-acute chronic diseases of the central nervous system, neurological diseases and diseases of the peripheral nervous system are specifically excluded. The license runs for the term of the patents in each country, or for ten years from the first commercial sale in each country, whichever is later. We paid an up-front fee and yearly payments and milestone payments until the patents covering the seliciclib compound, particular uses of the compound, and particular uses and derivatives of the compound were published as granted in either the United States or by EPO which occurred in 2001 and 2003, respectively. Milestones are also payable on the first commercialization of a product that consists of a new chemical entity that is covered by one of the licensed patents.

Table of Contents

We will be obligated to pay royalties based on our net sales of products covered by the patents. Royalties are payable on a country-by-country basis for the term of patent protection in each country or ten years from the first commercial sale of royalty-bearing products in that country, whichever is later. Royalties are payable on net sales. Net sales are defined as the gross amount invoiced by us or by our affiliates for the products, less normal trade discounts, credits for returned products, taxes and shipping charges. There is one royalty rate for products that are covered by valid licensed patent claims and a second, lower royalty rate for all other products that require a license under the licensed patents. 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.

**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.

Table of Contents

**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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

Table of Contents

*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.





Table of Contents

*Fast Track Designation*

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

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

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

- *Priority Review.* Under FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. We cannot suggest or in any way guarantee that any of our drug candidates will receive a priority review designation, or if a priority designation is received, that review or approval will be faster than conventional FDA procedures, or that the FDA will ultimately grant drug approval.
- *Accelerated Approval.* Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses, and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. In rare instances the FDA may grant accelerated approval of an NDA based on Phase 2 data and require confirmatory Phase 3 studies to be conducted after approval and/or as a condition of maintaining approval. We can give no assurance that any of our drugs will be reviewed under such procedures.

Table of Contents

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

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

*Other regulatory requirements*

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

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

Table of Contents

**Competition**

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

A large number of drug candidates are in development for the treatment of leukemia, lung cancer, lymphomas and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs or other products on the market or in clinical trials which may be competitive to sapacitabine in both hematological and oncology indications. These include 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.

**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.

Table of Contents

A scheduling Order was entered February 2, 2012, at which time the court set significant dates, the remaining of which are the following: 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.

**Employees**

As of September 30, 2012, we had 17 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.

Table of Contents**MANAGEMENT AND CORPORATE GOVERNANCE****The Board of Directors**

The following table sets forth certain information regarding our executive officers and directors as of December 31, 2011.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Spiro Rombotis	53	President and Chief Executive Officer; Class 2 Director
Paul McBarron	51	Executive Vice President Finance, Chief Financial Officer, Chief Operating Officer and Secretary; Class 3 Director
Dr. Nicholas Bacopoulos	63	Class 3 Director
Sir John Banham	71	Class 1 Director
Dr. Christopher Henney	70	Vice Chairman; Class 3 Director
Daniel K. Spiegelman(1)	53	Class 1 Director
Dr. David U Prichard	63	Chairman of the Board of Directors; Class 2 Director
Gregory T. Hradsky	51	Class 1 Director on behalf of our holders of Preferred Stock
Lloyd Sems	40	Class 2 Director on behalf of our holders of Preferred Stock

(1) Mr. Spiegelman resigned on June 6, 2012.

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

**Gregory T. Hradsky.** Mr. Hradsky has served as a director of the Company and on behalf of holders of the 6% Convertible Exchangeable Preferred Stock (the Preferred Stock) since May 2011. Mr. Hradsky has been an independent financial consultant since February 2006. He has served on the board of directors of Costar Technologies, Inc. since June 2008 where he is Chairman of the Audit Committee. Between May 2003 and February 2006, Mr. Hradsky was a Vice President of Avenue Capital Group, a global investment firm, where he managed a portfolio of distressed securities, post-reorganization equities and other investments. From 1999 until 2003, Mr. Hradsky was the founder and Managing Partner of Bellport Capital, an investment firm specializing in distressed securities. Prior to that, Mr. Hradsky was a Managing Director and Head of the Distressed Securities Group at UBS Securities LLC from 1993 until 1998. Mr. Hradsky joined UBS in 1991 as a research analyst focusing on distressed credits. Prior to UBS, Mr. Hradsky was a member of the Distressed Securities Group and the High Yield Research Department at the First Boston Corporation from 1988-1991. He began his career at T. Rowe Price Associates in 1983 and worked in the Fixed Income Department until 1986. Mr. Hradsky has a B.A. from Loyola College in Maryland and an M.B.A. from the Wharton School of the University of Pennsylvania.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

***Spiro Rombotis.*** Mr. Rombotis joined Cyclacel in August 1997 and has over 29 years of experience with pharmaceutical and biotechnology companies. He was previously Vice President of International Operations and Business Development; Managing Director, Europe; and Director, Japanese joint venture, at The Liposome Company, Inc. He also served as Vice President of Pharmaceuticals for Central and Eastern Europe and as Director of International Marketing at Bristol-Myers Squibb Company. He was Head of European Marketing and Sales, Head of Corporate Development and one of the first employees of Centocor, Inc. and worked in Business Development at Novartis AG. He holds a B.A. from Williams College and an M.B.A. and Master's degree in Hospital Management with honors, from the Kellogg Graduate School of Management, where he serves on the Kellogg Biotech Advisory Board. He also serves on the Board of Trustees of BioNJ, the biotechnology industry trade group in New Jersey.

Table of Contents

**Lloyd Sems.** Mr. Sems currently serves as President of Sems Capital, LLC and Capital Edge, LLC, both of which he founded in October 2003. He currently serves as a director of Selectica, Inc. (SLTC) since June 2, 2008 and also serves on the Board of Directors of Sport-Haley, Inc. (OTC Pink Sheets: SPOR), which he joined in April 2009. Previously, Mr. Sems served as Director of Research and Portfolio Manager for Watchpoint Asset Management. Mr. Sems holds a Bachelor of Science degree in Business Administration and Finance from Albright College. Mr. Sems also served on the Board of Directors of EMAK Worldwide, Inc. from February 2010 to April 2010.

**David U Prichard, Ph.D.** Dr. U Prichard joined the Board of Directors of Cyclacel in May 2004. He is currently President of Druid Consulting LLC, a pharmaceutical and biotechnology-consulting firm, providing customized services to life sciences clients in the United States and Europe, and a founding partner of Druid BioVentures LLP. Dr. U Prichard is also part-time Chief Scientific Officer of the operating company arm of The Harrington Discovery and Development Project (Cleveland, OH), a national initiative to accelerate new drug development inspired by physician-scientists. Previously, he was Chief Executive Officer of 3-Dimensional Pharmaceuticals, Inc. from 1999 to 2003. In addition, he held a variety of positions within the pharmaceutical and biotechnology industries, including, President and Chairman of Research and Development for SmithKline Beecham Pharmaceuticals; Executive Vice President and International Research Director, and a Member of the Board of Management of Zeneca Pharmaceuticals; General Manager, Research Department, ICI Pharmaceuticals, and Vice President Biomedical Research, ICI Pharmaceuticals; and Senior Vice President and Scientific Director for Nova Pharmaceutical Corporation. He is a director of Life Technologies, Inc., Iroko Pharmaceuticals, and Naurex Inc., and he served as a director of Alpharma, Inc., Guilford Pharmaceuticals Inc., Silence Therapeutics plc, Lynx Therapeutics, Inc. and non-executive Chairman of Oxagen Ltd. He was a Venture Partner with Red Abbey Venture Partners, private equity providers, from 2005-2010 Dr. U Prichard was Chairman of the Pennsylvania Biotechnology Association in 2004-2005, and from 1992 to 1997, he was a member of the board of directors of the Biotechnology Industry Organization (BIO). He received a B.Sc. in Pharmacology from University of Glasgow in 1970 and a Ph.D. in Pharmacology from University of Kansas in 1975.

**Paul McBarron.** Mr. McBarron joined Cyclacel in January 2002 and has over 24 years of experience with pharmaceutical and biotechnology companies. He has served as a financial executive at Sterling Drug, Sanofi-Winthrop and SmithKline Beecham and, from 1996 to 2001, as a senior member of the finance team at Shire Pharmaceuticals plc, where he held the positions of Director of Corporate Finance and Group Financial Controller. He joined Shire when it was an emerging public company. He qualified as a chartered accountant with Ernst & Young and serves on the Life Sciences Industry Advisory Board for the Scottish Government.

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



Table of Contents

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

**Daniel K. Spiegelman, M.B.A.** Mr. Spiegelman had served as one of Xcyte's directors since September 2004, and continued as a director of the Company until his resignation on June 6, 2012. Mr. Spiegelman had served as the Senior Vice President and Chief Financial Officer of CV Therapeutics, Inc. since September 1999. From January 1998 to September 1999, Mr. Spiegelman served as the Vice President and Chief Financial Officer of CV Therapeutics, Inc. From 1991 until 1998, Mr. Spiegelman was employed by Genentech, Inc., a biotechnology company, holding various positions in the Treasury department, including the position of Treasurer from 1996 to 1998. Mr. Spiegelman also serves as a member of the board of directors of Affymax, Inc., Omeros Inc, Oncothyreon, Inc. and Anthera Pharmaceuticals Inc, publicly-traded biopharmaceuticals companies, as well as some private biotech companies. Mr. Spiegelman holds a B.A. in Economics from Stanford University and an M.B.A. from Stanford Graduate School of Business

**Director Independence**

Our Board of Directors has reviewed the materiality of any relationship that each of our directors has with the Company, either directly or indirectly. Based upon this review, our Board of Directors has determined that each of the following directors is an independent director as such term is defined by rules of The NASDAQ Stock Market, Inc., or NASDAQ:

- Nicholas Bacopoulos, Ph.D.
  
- Sir John Banham
  
- Christopher Henney, Ph.D., D.Sc.
  
- David U Prichard, Ph.D.
  
- Gregory T. Hradsky, M.B.A.
  
- Lloyd Sems

The Board of Directors has established three standing committees, (1) the Compensation and Organization Development Committee, (2) the Audit Committee, and (3) the Nominating and Corporate Governance Committee. The Board of Directors has also determined that each member of these committees meets the independence requirements applicable to each such committee as prescribed by NASDAQ and the SEC.

Table of Contents

**Committees of the Board of Directors**

*Audit Committee.* Our Audit Committee met four times during fiscal 2011. The Audit Committee during such period had four members, Daniel K. Spiegelman (Chairman), Sir John Banham, Dr. Christopher Henney and Gregory T. Hradsky; upon Mr. Spiegelman's resignation, Sir John Banham became Chairman of the Audit Committee. All members of the Audit Committee satisfy the current independence standards promulgated by the NASDAQ and SEC, as such standards apply specifically to members of audit committees. The Board of Directors has determined that Mr. Spiegelman is an audit committee financial expert, as the SEC has defined that term in Item 407 of Regulation S-K.

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

*Compensation and Organization Development Committee.* Our Compensation and Organization Development Committee met three times during fiscal 2011. The Compensation and Organization Development Committee is composed entirely of directors who are not our current or former employees, all of whom qualify as independent under the definition promulgated by the NASDAQ and SEC. The Compensation and Organization Development Committee currently has three members: Dr. Christopher Henney (Chairman), Dr. Nicholas Bacopoulos and Dr. David U. Prichard. Generally, our Compensation and Organization Development Committee reviews, approves and makes recommendations regarding our compensation policies, practices and procedures to ensure that legal and fiduciary responsibilities of the Board of Directors are carried out and that such policies, practices and procedures contribute to our success. The Compensation and Organization Development Committee also develops and implements policies, principles and procedures for the selection and performance review of the Company's executive officers (including our Chief Executive Officer), other officers, directors, employees, consultants, and advisors; interprets and administers our Amended and Restated 2006 Equity Incentive Plan.

*Nominating and Corporate Governance Committee.* Our Nominating and Corporate Governance Committee met three times during fiscal 2011. The Nominating and Corporate Governance Committee during such period had four members, Sir John Banham (Chairman), Lloyd Sems, Daniel K. Spiegelman (who resigned on June 6, 2012) and Dr. David U. Prichard, all of whom qualify as independent under the definition promulgated by the NASDAQ and SEC. The functions of the Nominating and Corporate Governance Committee include making recommendations to the full Board of Directors as to particular nominees for election or appointment to the Board of Directors; making recommendations to the full Board of Directors as to the membership, structure and operations of the committees of the Board of Directors; reviewing and assessing the adequacy of our corporate governance guidelines, principles and practices and recommending changes to the full Board of Directors for approval; monitoring compliance with our Corporate Code of Conduct and Ethics; and reviewing and maintaining oversight of matters relating to the independence, operation and effectiveness of the Board of Directors and committee members.

Table of Contents**Executive Officers**

The following table sets forth certain information regarding our executive officers during fiscal 2011 who are not also members of our Board of Directors. All such executive officers are or were at-will employees.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Dr. Judy Chiao	52	Vice President, Clinical Development and Regulatory Affairs
Robert Sosnowski(1)	53	Vice President, Sales & Marketing

(1) Mr. Sosnowski resigned on June 30, 2012.

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

**Robert Sosnowski.** Mr. Sosnowski joined Cyclacel in April 2008 and resigned on June 30, 2012. He has more than 29 years experience in sales and marketing roles at several pharmaceutical and major biotechnology companies. Prior to joining Cyclacel, Mr. Sosnowski was President, Chief Executive Officer and Co-Founder, Dexgen Pharmaceuticals, Inc., a specialty pharmaceutical company, and Vice President, Sales and Marketing, Algos Pharmaceutical Corporation. In addition, he has held senior sales and marketing roles with Genentech, Inc., Centocor, Inc., The Liposome Company, Inc., Amgen, Inc. and The Upjohn Company. Mr. Sosnowski earned his Bachelor of Science degree in 1980 from the University of Connecticut.

**Executive Compensation****Summary Compensation Table**

The following table shows the compensation paid or accrued during the last two fiscal years ended December 31, 2010 and 2011 to (1) our President and Chief Executive Officer, (2) our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, and (3)

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

our next most highly compensated executive officer, other than our President and Chief Executive Officer and our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, who earned more than \$100,000 during the year ended December 31, 2011.

Table of Contents

Name and Principal Position	Year	Salary (\$)	Bonus (\$)(1)	Stock Awards (\$)(2)	Option Awards (\$)(3)	All Other Compensation (\$)(4)	Total (\$)
Spiro Rombotis	2011	490,383	100,000	62,250		33,131	685,764
President and Chief Executive Officer	2010	476,100	59,500		92,250	32,506	660,356
Paul McBarron(5)	2011	298,175	38,633	62,250		16,209	415,267
Executive Vice President, Finance, Chief Operating Officer, Chief Financial Officer, and Secretary	2010	289,768	36,350		92,250	17,732	436,100
Judy Chiao, MD	2011	321,947	42,000	49,800		20,766	434,513
Vice President, Clinical Development and Regulatory Affairs	2010	312,570	75,000		76,875	19,624	484,069

(1) Bonuses earned in 2009 were paid during fiscal year 2010. Bonuses earned in 2010 were paid during fiscal year 2010 and were not accrued in the Company's Financial Statements. Bonuses earned in 2011 were paid in fiscal year 2012 and were accrued in the Company's Financial Statements.

(2) This column represents the dollar amount recognized for financial statement reporting purposes for the fair value of stock awards. The fair value, a non-cash expense, was estimated using the Black-Scholes option-pricing method in accordance with ASC Topic 718. See Note 11 to our Financial Statements reported in our Form 10-K for our fiscal year ended December 31, 2010 and Note 11 to our Financial Statements reported in our Form 10-K for our fiscal year ended December 31, 2011 for details as to the assumptions used to determine the fair value of the stock awards and stock options. See also our discussion of stock-based compensation under Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates.

(3) These amounts represent the aggregate grant date fair value for option awards for fiscal years 2010 and 2011, respectively, computed in accordance with FASB ASC Topic 718. The grant date fair value of performance awards is determined based on the probable outcome of such performance conditions as of the grant date. A discussion of the assumptions used in determining grant date fair value may be found in Note 11 to our Financial Statements, included in our Annual Report on Form 10-K for the year ended December 31, 2011.

(4) Consists of the following for all executive officers: Payments for private medical and health insurance, life insurance and permanent health insurance; matching contributions made under the Company's UK Group Personal Pension Plan and the U.S. 401(k) Plan.

(5) Mr. McBarron's compensation was translated from British pound sterling to the U.S. dollar using the exchange rate of \$1.54679 as of December 31, 2010 and \$1.5453 as of December 31, 2011.

**Narrative Disclosure to Summary Compensation Table**

The Compensation and Organization Development Committee of our Board of Directors makes decisions regarding the compensation of our President and Chief Executive Officer. The Compensation and Organization Development Committee is composed entirely of independent

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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

Table of Contents

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

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

The Compensation and Organization Development Committee is authorized to engage and retain independent third party compensation and legal advisors to obtain advice and assistance on all matters related to executive compensation and benefit plans, and the Committee does intend to engage periodically an external consultant to provide independent verification of market position and ensure the appropriateness of executive compensation. The last time that the Compensation and Organization Development Committee engaged an external consultant was in 2008, when a representative of Radford Surveys and Consulting, a business unit of AON, was selected and engaged to be the independent compensation consultant to the Committee to assess our 2007 and 2008 executive compensation program. Using this extensive analysis, the Compensation and Organization Development Committee acted on the recommendations made to determine executive compensation and implement our compensation program structures for subsequent years. Although no external compensation consultant was engaged during 2010 or 2011, the Compensation and Organization Development Committee did consult independent external compensation survey data as part of the decision making process relating to such periods.

On December 10, 2010, our Board of Directors, at the recommendation of the Compensation and Organization Development Committee, made stock option grants under our Amended and Restated 2006 Equity Incentive Plan, or the 2006 Plan, to our executive officers at an exercise price of \$11.13 per share, which options vest ratably on a monthly basis over 48 months and are exercisable until December 10, 2020. On December 6, 2011, our Board of Directors, at the recommendation of the Compensation and Organization Development Committee, granted restricted stock units under the 2006 Plan to our executive officers, which restricted stock units cliff-vest on December 6, 2014.

During 2010, the Company granted 86,757 stock options to employees and directors of the Company with a weighted value exercise price of \$2.74 per share. During 2011, the Company granted 28,500 stock options to employees and directors of the Company with a weighted value exercise price of \$10.64 per share, as well as 34,000 restricted stock units.

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





Table of Contents

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

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

**Outstanding Equity Awards at Fiscal Year-End**

The following table shows grants of stock options and grants of unvested stock or unvested stock units outstanding on the last day of the fiscal year ended December 31, 2011, including non-performance based awards, to each of the executive officers named in the Summary Compensation Table. The Company does not have any unearned equity incentive awards.

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested
Spiro Rombotis	13,976	0(2)	\$ 44.80	6/13/2016		
	22,857	0(3)	\$ 48.65	12/20/2016		
	28,571	0(4)	\$ 38.71	12/06/2017		
	2,680	8,034(5)	\$ 11.13	12/10/2020		
					1,632(6)	6,756
					10,714(7)	44,250
Paul McBarron	9,097	0(8)	\$ 44.80	6/13/2016		
	14,286	0(9)	\$ 48.65	12/20/2016		
	14,286	0(10)	\$ 38.71	12/06/2017		
	21,429	0(11)	\$ 3.08	11/18/2018		
	2,680	8,034(12)	\$ 11.13	12/10/2020		
					1,632(13)	6,756
					10,714(14)	44,250
Judy Chiao	6,995	0(15)	\$ 44.80	6/13/2016		
	11,429	0(16)	\$ 48.65	12/20/2016		
	142,87	0(17)	\$ 38.71	12/06/2017		
	10,714	0(18)	\$ 3.08	11/18/2018		
	2,232	6,696(19)	\$ 11.13	12/10/2020		

818(20)	3,378
8,571(21)	35,500

Table of Contents

---

(1) The market value of the shares is determined by multiplying the number of shares by \$4.13, the closing price of our common stock on the NASDAQ Global Market on December 31, 2011, the last day of our fiscal year.

(2) These options were granted on June 14, 2006, two-thirds (2/3) of which vested immediately, and the balance of which vested ratably on a monthly basis over the following 12 months.

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

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

(5) These options were granted on December 10, 2010, and vest over a four-year period, such options vesting ratably on a monthly basis over 48 months.

(6) These shares of common stock represent restricted stock and are subject to forfeiture; the restrictions shall lapse over a four-year period, as follows: the restrictions with respect to one-fourth (1/4) of the restricted stock granted shall lapse on November 18, 2009, the first anniversary of the grant date, and the restrictions with respect to the balance of the restricted stock granted shall lapse ratably on a monthly basis over the following 36 months.

(7) These shares of common stock represent restricted stock units, which were granted on December 6, 2011, and are subject to forfeiture; the restrictions will lapse on the third anniversary of the date of grant.

(8) These options were granted on June 13, 2006, two-thirds (2/3) of which vested immediately, and the balance of which vested ratably on a monthly basis over the following 12 months.

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

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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

Table of Contents

(11) These options were granted on November 18, 2008, and vest over a three-year period, with one-third (1/3) of the options granted vesting on November 18, 2009, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 24 months.

(12) These options were granted on December 10, 2010, and vest over a four-year period, such options vesting ratably on a monthly basis over 48 months.

(13) These shares of common stock represent restricted stock and are subject to forfeiture; the restrictions shall lapse over a four-year period, as follows: the restrictions with respect to one-fourth (1/4) of the restricted stock granted shall lapse on November 18, 2009, the first anniversary of the grant date, and the restrictions with respect to the balance of the restricted stock granted shall lapse ratably on a monthly basis over the following 36 months.

(14) These shares of common stock represent restricted stock units, which were granted on December 6, 2011, and are subject to forfeiture; the restrictions will lapse on the third anniversary of the date of grant.

(15) These options were granted on June 13, 2006, two-thirds (2/3) of which vested immediately, and the balance of which vested ratably on a monthly basis over the following 12 months.

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

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

(18) These options were granted on November 18, 2008, and vest over a three-year period, with one-third (1/3) of the options granted vesting on November 18, 2009, the first anniversary of the grant date, and the balance of the options granted vesting ratably on a monthly basis over the following 24 months.

(19) These options were granted on December 10, 2010, and vest over a four-year period, such options vesting ratably on a monthly basis over 48 months.

(20) The restricted stock units were granted on November 18, 2008, and vest over a four-year period, with one-fourth (1/4) of the restricted stock units granted vesting on November 18, 2009, the first anniversary of the grant date, and the balance of the restricted stock units granted vesting ratably on a monthly basis over the following 36 months.

(21) These shares of common stock represent restricted stock units, which were granted on December 6, 2011, and are subject to forfeiture; the restrictions will lapse on the third anniversary of the date of grant.

**Nonqualified Deferred Compensation**

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

Table of Contents

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

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

The following summarizes the potential payments to each named executive officer for which we have entered into such an agreement, assuming that one of the events identified below occurs. The discussion assumes that the event occurred on December 31, 2011, the last business day of our fiscal year, at which time the closing price of our common stock as listed on the NASDAQ Global Market was \$0.59 per share.

*Spiro Rombotis, President and Chief Executive Officer*

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

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

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

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





Table of Contents

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

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

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

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

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

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

In the event of a Change in Control (as defined below) of the Company, and Dr. Chiao's employment with the continuing or surviving company, or the Controlling Company, is terminated (including if Dr. Chiao voluntarily terminates her employment for Good Reason, as defined below) at any time within six months following the effective date of a Change in Control, unless such termination is For Cause, death, disability or Dr. Chiao voluntarily leaves without Good Reason (as each such term is defined below), Dr. Chiao will be entitled to receive the following benefits from the Controlling Company in lieu of any further salary and bonus payments to Dr. Chiao for certain periods subsequent to the date of termination in consideration for Dr. Chiao's execution and delivery of a general release in favor of the Controlling Company: (i) payment by the Controlling Company of a lump sum severance payment equal to Dr. Chiao's annual salary for a period of twelve months from the date of termination; (ii) payment by the Controlling Company of all unpaid, accrued vacation through the date of termination; (iii) all options to purchase shares of the Company's Common Stock held by Dr. Chiao shall be vested and exercisable for twelve months following the effective date of the Change in Control; and (iv) the Controlling Company shall arrange coverage for Dr. Chiao and her dependents, as the case may be, under medical care and life insurance benefit plans substantially similar to those which Dr. Chiao and her dependents were entitled immediately prior to the effective date of the Change in Control for a period of up to twelve months after the effective date of the Change in Control, subject to certain exceptions as set forth in more detail in the CIC Agreement.



Table of Contents

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

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

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

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

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

**Termination**

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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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

Table of Contents

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

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

*Change in Control*

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

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

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

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

For the purposes of the 2006 Plan, a participant's award will be considered assumed if, following the change in control, the assumed award confers, for each share of the Company's Common Stock subject to the award immediately prior to the change in control, the right to receive the consideration (whether stock, cash, or other securities or property) received in the change in control for each share of Common Stock held on the effective date of the transaction; provided, however, that if the consideration received in the change of control is not solely common stock of the successor corporation or its parent, the committee administering the plan may, with the consent of the successor corporation, provide for the consideration per share to be received upon the exercise of the award, to be solely common stock of the successor corporation or its parent equal in fair market value to the per share consideration received by holders of the Company's Common Stock in the change of control.

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

- a person, partnership, joint venture, corporation or other entity, or two or more of any of the foregoing acting as a group (or any person within the meaning of Sections 13(d)(3) and 14(d) of the Exchange Act), other than the Company, a Subsidiary, or an employee benefit plan (or related trust) of the Company or a Subsidiary, become(s) the beneficial owner (as defined in Rule 13d-3 under the Exchange Act) of 30% or more of the then-outstanding voting stock of the Company;

Table of Contents

- during any period of two consecutive years, individuals who at the beginning of such period constitute the Board of Directors (together with any new director whose election by the Board of Directors or whose nomination for election by the Company's stockholders, was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of such period or whose election or nomination for election was previously so approved) cease for any reason to constitute a majority of the directors then in office;
- all or substantially all of the business of the Company is disposed of pursuant to a merger, consolidation or other transaction in which the Company is not the surviving corporation or the Company combines with another Company and is the surviving corporation (unless the stockholders of the Company immediately following such merger, consolidation, combination, or other transaction beneficially own, directly or indirectly, more than 50% of the aggregate voting stock or other ownership interests of (x) the entity or entities, if any, that succeed to the business of the Company or (y) the combined company);
- the Company is a party to a merger, consolidation, sale of assets or other reorganization, or a proxy contest, as a consequence of which the Board of Directors in office immediately prior to such transaction or event constitutes less than a majority of the Board of Directors thereafter; or
- the stockholders of the Company approve a sale of all or substantially all of the assets of the Company or a liquidation or dissolution of the Company.

**Director Compensation(1)**

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2011 to each of our non-employee directors:

<b>Name</b>	<b>Fees Earned or Paid in Cash (\$)</b>	<b>Option Awards \$(1)</b>	<b>Total (\$)</b>
David U Prichard, Ph.D.	81,250	58,237(2)	139,487
Sir John Banham	42,500	29,119(3)	71,619
Nicholas Bacopoulos, Ph.D.	40,750	29,119(4)	69,869
Christopher S. Henney, Ph.D., D.Sc.	64,000	58,237(5)	122,237
Gregory T. Hradsky	27,074	0	27,075
Lloyd Sems	27,074	0	27,075
Daniel K. Spiegelman	52,750	40,766(6)	93,516

(1) These amounts represent the grant date fair value of stock awards granted to each director in 2011 computed in accordance with FASB ASC Topic 718. The grant date fair value of performance awards is determined based on the probable outcome of such performance conditions as of the grant date. A discussion of the assumptions used in determining grant date fair value may be found in Note 11 to our Financial Statements, included in our Annual Report on Form 10-K for the year ended 2011, as amended.





Table of Contents

- (2) Fair value of the options granted on May 24, 2011 was \$10.71 per share. 42,858 options remain outstanding as of December 31, 2011.
- (3) Fair value of the options granted on May 24, 2011 was \$10.71 per share. 21,427 options remain outstanding as of December 31, 2011.
- (4) Fair value of the options granted on May 24, 2011 was \$10.71 per share. 14,284 options remain outstanding as of December 31, 2011.
- (5) Fair value of the options granted on May 24, 2011 was \$10.71 per share. 45,858 options remain outstanding as of December 31, 2011.
- (6) Fair value of the options granted on May 24, 2011 was \$10.71 per share. 27,357 options remain outstanding as of December 31, 2011.

**Director Compensation Program**

Under the terms of our Director Compensation Program, the non-employee members of our Board of Directors are paid a fixed annual fee, payable on a quarterly basis, in arrears, on the first day of each quarter, as follows:

Chairman of the Board	\$	85,000
Vice Chairman of the Board	\$	65,000
Chairman - Audit Committee	\$	55,000
Other Non-Management Board Members	\$	45,000

In addition, the non-employee members of our Board of Directors are entitled to receive stock options on an annual basis on the date of the Company's annual meeting as follows:

Chairman and Vice Chairman	7,142
Chairman of the Audit Committee	5,000
Other Board Members	3,571

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

The non-employee directors are also reimbursed for customary business expenses in connection with attending Board of Directors and committee meetings.

### Equity Compensation Plan Information

The following table provides certain aggregate information with respect to all of our equity compensation plans in effect as of December 31, 2011:

Plan Category	(a) No. of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Total equity compensation plans approved by security holders (1)	540,338	\$ 24.64	156,
Equity compensation plans not approved by security holders			

Table of Contents

---

(1) Consists of our Amended and Restated 2006 Equity Incentive Plan, or the 2006 Plan. The 2006 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units and performance units. The number of shares available for issuance, as of December 18, 2012, under the 2006 Plan is 839,327.

Table of Contents

**CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS**

We give careful attention to related person transactions because they may present the potential for conflicts of interest. We refer to related person transactions as those transactions, arrangements, or relationships in which:

- we were, are or are to be a participant;
- the amount involved exceeds \$120,000; and
- any of our Directors, Director nominees, executive officers or greater-than five percent stockholders (or any of their immediate family members) had or will have a direct or indirect material interest.

To identify related person transactions in advance, we rely on information supplied by our executive officers, Directors and certain significant stockholders. We maintain a comprehensive written policy for the review, approval or ratification of related person transactions, and our Audit Committee reviews all related person transactions identified by us. The Audit Committee approves or ratifies only those related person transactions that are determined by it to be, under all of the circumstances, in the best interest of our company and its stockholders. No related person transactions occurred in the last three fiscal years that required a review by the Audit Committee.

Table of Contents**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT(2)**

The following table sets forth certain information with respect to the beneficial ownership of our Common Stock and Preferred Stock as of December 18, 2012 for (a) our executive officers, (b) each of our directors, (c) all of our current directors and executive officers as a group, and (d) each stockholder known by us to own beneficially more than 5% of our Common Stock, relying solely upon the amounts and percentages disclosed in their public filings.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of December 18, 2012 pursuant to the exercise of options or warrants to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of stock shown to be beneficially owned by them based on information provided to us by these stockholders. We are not aware of any stockholders beneficially owning 5% or more of our securities.

Percentage of ownership is based on 8,452,954 shares of common stock outstanding as of December 18, 2012.

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

	Number of Shares of Common Stock Beneficially Owned(1)	Percentage of Common Stock Owned
<i><u>Directors and Executive Officers</u></i>		
Dr. Nicholas Bacopoulos (2)	12,117	*
Sir John Banham(3)	24,166	*
Dr. Judy Chiao(4)	55,142	*
Dr. Christopher Henney(5)	41,831	*
Paul McBarron(6)	82,911	*
Spiro Rombotis(7)	177,855	2.09%
Daniel K. Spiegelman(8)	0	*
Dr. David U Prichard(9)	36,914	*
Lloyd Sems	596	*
Gregory T. Hradsky	596	*
Executive officers and directors as a group (10 persons)(10)	436,637	4.99%
<i><u>5% or More Stockholders</u></i>		
Redmile Group, LLC(11)	763,752	9.04%
Jeremy C. Green(11)	763,752	9.04%

\* Represents beneficial ownership of less than 1% of the outstanding shares of our Common Stock.



Table of Contents

- (1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Beneficial ownership also includes shares of Common Stock subject to options and warrants currently exercisable or convertible, or exercisable or convertible within 60 days of December 18, 2012. Except as indicated by footnote, to our knowledge, all persons named in the table above have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned.
- (2) Includes options to purchase 11,760 shares of Common Stock that are exercisable within 60 days of December 18, 2012.
- (3) Includes options to purchase 18,903 shares of Common Stock that are exercisable within 60 days of December 18, 2012.
- (4) Includes options to purchase 48,261 shares of Common Stock that are exercisable within 60 days of December 18, 2012. Also includes 3,571 restricted stock units.
- (5) Includes options to purchase 39,904 shares of Common Stock that are exercisable within 60 days of December 18, 2012.
- (6) Includes options to purchase 64,904 shares of Common Stock that are exercisable within 60 days of December 18, 2012.
- (7) Includes options to purchase 71,210 shares of Common Stock that are exercisable within 60 days of December 18, 2012. Also includes 7,143 restricted stock units. Of the shares of Common Stock reported, 142 shares are held indirectly by Mr. Rombotis through his IRA account.
- (8) Mr. Spiegelman resigned from the Board of Directors on June 6, 2012.
- (9) Includes options to purchase 37,808 shares of Common Stock that are exercisable within 60 days of December 18, 2012.
- (10) See footnotes (2)-(9). Also includes options to purchase 145,604 shares of Common Stock held by Robert Sosnowski, our Vice President, Sales & Marketing, which are exercisable within 60 days of December 18, 2012.
- (11) Based on a Schedule 13G filed jointly by Jeremy C. Green and Redmile Group, LLC ( **Redmile** ) with the SEC on November 30, 2012. These securities are owned by certain investment limited partnerships for which Redmile serves as general partner and investment manager. Redmile, as the investment manager and general partner of those investment limited partnerships, and Mr. Green, as managing



## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

member and owner of Redmile, may therefore be deemed to beneficially own the securities owned by such investment limited partnerships insofar as they may be deemed to have the power to direct the voting or disposition of those securities. Redmile and Mr. Green, however, disclaim beneficial ownership of the securities, except to the extent of his or its pecuniary interests therein. The principal business address of each beneficial owner is 100 Pine Street, Suite 1925, San Francisco, California, 94111.

Table of Contents**SELLING STOCKHOLDER**

The following table presents information regarding the selling stockholder as of December 18, 2012. Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us.

No estimate can be given as to the amount or percentage of our common stock that will be held by the selling stockholder after any sales or other dispositions made pursuant to this Prospectus because the selling stockholder is not required to sell any of the shares being registered under this Prospectus. The table above assumes that the selling stockholder will sell all of the shares listed in this Prospectus

The information is based in part on information provided by or on behalf of the selling stockholder.

<b>Selling Stockholder</b>	<b>Shares Beneficially Owned Before Offering(1)</b>	<b>Percentage of Outstanding Shares Beneficially Owned Before Offering</b>	<b>Shares to be Sold in the Offering</b>	<b>Shares Beneficially Owned After Offering</b>	<b>Percentage of Outstanding Shares Beneficially Owned After Offering</b>
Aspire Capital(2)	233,440(3)	2.76%	1,689,317	0	0%

(1) Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In general, a person is deemed to be the beneficial owner of (i) any shares of our common stock over which such person has sole or shared voting power or investment power, plus (ii) any shares which such person has the right to acquire beneficial ownership of within 60 days, whether through the exercise of options, warrants or otherwise. The percentage of ownership set forth above assumes the sale by the Company to Aspire Capital of all shares being offered pursuant to this prospectus and is based on 8,452,954 shares of our common stock outstanding as of December 18, 2012 in addition to the Commitment Shares and the Initial Purchase Shares issued pursuant to the Purchase Agreement, together with securities exercisable or convertible into shares of common stock within 60 days of the date hereof for the selling stockholder.

(2) As of the date of the Purchase Agreement, Aspire Capital beneficially owned no shares of common stock of the Company. Steven G. Martin, Erik J. Brown and Christos Komissopoulos, the principals of Aspire Capital, are deemed to be beneficial owners of all of the shares of common stock owned by Aspire Capital. Messrs. Martin, Brown and Komissopoulos have shared voting and investment power over the shares being offered under the prospectus filed with the SEC in connection with the transactions contemplated under the Purchase Agreement. Aspire Capital is not a licensed broker dealer or an affiliate of a licensed broker dealer.

(3) As of the date hereof, 233,440 shares of our common stock have been acquired by Aspire Capital under the Purchase Agreement, consisting of the Commitment Shares and the Initial Purchase Shares. The Company may elect in its sole discretion to sell to Aspire Capital up to an additional number of shares under the Purchase Agreement equal to \$19.0 million in value, but Aspire Capital does not presently beneficially own those shares as determined in accordance with the rules of the SEC.



Table of Contents

**THE ASPIRE CAPITAL TRANSACTION**

**General**

On December 14, 2012, we entered into the Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over the 24-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital the Commitment Shares and Aspire Capital purchased the Initial Purchase Shares. Concurrently with entering into the Purchase Agreement, we also entered into the Registration Rights Agreement, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of December 18, 2012, there were 8,452,954 shares of our common stock outstanding (7,252,565 shares held by non-affiliates) excluding the 1,455,877 shares offered that may be issuable to Aspire Capital pursuant to the Purchase Agreement. If all of the 1,689,317 shares of our common stock offered hereby were issued and outstanding as of December 18, 2012, such shares would represent 17.1% of the total common stock outstanding, or 27% of the non-affiliate shares of common stock outstanding as of December 18, 2012. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering under the Securities Act 1,689,317 shares of our common stock, which includes the Commitment Shares and the Initial Purchase Shares that have already been issued to Aspire Capital and an additional 1,454,877 shares of common stock that we may issue to Aspire Capital after the registration statement of which this prospectus is a part is declared effective under the Securities Act. All 1,689,317 shares of common stock are being offered pursuant to this prospectus.

Under the Purchase Agreement, we have the right, but not the obligation, to sell more than the 1,689,317 shares of common stock offered in this prospectus. The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement shall be limited to 1,689,371 (the **Exchange Cap**), which represents 19.99% of our outstanding shares as of December 14, 2012, unless shareholder approval or an exception pursuant to the rules of the NASDAQ Global Market is obtained to issue more than 19.99%, to be in compliance with the applicable listing maintenance rules of the NASDAQ Global Market. This limitation shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Purchase Agreement is equal to or greater than \$6.29, the closing sale price of our common stock on December 14, 2012. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Global Market.

After the SEC has declared effective the registration statement of which this prospectus is a part, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per business day, up to \$19.0 million of our common stock in the aggregate at a Purchase Price calculated by reference to the prevailing market price of our common stock over a preceding 12-business day period (as more specifically described below); however, no sale pursuant to a Purchase Notice may exceed \$500,000 per trading day.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 100,000 shares, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on The NASDAQ Global Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that in no event will any shares of common stock be sold at a Purchase Price less than \$1.00, or the Floor Price, unless and until such time as the stockholders of the Company approve the transaction contemplated by the Purchase Agreement. This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. Additionally, the Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement if such shares proposed to be issued and sold, when aggregated with all other shares of the Company's common stock that Aspire Capital and its affiliates beneficially own, would result in Aspire Capital and its affiliates beneficially owning more than 19.99% of the Company's then issued and outstanding common stock.

Table of Contents

There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us. The rights and obligations of Aspire Capital under the Purchase Agreement are not assignable or transferable.

**Purchase of Shares under the Purchase Agreement**

Under the Purchase Agreement, on any trading day selected by us on which the closing price of our common stock is not less than \$1.00 per share, we may direct Aspire Capital to purchase up to 100,000 shares of our common stock per trading day so long as no sale pursuant to such Purchase Notice may exceed \$500,000 per trading day. The Purchase Price of such shares is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
  
- the arithmetic average of the three lowest closing sale prices for our common stock during the twelve consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 100,000 shares we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on The NASDAQ Capital Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 90% of the closing price on the NASDAQ Global Market on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by the Company in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

- (a) The closing sale price on the VWAP Purchase Date; or
  
- (b) 96% of the volume-weighted average price for our common stock traded on the NASDAQ Global Market during normal trading hours:
  - on the VWAP Purchase Date, if the aggregate shares traded on the NASDAQ Global Market have not exceeded the VWAP Purchase Share Volume Maximum; or
  
  - the portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the NASDAQ Global Market has exceeded the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of the common

stock falls below the VWAP Minimum Price Threshold.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the period(s) used to compute the Purchase Price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

#### **Minimum Share Price**

Under the Purchase Agreement, the Company and Aspire Capital may not effect any sales of shares of our common stock on any trading day that the closing sale price of our common stock is less than \$1.00 per share.

#### **Compliance with The NASDAQ Global Market Price**

The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement shall be limited to 1,689,371, or the Exchange Cap, which represents 19.99% of our outstanding shares as of December 14, 2012, unless shareholder approval or an exception pursuant to the rules of the NASDAQ Global Market is obtained to issue more than 19.99%, to be in compliance with the applicable listing maintenance rules of the NASDAQ Global Market. This limitation shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Purchase Agreement is equal to or greater than \$6.29, the closing sale price of our common stock on December 14, 2012. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Global Market. We currently do not intend to seek stockholder approval of the transactions contemplated by the Purchase Agreement.

Table of Contents

**Beneficial Ownership Limitation**

Under the Purchase Agreement, the Company and Aspire Capital may not effect any sales of shares of our common stock if such shares proposed to be issued and sold, when aggregated with all other shares of our common stock beneficially owned by Aspire Capital and its affiliates, would result in the beneficial ownership by Aspire Capital and its affiliates of more than 19.99% of our then issued and outstanding shares of common stock.

**Events of Default**

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following events of default:

- the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale of our shares of common stock, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; provided, however, that in connection with any post-effective amendment to such registration statement that is required to be declared effective by the SEC, such lapse or unavailability may continue for a period of no more than twenty consecutive business days, which such period shall be extended for an additional twenty business days if we receive a comment letter from the SEC in connection therewith;
- the suspension from trading or failure of our common stock to be listed on a Principal Market (as defined in the Purchase Agreement) for a period of three (3) consecutive business days;
- the delisting of our common stock from the NASDAQ Capital Market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the NASDAQ Global Select Market, the NASDAQ Global Market, the NYSE Amex Equities or the OTCOB or OTCOX market places of the OTC markets;
- our transfer agent's failure to issue to Aspire Capital shares of our common stock which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;
- any breach by us of the representations, warranties, covenants or other term or condition contained in the Purchase Agreement or any related agreements that would reasonably be expected to have a material adverse effect except, in the case of a breach of a covenant which is reasonably curable, only if such breach continues for a period of at least five business days;



## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

- if at any time the issuance of shares of common stock upon the submission of a Purchase Notice or VWAP Purchase Notice under this Agreement would result in the issuance of an aggregate of number of shares of common stock that would exceed the number of shares of common stock that we may issue under this agreement without breaching our obligations under the rules or regulations of the NASDAQ Global Market;
- if we become insolvent or are generally unable to pay our debts as they become due; or
- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Table of Contents

**Our Termination Rights**

The Purchase Agreement may be terminated by us at any time, at our discretion, without any cost to us.

**No Short-Selling or Hedging by Aspire Capital**

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging, which establishes a net short position with respect to our common stock during any time prior to the termination of the Purchase Agreement.

**Effect of Performance of the Purchase Agreement on Our Stockholders**

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 1,689,317 shares registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 24 months from the date of this prospectus. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline or to be highly volatile. Sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

**Amount of Potential Proceeds to be Received under the Purchase Agreement**

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to \$20.0 million of shares of our common stock. However, we estimate that we will sell no more than 1,698,317 shares to Aspire Capital under the Purchase Agreement (exclusive of the Commitment Shares), all of which are included in this offering. Subject to any required approval by our board of directors, we have the right but not the obligation to issue more than the 1,698,317 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 1,689,317 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of common stock issued to Aspire Capital at varying purchase prices in addition to the 158,982 Initial Purchase Shares that were sold to Aspire Capital for \$1.0 million:

Assumed Average Purchase Price after the Initial Purchase(1)	Number of Additional Shares to be Sold if Full Purchase(2)	Percentage of Outstanding Shares After Giving Effect to the Aspire Capital Transaction(3)	Proceeds from the Sale of Shares to Aspire Capital Under the Common Stock Purchase Agreement
\$1.00	1,455,877	15.05%	\$1,455,877

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

\$4.00	1,455,877	15.05%	\$5,823,508
\$7.00	1,455,877	15.05%	\$10,191,139
\$10.00	1,455,877	15.05%	\$14,558,770
\$13.00	1,461,537	15.10%	\$18,999,994

---

(1) The initial purchase to Aspire Capital is 158,982 shares of common stock for \$1,000,000.

(2) Excludes 74,458 shares issued as Commitment Shares and 158,982 issued as the Initial Purchase Shares.

(3) The denominator is based on 8,219,514 shares outstanding on December 18, 2012, plus the number of shares set forth in the adjacent column which we would have sold to Aspire Capital. The numerator is based on the number of shares which we would have sold under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column. Calculations disregard the potential application of the 19.99% exchange cap limitation, to the extent applicable.

Table of Contents

**PLAN OF DISTRIBUTION**

The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- at the market into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling stockholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling stockholder may transfer the shares of common stock by other means not described in this prospectus.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions.

The selling stockholder and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

Aspire Capital is an underwriter within the meaning of the Securities Act.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

Table of Contents

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

Table of Contents

**DESCRIPTION OF SECURITIES**

**Description of Common Stock**

We are authorized to issue 100,000,000 shares of common stock, \$0.001 par value. As of December 18], 2012, 8,452,954 shares of common stock were issued and outstanding. The following descriptions of our common stock and provisions of our amended and restated certificate of incorporation and amended and restated by-laws are only summaries, and we encourage you to review complete copies of these documents, which have been filed as exhibits to our periodic reports with the SEC.

**Dividends, Voting Rights and Liquidation**

Holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available for dividend payments. All outstanding shares of common stock are fully paid and non-assessable, and the shares of common stock to be issued upon completion of this offering will be fully paid and non-assessable. The holders of common stock have no preferences or rights of conversion, exchange, pre-emption or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. In the event of any liquidation, dissolution or winding-up of our affairs, holders of common stock will be entitled to share ratably in our assets that are remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

**Delaware Law and Certain Charter and By-law Provisions**

The provisions of (1) Delaware law, (2) our amended and restated certificate of incorporation, and (3) our amended and restated bylaws discussed below could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of control of us. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

*Delaware Statutory Business Combinations Provision.* We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. For purposes of Section 203, a business combination is defined broadly to include a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and, subject to certain exceptions, an interested stockholder is a person who, together with his or her affiliates and associates, owns (or within three years prior, did own) 15% or more of the corporation's voting

stock.



Table of Contents

*Classified Board of Directors; Removal of Directors for Cause.* Our amended and restated certificate of incorporation and amended and restated bylaws provide that our board of directors is divided into three classes, each serving staggered three-year terms ending at the annual meeting of our stockholders. All directors elected to our classified board of directors will serve until the election and qualification of their respective successors or their earlier resignation or removal. The board of directors is authorized to create new directorships and to fill such positions so created and is permitted to specify the class to which any such new position is assigned. The person filling such position would serve for the term applicable to that class. The board of directors (or its remaining members, even if less than a quorum) is also empowered to fill vacancies on the board of directors occurring for any reason for the remainder of the term of the class of directors in which the vacancy occurred. Members of the board of directors may only be removed for cause and only by the affirmative vote of 80% of our outstanding voting stock. These provisions are likely to increase the time required for stockholders to change the composition of the board of directors. For example, in general, at least two annual meetings will be necessary for stockholders to effect a change in a majority of the members of the board of directors.

*Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors.* Our amended and restated bylaws provide that, for nominations to the board of directors or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely notice of the proposal in writing to our Secretary. For an annual meeting, a stockholder's notice generally must be delivered not less than 45 days nor more than 75 days prior to the anniversary of the mailing date of the proxy statement for the previous year's annual meeting. For a special meeting, the notice must generally be delivered by the later of 90 days prior to the special meeting or ten days following the day on which public announcement of the meeting is first made. Detailed requirements as to the form of the notice and information required in the notice are specified in the amended and restated bylaws. If it is determined that business was not properly brought before a meeting in accordance with our bylaw provisions, such business will not be conducted at the meeting.

*Special Meetings of Stockholders.* Special meetings of the stockholders may be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors.

*No Stockholder Action by Written Consent.* Our amended and restated certificate of incorporation and amended and restated bylaws do not permit our stockholders to act by written consent. As a result, any action to be effected by our stockholders must be effected at a duly called annual or special meeting of the stockholders.

*Super-Majority Stockholder Vote Required for Certain Actions.* The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless the corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our amended and restated certificate of incorporation requires the affirmative vote of the holders of at least 80% of our outstanding voting stock to amend or repeal any of the provisions discussed in this section of this prospectus entitled "Anti-Takeover Provisions" or to reduce the number of authorized shares of common stock or preferred stock. This 80% stockholder vote would be in addition to any separate class vote that might in the future be required pursuant to the terms of any preferred stock that might then be outstanding. In addition, an 80% vote is also required for any amendment to, or repeal of, our amended and restated bylaws by the stockholders. Our amended and restated bylaws may be amended or repealed by a simple majority vote of the board of directors.

**Preferred Stock**

We have the authority to issue up to 5,000,000 shares of preferred stock. As of December 18, 2012, 1,213,142 shares of our preferred stock were outstanding (see "6% Convertible Exchangeable Preferred Stock" below). The description of preferred stock provisions set forth below is not complete and is subject to and qualified in its entirety by reference to our certificate of incorporation and the certificate of designations relating

to each series of preferred stock.

Table of Contents

The board of directors has the right, without the consent of holders of common stock, to designate and issue one or more series of preferred stock, which may be convertible into common stock at a ratio determined by the board of directors. A series of preferred stock may bear rights superior to common stock as to voting, dividends, redemption, distributions in liquidation, dissolution, or winding up, and other relative rights and preferences. The board may set the following terms of any series preferred stock, and a prospectus supplement will specify these terms for each series offered:

- the number of shares constituting the series and the distinctive designation of the series;
  
- dividend rates, whether dividends are cumulative, and, if so, from what date; and the relative rights of priority of payment of dividends;
  
- voting rights and the terms of the voting rights;
  
- conversion privileges and the terms and conditions of conversion, including provision for adjustment of the conversion rate;
  
- redemption rights and the terms and conditions of redemption, including the date or dates upon or after which shares may be redeemable, and the amount per share payable in case of redemption, which may vary under different conditions and at different redemption dates;
  
- sinking fund provisions for the redemption or purchase of shares;
  
- rights in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights of priority of payment; and
  
- any other relative powers, preferences, rights, privileges, qualifications, limitations and restrictions of the series.

Dividends on outstanding shares of preferred stock will be paid or declared and set apart for payment before any dividends may be paid or declared and set apart for payment on the common stock with respect to the same dividend period.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

If, upon any voluntary or involuntary liquidation, dissolution or winding up of the Company, the assets available for distribution to holders of preferred stock are insufficient to pay the full preferential amount to which the holders are entitled, then the available assets will be distributed ratably among the shares of all series of preferred stock in accordance with the respective preferential amounts (including unpaid cumulative dividends, if any) payable with respect to each series.

Holders of preferred stock will not be entitled to preemptive rights to purchase or subscribe for any shares of any class of capital stock of the corporation. The preferred stock will, when issued, be fully paid and non-assessable. The rights of the holders of preferred stock will be subordinate to those of our general creditors.

We have previously issued 2,046,813 shares of preferred stock in one series, designated as 6% Convertible Exchangeable Preferred Stock, of which 1,213,142 are currently outstanding and are quoted on the NASDAQ Global Market under the symbol CYCCP.

Table of Contents

**6% Convertible Exchangeable Preferred Stock**

**General**

Our board of directors has designated 2,046,813 shares of the preferred stock that were issued as convertible preferred stock on November 3, 2004. The shares of convertible preferred stock are duly and validly issued, fully paid and non-assessable. These shares will not have any preemptive rights if we issue other series of preferred stock. The convertible preferred stock is not subject to any sinking fund. We have no obligation to retire the convertible preferred stock. The convertible preferred stock has a perpetual maturity and may remain outstanding indefinitely, subject to the holder's right to convert the convertible preferred stock and our right to cause the conversion of the convertible preferred stock and exchange or redeem the convertible preferred stock at our option. Any convertible preferred stock converted, exchanged or redeemed or acquired by us will, upon cancellation, have the status of authorized but unissued shares of convertible preferred stock. We will be able to reissue these cancelled shares of convertible preferred stock.

**Dividends**

When and if declared by our board of directors out of the legally available funds, holders of the convertible preferred stock are entitled to receive cash dividends at an annual rate of 6% of the liquidation preference of the convertible preferred stock. Dividends are payable quarterly on the first day of February, May, August and November. If any dividends are not declared, they will accrue and be paid at such later date, if any, as determined by our board of directors. Dividends on the convertible preferred stock will be cumulative from the issue date. Dividends will be payable to holders of record as they appear on our stock books not more than 60 days nor less than 10 days preceding the payment dates, as fixed by our board of directors. If the convertible preferred stock is called for redemption on a redemption date between the dividend record date and the dividend payment date and the holder does not convert the convertible preferred stock (as described below), the holder shall receive the dividend payment together with all other accrued and unpaid dividends on the redemption date instead of receiving the dividend on the dividend date. Dividends payable on the convertible preferred stock for any period greater or less than a full dividend period will be computed on the basis of a 360-day year consisting of twelve 30-day months. Accrued but unpaid dividends will not bear interest.

If we do not pay or set aside cumulative dividends in full on the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends, all dividends declared upon shares of the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends will be declared on a pro rata basis until all accrued dividends are paid in full. For these purposes, pro rata means that the amount of dividends declared per share on the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends bear to each other will be the same ratio that accrued and unpaid dividends per share on the shares of the convertible preferred stock and such other preferred stock bear to each other. We will not be able to redeem, purchase or otherwise acquire any of our stock ranking on the same basis as the convertible preferred stock as to dividends or liquidation preferences unless we have paid or set aside full cumulative dividends, if any, accrued on all outstanding shares of convertible preferred stock.

Unless we have paid or set aside cumulative dividends in full on the convertible preferred stock and any other of the convertible preferred stock ranking on the same basis as to dividends:

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

- we may not declare or pay or set aside dividends on common stock or any other stock ranking junior to the convertible preferred stock as to dividends or liquidation preferences, excluding dividends or distributions of shares, options, warrants or rights to purchase common stock or other stock ranking junior to the convertible preferred stock as to dividends; or

Table of Contents

- we will not be able to redeem, purchase or otherwise acquire any of our other stock ranking junior to the convertible preferred stock as to dividends or liquidation preferences, except in very limited circumstances.

Under Delaware law, we may only make dividends or distributions to our stockholders from:

- our surplus; or
- the net profits for the current fiscal year before which the dividend or distribution is declared under certain circumstances.

On September 12, 2012, the Board decided not to declare the quarterly cash dividend on the Company's 6% Convertible Exchangeable Preferred Stock with respect to the third quarter of 2012 that would have otherwise been payable on November 1, 2012.

As previously disclosed, the Board 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 fiscal year 2010, the second, third and fourth quarters of fiscal year 2011 and the first, second and third quarters of fiscal year 2012. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are accrued. As the Company failed to pay in an aggregate amount equal to at least six quarterly dividends (whether or not consecutive) on the Preferred Stock, the size of the Company's Board was increased by two members and the holders of the Preferred Stock, voting separately as a class, voted on May 24, 2011 and elected two directors to fill the vacancies created thereby, which directorships shall terminate when the Company pays all accrued but unpaid dividends. As of September 30, 2012, approximately \$2.1 million of dividends remain accrued and unpaid.

**Conversion**

***Conversion Rights***

Holders of our convertible preferred stock may convert the convertible preferred stock at any time into a number of shares of common stock determined by dividing the \$10 liquidation preference by the conversion price of \$164.50, being the original conversion price of \$23.50 as adjusted following a reverse stock split, subject to adjustment as described below. This conversion price is equivalent to a conversion rate of approximately 0.06079 shares of common stock for each share of convertible preferred stock. We will not make any adjustment to the conversion price for accrued or unpaid dividends upon conversion. We will not issue fractional shares of common stock upon conversion. However, we will instead pay cash for each fractional share based upon the market price of the common stock on the last business day prior to the conversion date. If we call the convertible preferred stock for redemption, the holder's right to convert the convertible preferred stock will expire at the close of business on the business day immediately preceding the date fixed for redemption, unless we fail to pay the redemption price.

*Automatic Conversion*

Unless we redeem or exchange the convertible preferred stock, we may elect to convert some or all of the convertible preferred stock into shares of our common stock if the closing price of our common stock has exceeded 150% of the conversion price for at least 20 out of 30 consecutive trading days ending within five trading days prior to the notice of automatic conversion. If we elect to convert less than all of the shares of convertible preferred stock, we shall select the shares to be converted by lot or pro rata or in some other equitable manner in our discretion. On or after November 3, 2007, we may not elect to automatically convert the convertible preferred stock if full cumulative dividends on the convertible preferred stock for all past dividend periods have not been paid or set aside for payment.



Table of Contents

*Conversion Price Adjustment General*

The conversion price of \$164.50 will be adjusted if:

- (1) we dividend or distribute common stock in shares of our common stock;
- (2) we subdivide or combine our common stock;
- (3) we issue to all holders of common stock certain rights or warrants to purchase our common stock at less than the current market price;
- (4) we dividend or distribute to all holders of our common stock shares of our capital stock or evidences of indebtedness or assets, excluding:
  - those rights, warrants, dividends or distributions referred to in (1) or (3), or
  - dividends and distributions paid in cash;
- (5) we made a dividend or distribution consisting of cash to all holders of common stock;
- (6) we purchase common stock pursuant to a tender offer made by us or any of our subsidiaries; and
- (7) a person other than us or any of our subsidiaries makes any payment on a tender offer or exchange offer and, as of the closing of the offer, the board of directors is not recommending rejection of the offer. We will only make this adjustment if the tender or exchange offer increases a person's ownership to more than 25% of our outstanding common stock, and only if the payment per share of common stock exceeds the current market price of our common stock. We will not make this adjustment if the offering documents disclose our plan to engage in any consolidation, merger, or transfer of all or substantially all of our properties and if specified conditions are met.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

If we implement a stockholder rights plan, this new rights plan must provide that, upon conversion of the existing convertible preferred stock the holders will receive, in addition to the common stock issuable upon such conversion, the rights under such rights plan regardless of whether the rights have separated from the common stock before the time of conversion. The distribution of rights or warrants pursuant to a stockholder rights plan will not result in an adjustment to the conversion price of the convertible preferred stock until a specified triggering event occurs.

The occurrence and magnitude of certain of the adjustments described above is dependent upon the current market price of our common stock. For these purposes, current market price generally means the lesser of:

- the closing sale price on certain specified dates, or
- the average of the closing prices of the common stock for the ten trading day period immediately prior to certain specified dates.

We may make a temporary reduction in the conversion price of the convertible preferred stock if our board of directors determines that this decrease would be in our best interest. We may, at our option, reduce the conversion price if our board of directors deems it advisable to avoid or diminish any income tax to holders of common stock resulting from any dividend or distribution of stock or rights to acquire stock or from any event treated as such for income tax purposes.

Table of Contents

*Conversion Price Adjustment Merger, Consolidation or Sale of Assets*

If we are involved in a transaction in which shares of our common stock are converted into the right to receive other securities, cash or other property, or a sale or transfer of all or substantially all of our assets under which the holders of our common stock shall be entitled to receive other securities, cash or other property, then appropriate provision shall be made so that the shares of convertible preferred stock will convert into:

(1) if the transaction is a common stock fundamental change, as defined below, common stock of the kind received by holders of common stock as a result of common stock fundamental change in accordance with paragraph (1) below under the subsection entitled Fundamental Change Conversion Price Adjustments, and

(2) if the transaction is not a common stock fundamental change, and subject to funds being legally available at conversion, the kind and amount of the securities, cash or other property that would have been receivable upon the recapitalization, reclassification, consolidation, merger, sale, transfer or share exchange by a holder of the number of shares of common stock issuable upon conversion of the convertible preferred stock immediately prior to the recapitalization, reclassification, consolidation, merger, sale, transfer or share exchange, after giving effect to any adjustment in the conversion price in accordance with paragraph (2) below under the subsection entitled Fundamental Change Conversion Price Adjustments.

The company formed by the consolidation, merger, asset acquisition or share acquisition shall provide for this right in its organizational document. This organizational document shall also provide for adjustments so that the organizational document shall be as nearly practicably equivalent to adjustments in this section for events occurring after the effective date of the organizational document.

The following types of transactions, among others, would be covered by this adjustment:

(1) we recapitalize or reclassify our common stock, except for:

- a change in par value,
- a change from par value to no par value,
- a change from no par value to par value, or

- a subdivision or combination of our common stock.

(2) we consolidate or merge into any other person, or any merger of another person into us, except for a merger that does not result in a reclassification, conversion, exchange or cancellation of common stock,

(3) we sell, transfer or lease all or substantially all of our assets and holders of our common stock become entitled to receive other securities, cash or other property, or

(4) we undertake any compulsory share exchange.

***Fundamental Change Conversion Price Adjustments***

If a fundamental change occurs, the conversion price will be adjusted as follows:

(1) in the case of a common stock fundamental change, the conversion price shall be the conversion price after giving effect to any other prior adjustments effected pursuant to the preceding paragraphs, multiplied by a fraction, the numerator of which is the purchaser stock price, as defined below, and the denominator of which is the applicable price, as defined below. However, in the event of a common stock fundamental change in which:

Table of Contents

- 100% of the value of the consideration received by a holder of our common stock is common stock of the successor, acquirer or other third party, and cash, if any, paid with respect to any fractional interests in such common stock resulting from such common stock fundamental change, and

- All of our common stock shall have been exchanged for, converted into or acquired for, common stock of the successor, acquirer or other third party, and any cash with respect to fractional interests,

- the conversion price shall be the conversion price in effect immediately prior to such common stock fundamental change multiplied by a fraction, the numerator of which is one (1) and the denominator of which is the number of shares of common stock of the successor, acquirer or other third party received by a holder of one share of our common stock as a result of the common stock fundamental change; and

(2) in the case of a non-stock fundamental change, the conversion price shall be the lower of:

- the conversion price after giving effect to any other prior adjustments effected pursuant to the preceding paragraph and

- the product of

A. the applicable price, and

B. a fraction, the numerator of which is \$10 and the denominator of which is (x) the amount of the redemption price for one share of convertible preferred stock if the redemption date were the date of the non-stock fundamental change (or if the date of such non-stock fundamental change falls within the period beginning on the first issue date of the convertible preferred stock through October 31, 2005, the twelve-month period commencing November 1, 2005 and the twelve-month period commencing November 1, 2006, the product of 106.0%, 105.4% or 104.8%, respectively, and \$10) plus (y) any then-accrued and unpaid distributions on one share of convertible preferred stock.

Holders of convertible preferred stock may receive significantly different consideration upon conversion depending upon whether a fundamental change is a non-stock fundamental change or a common stock fundamental change. In the event of a non-stock fundamental change, the shares of convertible preferred stock will convert into stock and other securities or property or assets, including cash, determined by the number of shares of common stock receivable upon conversion at the conversion price as adjusted in accordance with (2) above. In the event of a common stock fundamental change, under certain circumstances, the holder of convertible preferred stock will receive different consideration depending on whether the holder converts his or her shares of convertible preferred stock on or after the common stock fundamental change.



Table of Contents

*Definitions for the Fundamental Change Adjustment Provision*

**applicable price** means:

- in a non-stock fundamental change in which the holders of common stock receive only cash, the amount of cash received by a holder of one share of common stock, and
- in the event of any other fundamental change, the average of the daily closing price for one share of common stock during the 10 trading days immediately prior to the record date for the determination of the holders of common stock entitled to receive cash, securities, property or other assets in connection with the fundamental change or, if there is no such record date, prior to the date upon which the holders of common stock shall have the right to receive such cash, securities, property or other assets

**common stock fundamental change** means any fundamental change in which more than 50% of the value, as determined in good faith by our board of directors, of the consideration received by holders of our common stock consists of common stock that, for the 10 trading days immediately prior to such fundamental change, has been admitted for listing or admitted for listing subject to notice of issuance on a national securities exchange or quoted on The NASDAQ National Market, except that a fundamental change shall not be a common stock fundamental change unless either:

- we continue to exist after the occurrence of the fundamental change and the outstanding convertible preferred stock continues to exist as outstanding convertible preferred stock, or
- not later than the occurrence of the fundamental change, the outstanding convertible preferred stock is converted into or exchanged for shares of preferred stock, which preferred stock has rights, preferences and limitations substantially similar, but no less favorable, to those of the convertible preferred stock.

**fundamental change** means the occurrence of any transaction or event or series of transactions or events pursuant to which all or substantially all of our common stock shall be exchanged for, converted into, acquired for or shall constitute solely the right to receive cash, securities, property or other assets, whether by means of an exchange offer, liquidation, tender offer, consolidation, merger, combination, reclassification, recapitalization or otherwise. However, for purposes of adjustment of the conversion price, in the case of any series of transactions or events, the fundamental change shall be deemed to have occurred when substantially all of the common stock shall have been exchanged for, converted into or acquired for, or shall constitute solely the right to receive, such cash, securities, property or other assets, but the adjustment shall be based upon the consideration that the holders of our common stock received in the transaction or event as a result of which more than 50% of our common stock shall have been exchanged for, converted into or acquired for, or shall constitute solely the right to receive, such cash, securities, property or other assets.

**non-stock fundamental change** means any fundamental change other than a common stock fundamental change.

**purchaser stock price** means the average of the daily closing price for one share of the common stock received by holders of the common stock in the common stock fundamental change during the 10 trading days immediately prior to the date fixed for the determination of the holders of the common stock entitled to receive such common stock or, if there is no such date, prior to the date upon which the holders of the common stock shall have the right to receive such common stock.

***Liquidation Rights***

In the event of our voluntary or involuntary dissolution, liquidation, or winding up, the holders of the convertible preferred stock shall receive a liquidation preference of \$10 per share and all accrued and unpaid dividends through the distribution date. Holders of any class or series of preferred stock ranking on the same basis as your convertible preferred stock as to liquidation shall also be entitled to receive the full respective liquidation preferences and any accrued and unpaid dividends through the distribution date. Only after the preferred stock holders have received their liquidation preference and any accrued and unpaid dividends will we distribute assets to common stock holders or any of our other stock ranking junior to the shares of convertible preferred stock upon liquidation. If upon such dissolution, liquidation or winding up, we do not have enough assets to pay in full the amounts due on the convertible preferred stock and any other preferred stock ranking on the same basis with the convertible preferred stock as to liquidation, the holders of the convertible preferred stock and such other preferred stock will share ratably in any such distributions of our assets:



Table of Contents

- first in proportion to the liquidation preferences until the preferences are paid in full, and
- then in proportion to the amounts of accrued but unpaid dividends.

After we pay any liquidation preference and accrued dividends, holders of the convertible preferred stock will not be entitled to participate any further in the distribution of our assets. The following events will not be deemed to be a dissolution, liquidation or winding up of Cyclacel:

- the sale of all or substantially all of the assets;
- our merger or consolidation into or with any other corporation; or
- our liquidation, dissolution, winding up or reorganization immediately followed by a reincorporation as another corporation.

***Optional Redemption***

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, 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

If we redeem less than all of the shares of convertible preferred stock, we shall select the shares to be redeemed by lot or pro rata or in some other equitable manner in our sole discretion.

***Exchange Provisions***

We may exchange the convertible preferred stock in whole, but not in part, for debentures on any dividend payment date on or after November 1, 2005 at the rate of \$10 principal amount of debentures for each outstanding share of convertible preferred stock. Debentures will be issuable in denominations of \$1,000 and integral multiples of \$1,000, as discussed in the section entitled "Description of Debentures" below. If the

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

exchange results in an amount of debentures that is not an integral multiple of \$1,000, we will pay in cash an amount in excess of the closest integral multiple of \$1,000. We will mail written notice of our intention to exchange the convertible preferred stock to each record holder not less than 30 nor more than 60 days prior to the exchange date.

We refer to the date fixed for exchange of the convertible preferred stock for debentures as the exchange date. On the exchange date, the holder's rights as a stockholder of Cyclacel shall cease, the shares of convertible preferred stock will no longer be outstanding, and will only represent the right to receive the debentures and any accrued and unpaid dividends, without interest. We may not exercise our option to exchange the convertible preferred stock for the debentures if:

Table of Contents

- full cumulative dividends on the convertible preferred stock to the exchange date have not been paid or set aside for payment, or
- an event of default under the indenture would occur on conversion, or has occurred and is continuing.

***Voting Rights***

Holders of our convertible preferred stock have no voting rights except as described below or as required by law. Shares of our convertible preferred stock held by us or any entity controlled by us will not have any voting rights.

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. These voting rights will terminate when we have declared and either paid or set aside for payment all accrued and unpaid dividends. The terms of office of all directors so elected will terminate immediately upon the termination of these voting rights. On September 12, 2012, the Board decided not to declare the quarterly cash dividend on the Company's 6% Convertible Exchangeable Preferred Stock with respect to the third quarter of 2012 that would have otherwise been payable on November 1, 2012. As previously disclosed, the Board 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 fiscal year 2010, the second, third and fourth quarters of fiscal year 2011 and the first, second and third quarters of fiscal year 2012.

Without the vote or consent of the holders of at least a majority of the shares of convertible preferred stock, we may not:

- adversely change the rights, preferences and limitations of the convertible preferred stock by modifying our certificate of incorporation or bylaws, or
- authorize, issue, reclassify any of our authorized stock into, increase the authorized amount of, or authorize or issue any convertible obligation or security or right to purchase, any class of stock that ranks senior to the convertible preferred stock as to dividends or distributions of assets upon liquidation, dissolution or winding up of the stock

No class vote on the part of convertible preferred stock shall be required (except as otherwise required by law or resolution of our board of directors) in connection with the authorization, issuance or increase in the authorized amount of any shares of capital stock ranking junior to or on parity with the convertible preferred stock both as to the payment of dividends and as to distribution of assets upon our liquidation, dissolution or winding up, whether voluntary or involuntary, including our common stock and the convertible preferred stock.



Table of Contents

In addition, without the vote or consent of the holders of at least a majority of the shares of convertible preferred stock we may not:

- enter into a share exchange that affects the convertible preferred stock, or
- consolidate with or merge into another entity, or
- permit another entity to consolidate with or merge into us,

unless the convertible preferred stock remains outstanding and its rights, privileges and preferences are unaffected or it is converted into or exchanged for convertible preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to the convertible preferred stock.

In determining a majority under these voting provisions, holders of convertible preferred stock will vote together with holders of any other preferred stock that rank on parity as to dividends and that have like voting rights.

**Warrants**

The following is a brief summary of the terms of our outstanding warrants.

- *April 2006 Securities Purchase Agreement* On April 26 2006, we entered into a Securities Purchase Agreement pursuant to which we sold to certain investors, for an aggregate purchase price of \$45.3 million, 918,367 shares of its common stock and warrants to purchase up to 367,347 additional shares of its common stock. The purchase price for the common stock and the exercise price for the warrants is \$49.00 per share. The warrants became exercisable six months after the closing and have an expiration date seven years thereafter. As of December 18, 2012 all warrants are outstanding.
- *The February 2007 Warrants* On February 16, 2007, as part of a registered direct offering of our units, we sold warrants to purchase up to an aggregate of 151,773 shares of common stock at an exercise price of \$59.08 per share of common stock, such warrants expiring at 5:00 p.m., Eastern Time, on February 16, 2014. As of December 18, 2012, there were 151,773 shares available for purchase under the February 2007 Warrants.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

- *The July 2009 Warrants* On July 29, 2009, as part of a registered direct offering of our units, we sold warrants to purchase up to an aggregate of 98,893 shares of common stock at an exercise price of \$7.00 per share of common stock, such warrants expiring at 5:00 p.m., Eastern Time, on July 29, 2014. Unless otherwise specified in the applicable warrant, except upon at least 61 days prior notice from the holder to us, the holder will not have the right to exercise any portion of the warrant if the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. As of December 18, 2012, there were 98,893 shares available for purchase under the July 2009 Warrants.

- *The January 13, 2010 Warrants* On January 13, 2010, as part of a registered direct offering of our units, we sold warrants to purchase up to an aggregate of 101,785 shares of common stock at an exercise price of \$22.82 per share of common stock, such warrants expiring at 5:00 p.m., Eastern Time, on January 13, 2015. Unless otherwise specified in the applicable warrant, except upon at least 61 days prior notice from the holder to us, the holder will not have the right to exercise any portion of the warrant if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. As of December 18, 2012, there were 101,785 shares available for purchase under the January 13, 2010 Warrants.

Table of Contents

- *The January 25, 2010 Warrants* On January 25, 2010, as part of a registered direct offering of our units, we sold warrants to purchase up to an aggregate of 100,714 shares of common stock at an exercise price of \$19.95 per share of common stock, such warrants expiring at 5:00 p.m. Eastern Time, on January 25, 2015. Unless otherwise specified in the applicable warrant, except upon at least 61 days prior notice from the holder to us, the holder will not have the right to exercise any portion of the warrant if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. As of December 18, 2012, there were 100,715 shares available for purchase under the January 25, 2010 Warrants.
- *The Kingsbridge Warrant* On November 24, 2009, we issued to Kingsbridge Capital Limited, or Kingsbridge, an amended and restated warrant to purchase an aggregate of 25,000 shares of our common stock at an exercise price of \$9.80 per share, such warrant expiring on June 10, 2013. The Kingsbridge Warrant may not be exercised to the extent that such exercise would cause the warrant holder to beneficially own (or be deemed to beneficially own) a number of shares of our common stock that would exceed 9.9% of our then outstanding shares of common stock following such exercise. As of December 18, 2012, there were 14,285 shares available for purchase under the Kingsbridge Warrant.
- *October 2010 Warrants* On October 7, 2010, as part of the Private Placement, we sold the Warrants to purchase up to an aggregate of 594,513 shares of common stock at an exercise price of \$13.44 per share of common stock, such Warrants expiring at 5:00 p.m. Eastern Time, on October 7, 2015. Unless otherwise specified in the applicable Warrant, except upon at least 61 days prior notice from the holder to us, the holder will not have the right to exercise any portion of such warrant if the holder, together with its affiliates, would beneficially own in excess of 4.99%, 9.99% or 19.99% , as applicable, of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. As of December 18, 2012, there were 594,513 shares available for purchase under the Warrants.
- *July 2011 Underwritten Offering* On July 7, 2011, we closed an underwritten offering for an aggregate of 1,088,235 units, at an offering price of \$9.52 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 \$9.52 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 (\$6.23 per share) and \$2.5 million (\$4.62 per warrant) to common shares and warrants, respectively. As of December 18, 2012, there were 544,117 shares available for purchase under the July 11, 2011 Warrants.

*Exercisability.* The exercise price and number of shares of common stock issuable upon exercise of all of the warrants may be adjusted in certain circumstances, including in the event of a stock dividend, or our recapitalization, reorganization, merger or consolidation.

*Exercise of Warrants.* All of the warrants except the Warrants may be exercised upon surrender of the warrant on or prior to the expiration date at the offices of the warrant agent, with the exercise form set forth in the warrant completed and executed as indicated, either accompanied by full payment of the exercise price, by certified check payable to us, for the number of warrants being exercised or, under certain circumstances, by means of a cashless exercise, as provided for in the warrant. Notwithstanding the foregoing, the holder will not be required to physically surrender the warrant unless and until the aggregate warrant shares represented by the warrant are exercised. The Warrants may be exercised in

the same manner, except that such securities are exercisable by delivery of a written notice, with payment made within two trading days of the delivery of the notice of exercise.

*Cashless Exercise.* If, at any time during the exercisability period of any of the warrants, the holder is not permitted to sell shares of common stock issuable upon exercise of the relevant warrant pursuant to the registration statement or an exemption from registration is not available, and the fair market value of our common stock exceeds the exercise price of the warrants, the holder may elect to effect a cashless exercise of the warrants, in whole or in part, by surrendering the warrants to us, together with delivery to us of a duly executed exercise notice, and canceling a portion of the relevant warrant in payment of the purchase price payable in respect of the number of shares of our common stock purchased upon such exercise.



Table of Contents

*Buy-in Right.* If we fail to issue shares of common stock to the holder of a Warrant within three business days of our receipt of a duly executed exercise notice, then the holder or any third party on behalf of the holder may, for such holder's account, purchase in an open market transaction or otherwise, shares of common stock to deliver in satisfaction of a sale by the holder of shares of common stock issuable upon such exercise that the holder anticipated receiving from us. At such holder's request and in its discretion, either (i) pay cash to the holder in an amount equal to the holder's total purchase price (including brokerage commissions, if any) for the shares of common stock so purchased (the **Buy-In Price**), at which point the Company's obligation to deliver such certificate (and to issue such shares of common stock) shall terminate, or (ii) promptly honor its obligation to deliver to the holder a certificate or certificates representing such shares and pay cash to the holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) such number of shares of common stock, times (B) the Closing Bid Price (as defined in such warrants) on the date of exercise.

*Transferability.* Subject to applicable laws and the restriction on transfer set forth in the relevant subscription agreement, none of the warrants may be transferred by the holder without our consent, such consent not to be unreasonably withheld or delayed, upon surrender of the warrants to us together with the appropriate instruments of transfer.

*Exchange Listing.* We do not plan on making an application to list any of the warrants on The NASDAQ Global Market, any national securities exchange or other nationally recognized trading system. The common stock underlying the warrants is listed on the NASDAQ Global Market.

*Fundamental Transactions.* In the event of any fundamental transaction, as described in the warrants, and generally including any merger with or into another entity (whether or not we are the surviving entity but excluding a migratory merger effected solely for the purpose of changing our jurisdiction of incorporation), sale of all or substantially all of our assets, tender offer or exchange offer, our consummation of a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) or reclassification of our common stock, then upon any subsequent exercise of a warrant, the holder shall have the right to receive, as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of Cyclacel, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, the holders of the Warrants and the Option Warrants, in the event of a fundamental transaction (i) in which holders of common stock receive all cash or substantially all cash or (ii) with a person whose common stock or equivalent equity security is not quoted or listed on an eligible market, as defined in such warrant, and, in either case, at the request of the holder delivered within 30 days after consummation of the fundamental transaction, we (or our successor entity) must purchase such warrant from the holder by paying to the holder, within seven business days after such request (or, if later, on the effective date of the fundamental transaction), cash in an amount equal to the Black Scholes value, as defined in such warrant, of the remaining unexercised portion of such Warrant or Option Warrant on the date of such fundamental transaction. Fundamental transactions shall not include any transaction in which the Company is not a voluntary party thereto.

*Waivers and Amendments.* The provisions of each warrant may be amended and we may not take any action prohibited by such warrant, or omit to perform any act required to be performed pursuant to such warrant, only with the written consent of the holder of that warrant.

*Rights as a Stockholder.* The warrant holders do not have the rights or privileges of holders of common stock, including any voting rights, until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.



Table of Contents

*No Fractional Shares.* No fractional shares will be issued upon exercise of any of the warrants. With respect to all warrants, except the Warrants and Option Warrants, we will pay to the holder thereof, in lieu of the issuance of any fractional share which is otherwise issuable to the warrant holder, an amount in cash based on the market value of the common stock on the last trading day prior to the exercise date. With respect to the Warrants and the Option Warrants, the number of shares of common stock to be issued will be rounded up to the nearest whole number.

**Listing**

Our common stock is listed on the NASDAQ Global Market under the symbol CYCC. Our preferred stock is listed on the NASDAQ Capital Market under the symbol CYCCP.

**Transfer Agent and Registrar**

American Stock Transfer & Trust Company is the transfer agent and registrar for our common stock. Their address is 59 Maiden Lane, Plaza Level, New York, NY 10038, and their telephone number is (800) 937-5449.

Table of Contents

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS**

**General**

The following is a discussion of the material U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common stock by a non-U.S. holder, as defined below, that acquires our common stock pursuant to this offering. This discussion assumes that a non-U.S. holder will hold our common stock issued pursuant to this offering as a capital asset within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code. This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular investor in light of the investor's individual circumstances. In addition, this discussion does not address (i) U.S. federal non-income tax laws, such as gift or estate tax laws, (ii) state, local or non-U.S. tax consequences, (iii) the special tax rules that may apply to certain investors, including, without limitation, banks, insurance companies, financial institutions, controlled foreign corporations, passive foreign investment companies, broker-dealers, grantor trusts, personal holding companies, taxpayers who have elected mark-to-market accounting, tax-exempt entities, regulated investment companies, real estate investment trusts, a partnership or other entity or arrangement classified as a partnership for United States federal income tax purposes or other pass-through entities, or an investor in such entities or arrangements, or U.S. expatriates or former long-term residents of the United States, (iv) the special tax rules that may apply to an investor that acquires, holds, or disposes of our common stock as part of a straddle, hedge, constructive sale, conversion or other integrated transaction, or (v) the impact, if any, of the alternative minimum tax.

This discussion is based on current provisions of the Code, applicable U.S. Treasury Regulations promulgated thereunder, judicial opinions, and published rulings of the Internal Revenue Service, or the IRS, all as in effect on the date of this prospectus and all of which are subject to differing interpretations or change, possibly with retroactive effect. We have not sought, and will not seek, any ruling from the IRS or any opinion of counsel with respect to the tax consequences discussed herein, and there can be no assurance that the IRS will not take a position contrary to the tax consequences discussed below or that any position taken by the IRS would not be sustained.

As used in this discussion, the term "U.S. person" means a person that is, for U.S. federal income tax purposes, (i) a citizen or individual resident of the United States, (ii) a corporation (or other entity taxed as a corporation) created or organized (or treated as created or organized) in the United States or under the laws of the United States or any state thereof or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (iv) a trust if (A) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust, or (B) it has in effect a valid election under applicable U.S. Treasury Regulations to be treated as a U.S. person. As used in this discussion, the term "non-U.S. holder" means a beneficial owner of our common stock (other than a partnership or other entity treated as a partnership or as a disregarded entity for U.S. federal income tax purposes) that is not a U.S. person.

The tax treatment of a partnership and each partner thereof will generally depend upon the status and activities of the partnership and such partner. A holder that is treated as a partnership for U.S. federal income tax purposes or a partner in such partnership should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it and its partners of the acquisition, ownership and disposition of our common stock.

**THIS DISCUSSION IS ONLY A SUMMARY OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, INCLUDING**

**THE APPLICABILITY AND EFFECT OF ANY STATE, LOCAL, AND NON-U.S. TAX LAWS, AS WELL AS U.S. FEDERAL ESTATE AND GIFT TAX LAWS, AND ANY APPLICABLE TAX TREATY.**

Table of Contents

**Income Tax Consequences of an Investment in Common Stock**

***Distributions on Common Stock***

As discussed under *Dividend Policy*, we do not anticipate paying dividends. If we pay cash or distribute property to holders of shares of common stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the holder's adjusted tax basis in our common stock. Any remaining excess will be treated as gain from the sale or exchange of the common stock and will be treated as described under *Gain or Loss on Sale, Exchange or Other Taxable Disposition of Common Stock* below.

Dividends paid to a non-U.S. holder that are not effectively connected with the non-U.S. holder's conduct of a trade or business in the United States generally will be subject to withholding of U.S. federal income tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder that wishes to claim the benefit of an applicable tax treaty withholding rate generally will be required to (i) complete IRS Form W-8BEN (or other applicable form) and certify under penalties of perjury that such holder is not a U.S. person and is eligible for the benefits of the applicable tax treaty or (ii) if our common stock is held through certain foreign intermediaries, satisfy the relevant certification requirements of applicable U.S. Treasury Regulations. These forms may need to be periodically updated.

A non-U.S. holder eligible for a reduced rate of withholding of U.S. federal income tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under an applicable income tax treaty and the manner of claiming the benefits of such treaty (including, without limitation, the need to obtain a U.S. taxpayer identification number).

Dividends that are effectively connected with a non-U.S. holder's conduct of a trade or business in the United States, and, if required by an applicable income tax treaty, attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States, are subject to U.S. federal income tax on a net income basis at the U.S. federal income tax rates generally applicable to a U.S. holder and are not subject to withholding of U.S. federal income tax, provided that the non-U.S. holder establishes an exemption from such withholding by complying with certain certification and disclosure requirements. Any such effectively connected dividends (and, if required, dividends attributable to a U.S. permanent establishment or fixed base) received by a non-U.S. holder that is treated as a foreign corporation for U.S. federal income tax purposes may be subject to an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty.

***Gain or Loss on Sale, Exchange or Other Taxable Disposition of Common Stock***

Any gain recognized by a non-U.S. holder on a sale or other taxable disposition of our common stock generally will not be subject to U.S. federal income tax, unless:



Table of Contents

(i) the gain is effectively connected with a trade or business of the non-U.S. holder in the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment or fixed base of the non-U.S. holder),

(ii) the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met, or

(iii) we are or have been a United States real property holding corporation, or a USRPHC, for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the non-U.S. holder held the common stock, and, in the case where the shares of our common stock are regularly traded on an established securities market, the non-U.S. holder holds or held (at any time during the shorter of the five-year period ending on the date of disposition or the non-U.S. holder's holding period) more than 5% of our common stock. A corporation generally is a USRPHC if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we currently are a USRPHC, and we expect to remain a USRPHC.

Any gain recognized by a non-U.S. holder that is described in clause (i) or (iii) of the preceding paragraph generally will be subject to tax at the U.S. federal income tax rates generally applicable to a U.S. person and be required to file a U.S. tax return. Such non-U.S. holders are urged to consult their tax advisors regarding the possible application of these rules. Any gain of a corporate non-U.S. holder that is described in clause (i) above may also be subject to an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. An individual non-U.S. holder that is described in clause (ii) of such paragraph generally will be subject to a flat 30% tax (or a lower applicable tax treaty rate) on the U.S. source capital gain derived from the disposition, which may be offset by U.S. source capital losses during the taxable year of the disposition.

**Information Reporting and Backup Withholding**

We generally must report annually to the IRS and to each non-U.S. holder of our common stock the amount of dividends paid to such holder on our common stock and the tax, if any, withheld with respect to those dividends. Copies of the information returns reporting those dividends and withholding may also be made available to the tax authorities in the country in which the non-U.S. holder is a resident under the provisions of an applicable income tax treaty or agreement. Information reporting also is generally required with respect to the proceeds from sales and other dispositions of our common stock to or through the U.S. office (and in certain cases, the foreign office) of a broker.

Under some circumstances, U.S. Treasury Regulations require backup withholding of U.S. federal income tax, currently at a rate of 28% (scheduled to increase to 31% in 2011), on reportable payments with respect to our common stock. A non-U.S. holder generally may eliminate the requirement for information reporting (other than in respect to dividends, as described above) and backup withholding by providing certification of its foreign status, under penalties of perjury, on a duly executed applicable IRS Form W-8 or by otherwise establishing an exemption. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that a holder is a U.S. person.

Backup withholding is not a tax. Rather, the amount of any backup withholding will be allowed as a credit against a non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such non-U.S. holder to a refund, provided that certain required information is timely



Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

furnished to the IRS. Non-U.S. holders should consult their own tax advisors regarding the application of backup withholding and the availability of and procedure for obtaining an exemption from backup withholding in their particular circumstances.

Table of Contents

**LEGAL MATTERS**

Certain legal matters in connection with the offering and the validity of the common stock offered by this prospectus will be passed upon for us by Mintz, Levin, Cohen, Ferris, Glovsky & Popeo, P.C.

**EXPERTS**

The consolidated financial statements of Cyclacel Pharmaceuticals, Inc. at December 31, 2011, and for the year ended December 31, 2011 and for the period from August 13, 1996 (inception) to December 31, 2011 appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP (US), independent registered public accounting firm, as set forth in their report thereon appearing herein which, as to the period from August 13, 1996 (inception) to December 31, 2011, are based in part on the report of Ernst & Young LLP (UK), independent registered public accounting firm. The financial statements referred to above are included in reliance upon such reports given on the authority of such firms as experts in accounting and auditing.

The consolidated financial statements of Cyclacel Pharmaceuticals, Inc. as of December 31, 2010 and 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, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP (UK), independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE 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](http://www.cyclacel.com) as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We have not incorporated by reference in this prospectus 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.

Table of Contents

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

	<b>Page</b>
<b>Audited Financial Statements</b>	
<u>Reports of Independent Registered Public Accounting Firms</u>	F-2
<u>Consolidated Balance Sheets reissued and recast as of December 31, 2010 and 2011 (1)</u>	F-4
<u>Consolidated Statements of Operations reissued and recast for the years ended December 31, 2009, 2010 and 2011 and the period from August 13, 1996 (inception) to December 31, 2011 (1)</u>	F-5
<u>Consolidated Statements of Comprehensive Income reissued and recast for the years ended December 31, 2009, 2010 and 2011 and the period from August 13, 1996 (inception) to December 31, 2011 (1)</u>	F-6
<u>Consolidated Statements of Stockholders' Equity (Deficit) reissued and recast for the period from August 13, 1996 (inception) to December 31, 2011 (1)</u>	F-7
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2010 and 2011 and the period from August 13, 1996 (inception) to December 31, 2011</u>	F-16
<u>Notes to Consolidated Financial Statements (1)</u>	F-19
<b>Unaudited Financial Statements</b>	
<u>Unaudited Condensed Consolidated Balance Sheets as of December 30, 2011 and September 30, 2012</u>	F-47
<u>Unaudited Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2011, and 2012 and the period from August 13, 1996 (inception) to September 30, 2012</u>	F-48
<u>Unaudited Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2011 and 2012 and the period from August 13, 1996 (inception) to September 30, 2012</u>	F-49
<u>Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2011 and 2012 and the period from August 13, 1996 (inception) to September 30, 2012</u>	F-50
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	F-51

---

(1) The Company has reissued and recast the consolidated financial statements included within the Company's Annual Report on Form 10-K for the year ended December 31, 2011, as further described in Note 1, for a reverse stock split, discontinued operations and the retrospective adoption of Accounting Standards Update 2011-05 (ASU 2011-05).

Table of Contents

**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, comprehensive income, 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 (except Note 1, as to which the date is December 21, 2012) 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 \$6,748,000 and \$282,873,000, respectively. Our opinion on the statements of operations, comprehensive income, 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,

except for Note 1,

as to which the date is

December 21, 2012

F-2

---

Table of Contents

**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, comprehensive income, 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

Except for Note 1

as to which the date is

December 21, 2012



Table of Contents

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

**CONSOLIDATED BALANCE SHEETS**

(In \$000s, except share amounts)

	2010	December 31,	2011
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 29,495	\$	24,449
Prepaid expenses and other current assets	1,244		1,069
Current assets of discontinued operations	312		313
Total current assets	31,051		25,831
Property, plant and equipment (net)	408		167
Total assets	\$ 31,459	\$	25,998
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>			
Current liabilities:			
Accounts payable	\$ 1,590	\$	1,717
Accrued and other current liabilities	3,754		4,183
Warrants and other derivatives	680		71
Current liabilities of discontinued operations	511		527
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; 6,652,131 and 7,745,780 shares issued and outstanding at December 31, 2010 and 2011, respectively	7		8
Additional paid-in capital	266,706		276,498
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.



Table of Contents

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

**CONSOLIDATED STATEMENTS OF OPERATIONS**

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

	Year ended December 31, 2009	Year ended December 31, 2010	Year ended December 31, 2011	Period from August 13, 1996 (inception) to December 31, 2011
<b>Revenues:</b>				
Collaboration and research and development revenue	\$	\$	100	\$ 3,100
Grant revenue	1	12		3,648
<b>Total revenues</b>	<b>1</b>	<b>112</b>		<b>6,748</b>
<b>Operating expenses:</b>				
Research and development	9,766	6,414	9,206	185,799
General and administrative	6,631	8,833	6,542	80,831
Goodwill and intangibles impairment				2,747
Other restructuring costs	366			2,634
<b>Total operating expenses</b>	<b>16,763</b>	<b>15,247</b>	<b>15,748</b>	<b>272,011</b>
<b>Operating loss</b>	<b>(16,762)</b>	<b>(15,135)</b>	<b>(15,748)</b>	<b>(265,263)</b>
Other income (expense):				
Costs associated with aborted 2004 IPO				(3,550)
Payment under guarantee	(1,652)			(1,652)
Change in valuation of liabilities measured at fair value	(343)	(338)	609	6,327
Foreign exchange losses	(144)	(68)	(74)	(4,397)
Interest income	102	37	45	13,725
Interest expense	(170)	(43)		(4,567)
Total other (expense) income, net	(2,207)	(412)	580	5,986
<b>Loss from continuing operations before taxes</b>	<b>(18,969)</b>	<b>(15,547)</b>	<b>(15,168)</b>	<b>(259,277)</b>
Income tax benefit	948	657	565	18,444
<b>Net loss from continuing operations</b>	<b>(18,021)</b>	<b>(14,890)</b>	<b>(14,603)</b>	<b>(240,833)</b>
<b>Discontinued operations:</b>				
Loss from discontinued operations, net of tax of \$0 for all periods presented	(1,549)	(1,131)	(640)	(12,716)
<b>Net loss</b>	<b>(19,570)</b>	<b>(16,021)</b>	<b>(15,243)</b>	<b>(253,549)</b>
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)
<b>Net loss applicable to common shareholders</b>	<b>\$ (20,798)</b>	<b>\$ (19,703)</b>	<b>\$ (15,971)</b>	<b>\$ (298,844)</b>
Net loss per share, continuing operations basic and diluted	\$ (6.07)	\$ (3.43)	\$ (2.13)	
Net loss per share, discontinued operations basic and diluted	\$ (0.49)	\$ (0.21)	\$ (0.09)	
Net loss per share basic and diluted	\$ (6.56)	\$ (3.64)	\$ (2.22)	

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Weighted average common shares outstanding	3,170,977	5,406,385	7,185,877
--	-----------	-----------	-----------

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

F-5

---

Table of Contents

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

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(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
Net loss from continuing operations	\$ (18,021)	\$ (14,890)	\$ (14,603)	\$ (240,833)
Loss from discontinued operations	(1,549)	(1,131)	(640)	(12,716)
<b>Net loss</b>	<b>(19,570)</b>	<b>(16,021)</b>	<b>(15,243)</b>	<b>(253,549)</b>
Translation adjustment	(5,589)	(2,073)	648	5,274
Unrealized foreign exchange gain (loss) on intercompany loans	5,651	2,084	(622)	(5,217)
<b>Comprehensive loss</b>	<b>\$ (19,508)</b>	<b>\$ (16,010)</b>	<b>\$ (15,217)</b>	<b>\$ (253,492)</b>

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

Table of Contents

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

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

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

	Preferred Stock	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		38,111	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		38,111	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		38,111	6,482	62	(1,294)	(6,788)	(1,538)

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

Table of Contents

**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
Issue of shares for cash, net of issuance costs			76,984		12,717			12,717
Issue of shares on conversion of bridging loan			12,943		1,638			1,638
Issue of shares in lieu of cash bonus			1,294		164			164
Issue of shares for research & development agreement					409			409
Exercise of share options			324		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			129,656		21,617	(132)	(1,028)	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			129,656		21,911	(598)	(1,047)	(2,856)

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

Table of Contents

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

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

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

	Preferred Stock		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
Issue of shares for cash, net of issuance costs			779					
Exercise of share options for cash				106				106
Issue of shares for license agreement			644	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			131,079	23,778	(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			131,079	23,706	(2,253)	(349)	(53,251)	(32,147)

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

Table of Contents

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

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

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

	Preferred Stock No.	\$000	Common Stock No.	\$000	Additional paid-in capital \$000	Accumulated other comprehensive income/(loss) \$000	Deferred compensation \$000	Deficit accumulated during development stage \$000	Total \$000
Issue of shares for cash, net of issuance costs			215,755		27,635				27,635
Exercise of share options for cash			936		115				115
Conversion of Preferred C Ordinary shares			538,449	1	58,147				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			886,219	1	109,603	(3,596)	(132)	(68,228)	37,648
Issues of shares for cash, net of issuance costs			61,510		8,541				8,541
Exercise of warrants for cash			3,233						
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			950,962	1	116,094	(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			950,962	1	116,094	(2,958)		(109,018)	4,119

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

Table of Contents

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

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

	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			92,630						
Issue of shares on conversion of Loan Note Instrument			65,187						
Reverse Acquisition	2,046,813	2	281,133		16,253				16,255
Loan from Cyclacel Group plc waived					10,420				10,420
Issue of common stock and warrants for cash			918,367	1	42,361				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	2,308,279	2	194,728	(2,537)		(138,276)	53,919

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



Table of Contents

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

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

	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			3,644		163				163
Issue of common stock for cash on registered direct offering, net of expenses			607,095	1	33,356				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	2,919,018	3	222,923	(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	2,919,018	3	223,394	(42)		(202,715)	20,642

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

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Table of Contents

	Preferred Stock No.		Common Stock No.		Additional paid-in capital (as restated) \$000	Accumulated other comprehensive income/(loss) \$000	Deferred compensation \$000	Deficit accumulated during development stage \$000	Total (as restated) \$000
Warrant re-pricing					44				44
Issue of common stock for cash on registered direct offering, net of expenses			571,429	1	2,846				2,847
Issue of common stock upon draw down of Committed Equity Finance Facility			179,289		1,030				1,030
Issue of common stock upon exercise of stock options, restricted stock units and restricted stock			7,887		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	3,677,623	4	228,131	20		(222,285)	5,872

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

Table of Contents

	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			742,857	1	11,896				11,897
Issue of common stock upon draw down of Committed Equity Finance Facility			402,704		4,863				4,863
Warrant exercise			374,038		2,499				2,499
Issue of common stock on private placement, net of expenses			1,189,028	1	13,979				13,980
Stock-based awards exercised			29,367		77				77
Preferred stock conversions	(833,671)	(1)	236,514		3,516			(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	6,652,131	7	266,706	31		(241,821)	24,924

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

Table of Contents

	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			1,088,235	1	9,271				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			5,414		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	7,745,780	8	276,498	57		(257,064)	19,500

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

Table of Contents

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

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year ended December 31, 2009 \$000	Year ended December 31, 2010 \$000	Year ended December 31, 2011 \$000	Period from August 13, 1996 (inception) to December 31, 2011 \$000
<b>Operating activities:</b>				
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)

Table of Contents

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

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

	Year ended December 31, 2009 \$000	Year ended December 31, 2010 \$000	Year ended December 31, 2011 \$000	Period from August 13, 1996 (inception) to December 31, 2011 \$000
<b>Investing activities:</b>				
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)
<b>Financing activities:</b>				
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
<b>Supplemental cash flow information:</b>				

Table of Contents

	Year ended December 31, 2009 \$000	Year ended December 31, 2010 \$000	Year ended December 31, 2011 \$000	Period from August 13, 1996 (inception) to December 31, 2011 \$000
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

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1 Organization of the Company**

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

Cyclacel's clinical development priorities are focused on sapacitabine in the following indications:

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

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

The Company has ongoing clinical programs in development awaiting further data. Once data becomes available and is reviewed, 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 marketed directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. However, the distribution agreements for the promotion and sale of these products were terminated effective September 30, 2012. 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.



*Capital Resources*

The Company's existing capital is not sufficient to complete the development and commercialization of any of its product candidates.

*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.

Table of Contents

*Developments*

Reverse Stock Split

On August 24, 2012, the Company effected a 1-for-7 reverse stock split of its shares of common stock in order to increase the per share trading price of the Company's shares of common stock to satisfy the \$1.00 minimum bid price requirement for continued listing on the NASDAQ Global Market. The Company received notification from NASDAQ that as of September 11, 2012, the Company evidenced a closing bid price of its common stock price in excess of the \$1.00 minimum requirement for at least 10 consecutive trading days. Accordingly, the Company has regained compliance with Listing Rule 5450(a)(1). All share and per share information presented gives effect to the reverse stock split.

Termination and Settlement Agreement

On August 10, 2012, the Company entered into an agreement with Sinclair to terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid. The termination agreement includes a minimum royalty arrangement based on future net revenues, under which Sinclair will pay the Company a minimum of approximately \$1.0 million in quarterly installments over the three years ending on September 30, 2015. The operating results associated with the promotion and sale of Xclair®, Numoisyn® Liquid and Numoisyn® Lozenges are classified within Income (loss) from discontinued operations, net of tax in the consolidated statements of operations for all periods presented, and the associated assets and liabilities are classified within current assets of discontinued operations and current liabilities of discontinued operations, as appropriate, in the condensed consolidated balance sheets for all applicable periods presented. See *Note 3 Discontinued Operations* for further details.

Recent Accounting Pronouncement

During the first quarter of 2012, the Company adopted the accounting standard update regarding the presentation of comprehensive income. This update was issued to increase the prominence of items reported in other comprehensive income. The update requires that all nonowner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements and requires retrospective application of this standard. In connection with the adoption of this standard, the consolidated financial statements include a separate statement of comprehensive income.

**2                      Summary of Significant Accounting Policies**

*Use of Estimates*

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

F-20

---

Table of Contents

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

All of the Company's product revenues, which relate to the promotion and sales of the of Xclair®, Numoisyn® Liquid and Numoisyn® Lozenges, have been classified within loss from discontinued operations, net of tax, in the consolidated statement of operations for all periods presented. 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 current assets of discontinued operations).

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 and reported within loss from discontinued operations, net of tax. 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.

Table of Contents

Trade accounts receivable are included in current assets of discontinued operations 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 and are included in current assets of discontinued operations. 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. 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 loss from discontinued operation, net of tax on the consolidated statement of operations. There were no such write-downs during the years ended December 31, 2010 and December 31, 2011.

***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 6, 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***

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

F-22

---

Table of Contents

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*

Revenue from product sales relate to operations that have been discontinued. Accordingly, such revenue has been reported as a component of loss from discontinued operations, net of tax on the consolidated statements of operations. 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 and reported in loss from discontinued operations. 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.





Table of Contents

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.

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

Table of Contents

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	478,554	498,562	502,249
Restricted Stock and Restricted Stock Units	13,021	8,555	38,089
Convertible preferred stock	124,426	73,747	73,747
Common stock issuable to Kingsbridge	46,943		
Options issued in connection with the October 2010 financing		891,771	
Common stock warrants	1,006,338	1,429,313	1,973,431
Total shares excluded from calculation	1,669,282	2,901,948	2,587,516

***Derivative Instruments***

The accounting for derivatives requires significant judgments and estimates in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The use of different assumptions may have a material effect on the estimated fair value amount and the Company's results of operations.

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



Table of Contents

***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 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 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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Table of Contents**3 Discontinued Operations**

On August 10, 2012, the Company entered into an agreement with Sinclair to terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid.

Product revenue, cost of goods sold and selling, general and administrative costs related to the promotion and sales of the of Xclair®, Numoisyn® Liquid and Numoisyn® Lozenges have been reclassified from operating results from continuing operations to loss from discontinued operations in the consolidated statement of operations for all periods presented as follows:

	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
Product revenue	\$	910	\$	574	\$	699	\$ 3,021
Cost of goods sold		(545)		(418)		(360)	(1,752)
Selling, general and administrative		(1,907)		(1,287)		(979)	(8,688)
Goodwill and intangible impairment							(5,187)
Interest expense		(7)					(110)
<b>Loss from discontinued operations, net of tax</b>	\$	(1,549)	\$	(1,131)	\$	(640)	\$ (12,716)

The assets and liabilities associated with product promotion and sale have been classified within assets and liabilities of discontinued operations in the accompanying consolidated balance sheets:

	December 31, 2010		December 31, 2011	
<b>Current assets of discontinued operations:</b>				
Inventory	\$	174	\$	182
Accounts receivable		138		131
<b>Total current assets of discontinued operations</b>	\$	312	\$	313
<b>Current liabilities of discontinued operations:</b>				
Accounts payable	\$	133	\$	46
Returns provision		268		202
Accrued liabilities and other current liabilities		110		279
<b>Total current liabilities of discontinued operations</b>	\$	511	\$	527



Table of Contents

**4 Significant Contracts**

*Distribution, Licensing and Research Agreements*

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

Pursuant to the Daiichi Sankyo license under which the Company licenses certain patent rights for sapacitabine, its lead drug candidate, the Company is under an obligation to use reasonable endeavors to develop a product and obtain regulatory approval to sell a product and has agreed to pay Daiichi Sankyo an up-front fee, reimbursement for Daiichi Sankyo's enumerated expenses, milestone payments and royalties on a country-by-country basis. 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. As described in Note 3, each of the agreements covering the three products was terminated as of September 30, 2012. 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 had a minimum purchase obligation equivalent to the value of product purchased in the previous year. For the year ended December 31, 2011 this equated to \$0.2 million.

**5 Cash and Cash Equivalents**

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

**December 31,**

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

	<b>2010</b>	<b>2011</b>
	<b>\$000</b>	<b>\$000</b>
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

F-28

---

Table of Contents**6 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			Total \$000
	Level 1 \$000	Level 2 \$000	Level 3 \$000	
Cash equivalents	19,894			19,894
Warrants liability			51	51
Other derivatives			20	20
Total	19,894		71	19,965

***Warrants Liability***

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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:

F-29

---

Table of Contents

	December 31,	
	2010	2011
Exercise price	\$ 59.08	\$ 59.08
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 \$4.13 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:



Table of Contents

	<b>Level 3 \$000</b>
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

**7 Prepaid Expenses and Other Current Assets**

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

	<b>2010 \$000</b>	<b>December 31,</b>	<b>2011 \$000</b>
Research and development tax credit receivable	660		544
Prepayments	314		317
Other current assets	270		208
	1,244		1,069

**8 Property, Plant and Equipment**

Property, plant and equipment consisted of the following:

	<b>Useful lives in years from date of acquisition</b>	<b>2010 \$000</b>	<b>December 31,</b>	<b>2011 \$000</b>
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.

Table of Contents

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.

**9 Accrued and Other Current Liabilities**

Accrued and other current liabilities consisted of the following:

	2010 \$000	December 31, 2011 \$000
Accrued research and development	2,793	3,471
Other current liabilities	961	712
	3,754	4,183

**10 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**



Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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

F-32

---

Table of Contents

Rent expense, which includes lease payments related to the Company's research and development facilities and corporate headquarters and other rent related expenses, was \$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 6 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. As discussed in Note 3, the Company terminated the distribution agreements related to the ALIGN products effective September 30, 2012.

***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.

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

A Scheduling Order was entered February 2, 2012, at which time the court set significant dates, the remainder of which are the following: 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.

F-33

---

Table of Contents

**11 Stockholders Equity**

All share and per share information presented gives effect to the reverse stock split, which occurred on August 24, 2012.

*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 0.06079 shares of common stock for each share of Preferred Stock based on a price of \$164.50. During 2010, 833,671 shares of Preferred Stock were converted into 236,514 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 73,747 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 \$246.75, 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:

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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.

Table of Contents*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:

	<b>Year ended December 31, 2010</b>
Preferred shares exchanged	833,671
Common shares issued:	
At stated convertible option	50,679
Incremental shares issued under the exchange transaction	185,835
Total common shares issued	236,514

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 1,088,235 units, at an offering price of \$9.52 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 \$9.52 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 (\$6.23 per share) and \$2.5 million (\$4.62 per warrant) to common shares and warrants, respectively.

*October 2010 Private Placement*

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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 \$13.44 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 1,189,027 units at a price of \$12.78 per unit. The investors also had the right to acquire up to 594,513 additional units at a price of \$11.69 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 (\$7.49 per share), \$3.3 million (\$5.53 per warrant) and \$1.8 million (\$3.01 per optional unit) to common shares, warrants and the additional optional units, respectively.

Table of Contents

*January 2010 Registered Direct Financings*

On January 25, 2010, the Company completed the sale of 335,714 units in a registered direct offering at a purchase price of \$17.50 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 \$19.95 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 (\$13.51 per share) to common shares and \$0.9 million (\$9.03 per warrant) to the warrants.

On January 13, 2010, the Company completed the sale of 407,143 units in a registered direct offering to certain institutional investors. Each unit was sold at a purchase price of \$17.57 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 \$22.82 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 (\$13.65 per share) to common shares and \$0.9 million (\$9.24 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 571,429 units in a registered direct offering at a purchase price of \$5.95 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 \$7.00 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 \$7.00 per share of common stock. During the first quarter of 2010, 6,181 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.



Table of Contents

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 98,893 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 583,513 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 December 31, 2010, the Company sold 402,704 shares of its common stock to Kingsbridge under the CEFF, in consideration of aggregate proceeds of \$4.9 million. During the year ended December 31, 2009, the Company sold an aggregate of 179,289 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 151,773 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 \$4.13 per share at December 31, 2011 as compared to the common stock price of \$10.29 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:

<b>Issued in Connection With</b>	<b>Expiration Date</b>	<b>Common Shares Issuable</b>	<b>Weighted Average Exercise Price</b>
April 2006 stock issuance	2013	367,347	\$ 49.00
February 2007 stock issuance	2014	151,773	\$ 59.08
December 2007 CEFF	2013	14,285	\$ 9.80

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

July 2009 Series II stock issuance	2014	98,893	\$	7.00
January 2010 stock issuance	2015	101,785	\$	22.82
January 2010 stock issuance	2015	100,714	\$	19.95
October 2010 stock issuance	2015	594,513	\$	13.44
July 2011 stock issuance	2016	544,117	\$	9.52
Total		1,973,427	\$	22.96

F-37

---

Table of Contents*Exercise of Stock Options*

During 2010, there were 24,902 stock option exercises totaling approximately \$0.1 million. During 2011, 948 shares of common stock were issued from the exercise of stock options resulting in proceeds of approximately \$3,000.

**12 Stock-Based Compensation Arrangements**

All stock-based compensation information presented gives effect to the reverse stock split, which occurred on August 24, 2012.

ASC 718 requires compensation expense associated with share-based awards to be recognized over the requisite service period, which for the Company is the period between the grant date and the date the award vests or becomes exercisable. Most of the awards granted by the Company (and still outstanding), vest ratably over four years, with 1/4 of the award vesting one year from the date of grant and 1/48 of the award granted vesting each month thereafter. 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 \$000	Year ended December 31, 2010 \$000	Year ended December 31, 2011 \$000
Research and development	271	351	171
Selling, general and administrative	484	1,344	669
Discontinued operations	55	51	42
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

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

number of shares reserved under the 2006 Plans to 5.2 million shares of common stock from 3.0 million shares of common stock.

F-38

---

Table of Contents

During 2011, the Company granted approximately 28,500 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 0.1 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 32,000 options to employees and directors with a grant date fair value of \$0.1 million, of which \$28,000 was expensed in 2009. The weighted average grant-date fair value of options granted during 2011, 2010, and 2009 was \$8.05, \$9.80 and \$2.73 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 948 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 24,901 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 2,454 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:

<b>Cyclacel Pharmaceuticals, Inc.</b>	<b>Number of options outstanding</b>	<b>Weighted average exercise price</b>	<b>Weighted average remaining contractual term (years)</b>	<b>Aggregate intrinsic value</b>
Options outstanding at December 31, 2009	478,554	\$ 29.47	7.76	\$ 698
Granted	86,758	\$ 12.74		
Exercised	(24,901)	\$ 3.01		
Cancelled/forfeited	(41,849)	\$ 31.78		
Options outstanding at December 31, 2010	498,562	\$ 27.72	7.22	\$ 938
Granted	28,500	\$ 10.64		
Exercised	(948)	\$ 2.87		
Cancelled/forfeited	(23,865)	\$ 40.53		
Options outstanding at December 31, 2011	502,249	\$ 26.11	6.44	\$ 140
Unvested at December 31, 2011	90,237	\$ 12.11	8.75	\$ 3
Vested and exercisable at December 31, 2011	412,012	\$ 29.19	5.93	\$ 136

Table of Contents

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

Exercise price (\$)	Number outstanding	Weighted Average remaining contractual life	Number exercisable
2.03 13.86	217,130	7.77	144,770
15.05 34.65	53,983	7.15	36,713
36.82 40.67	72,602	5.82	71,996
44.10 48.65	127,320	4.57	127,319
54.60 105.00	31,214	4.93	31,214
	502,249		412,012

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	\$2.73	\$9.80	\$8.05

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.

Table of Contents

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 948 options during 2011. The Company received approximately \$0.1 million from the exercise of 24,902 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 7,142 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:

	<b>Restricted Stock</b>	<b>Weighted Average Grant Date Value Per Share</b>
Non-vested at December 31, 2009	5,204	\$ 3.08
Vested	(1,786)	\$ 3.08
Non-vested at December 31, 2010	3,418	\$ 3.08
Vested	(1,786)	\$ 3.08
Non-vested at December 31, 2011	1,632	\$ 3.08

Table of Contents*Restricted Stock Units*

The Company issued 13,100 and 34,000 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	7,812	\$ 3.08
Vested	(2,670)	\$ 3.08
Non-vested at December 31, 2010	5,142	\$ 3.08
Granted	34,000	\$ 5.81
Vested	(2,679)	\$ 3.08
Non-vested at December 31, 2011	36,463	\$ 5.60

**13 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 \$000	Sales tax assessment \$000	Total \$000
Balance at December 31, 2009	1,062		1,062
Cash payments	(1,104)		(1,104)



Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Adjustments for lease-related deferred expenses and liabilities	42	42
Balance at December 31, 2010		

F-42

---

Table of Contents**14 Employee Benefit Plans****Pension Plan**

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

**15 Taxes**

Loss before taxes is comprised of the following components for the years ended December 31, 2009, 2010 and 2011:

	Year ended December 31, 2009 \$000	Year ended December 31, 2010 \$000	Year ended December 31, 2011 \$000
<b>Net loss from continuing operations before taxes:</b>			
Domestic	(1,464)	(3,533)	904
Foreign	(17,505)	(12,014)	(16,072)
Net loss from continuing operations before taxes	(18,969)	(15,547)	(15,168)
<b>Loss from discontinued operations before taxes:</b>			
Domestic	(1,549)	(1,131)	(640)
Loss from discontinued operations before taxes	(1,549)	(1,131)	(640)
<b>Total loss before taxes:</b>			
Domestic	(3,013)	(4,664)	264
Foreign	(17,505)	(12,014)	(16,072)
<b>Loss before taxes</b>	<b>(20,518)</b>	<b>(16,678)</b>	<b>(15,808)</b>



Table of Contents

The benefit for income taxes consists of the following:

	Year ended December 31, 2009 \$000	Year ended December 31, 2010 \$000	Year ended December 31, 2011 \$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 \$000	Year ended December 31, 2010 \$000	Year ended December 31, 2011 \$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 in tax rates	814	570	2,669
	(948)	(657)	(565)

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

	2010 \$000	December 31, 2011 \$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

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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

Table of Contents

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.

**16 Geographic Information**

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

	Year ended December 31, 2009 \$000	Year ended December 31, 2010 \$000	Year ended December 31, 2011 \$000
<b>Revenue</b>			
United Kingdom	1	112	
<b>Total Revenue</b>	1	112	
<b>Net loss</b>			
United States:			
Continuing operations	(1,458)	(3,531)	565
Discontinued operations	(1,549)	(1,131)	(640)
Total United States	(3,007)	(4,662)	(75)
United Kingdom	(16,563)	(11,359)	(15,168)
<b>Total Net Loss</b>	(19,570)	(16,021)	(15,243)

Table of Contents

	2010 \$000	December 31, 2011 \$000
<b>Total Assets</b>		
United States:		
Continuing operations	29,743	20,402
Discontinued operations	312	313
Total United States	30,055	20,715
United Kingdom	1,404	5,283
<b>Total Assets</b>	<b>31,459</b>	<b>25,998</b>
<b>Long Lived Assets, net</b>		
United States:		
Continuing operations	161	45
Discontinued operations		
Total United States	161	45
United Kingdom	247	122
<b>Total Long Lived Assets, net</b>	<b>408</b>	<b>167</b>

Table of Contents

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

**CONDENSED CONSOLIDATED BALANCE SHEETS**

(In \$000s, except share amounts)

	December 31, 2011	September 30, 2012 (Unaudited)
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 24,449	\$ 17,837
Prepaid expenses and other current assets	1,069	1,235
Current assets of discontinued operations	313	881
<b>Total current assets</b>	<b>25,831</b>	<b>19,953</b>
Property, plant and equipment (net)	167	140
Long-term assets of discontinued operations		433
<b>Total assets</b>	<b>\$ 25,998</b>	<b>\$ 20,526</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,717	\$ 1,642
Accrued liabilities and other current liabilities	4,183	4,127
Economic rights		1,070
Other liabilities measured at fair value	71	20
Current liabilities of discontinued operations	527	438
<b>Total current liabilities</b>	<b>6,498</b>	<b>7,297</b>
<b>Total liabilities</b>	<b>6,498</b>	<b>7,297</b>
<b>Stockholders equity:</b>		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2011 and September 30, 2012; 1,213,142 shares issued and outstanding at December 31, 2011 and September 30, 2012. Aggregate preference in liquidation of \$13,708,505 and \$14,254,419 at December 31, 2011 and September 30, 2012, respectively	1	1
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2011 and September 30, 2012; 7,745,779 and 8,434,292 shares issued and outstanding at December 31, 2011 and September 30, 2012, respectively	8	8
Additional paid-in capital	276,498	278,655
Accumulated other comprehensive loss	57	51
Deficit accumulated during the development stage	(257,064)	(265,486)
<b>Total stockholders equity</b>	<b>19,500</b>	<b>13,229</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 25,998</b>	<b>\$ 20,526</b>

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



Table of Contents

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

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from August 13, 1996 (inception) to September 30, 2012
	2011	2012	2011	2012	
<b>Revenues:</b>					
Collaboration and research and development revenue	\$	\$	\$	\$	\$ 3,100
Grant revenue		38		64	3,712
Total revenues		38		64	6,812
<b>Operating expenses:</b>					
Research and development	2,066	1,532	7,005	4,596	190,395
General and administrative	1,814	2,028	5,136	5,917	86,748
Goodwill and intangible impairment					2,747
Restructuring costs					2,634
<b>Total operating expenses</b>	<b>3,880</b>	<b>3,560</b>	<b>12,141</b>	<b>10,513</b>	<b>282,524</b>
Operating loss	(3,880)	(3,522)	(12,141)	(10,449)	(275,712)
<b>Other income (expense):</b>					
Costs associated with aborted 2004 IPO					(3,550)
Payment under guarantee					(1,652)
Change in valuation of Economic Rights		(63)		27	27
Change in valuation of other liabilities measured at fair value	440	1	643	51	6,378
Foreign exchange (losses)/gains	28	6	(59)	237	(4,060)
Interest income	9	5	33	17	13,742
Interest expense					(4,567)
Other income		1		77	77
Total other income (expense)	477	(50)	617	409	6,395
<b>Loss from continuing operations before taxes</b>	<b>(3,403)</b>	<b>(3,572)</b>	<b>(11,524)</b>	<b>(10,040)</b>	<b>(269,317)</b>
Income tax benefit	126	419	443	714	19,158
<b>Net loss from continuing operations</b>	<b>(3,277)</b>	<b>(3,153)</b>	<b>(11,081)</b>	<b>(9,326)</b>	<b>(250,159)</b>
<b>Discontinued operations:</b>					
Income (loss) from discontinued operations, net of tax of \$0 for all periods presented	(168)	1,263	(504)	904	(11,812)
<b>Net loss</b>	<b>(3,445)</b>	<b>(1,890)</b>	<b>(11,585)</b>	<b>(8,422)</b>	<b>(261,971)</b>
Dividends on preferred ordinary shares					(38,123)
Deemed dividend on convertible exchangeable preferred shares					(3,515)
Dividend on convertible exchangeable preferred shares	(182)	(182)	(546)	(546)	(4,203)
<b>Net loss applicable to common shareholders</b>	<b>\$ (3,627)</b>	<b>\$ (2,072)</b>	<b>\$ (12,131)</b>	<b>\$ (8,968)</b>	<b>\$ (307,812)</b>

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Net loss per share, continuing operations					
Basic and diluted	\$	(0.45)	\$	(0.40)	\$ (1.66) \$ (1.20)
Net income (loss) per share, discontinued operations					
Basic and diluted	\$	(0.02)	\$	0.15	\$ (0.07) \$ 0.11
Net loss per share	\$	(0.47)	\$	(0.25)	\$ (1.73) \$ (1.09)
Weighted average common shares outstanding					
		<b>7,673,096</b>		<b>8,429,269</b>	<b>6,997,391</b> <b>8,227,721</b>

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

Table of Contents

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

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

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

**(Unaudited)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>		<b>Period from</b>
	<b>September 30,</b>		<b>September 30,</b>		<b>August 13, 1996</b>
	<b>2011</b>	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>(inception) to</b>
					<b>September 30,</b>
					<b>2012</b>
<b>Comprehensive loss</b>	(3,435)	(1,917)	(11,567)	(8,428)	(261,920)

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

Table of Contents

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

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

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

	2011	Nine Months Ended September 30, 2012	2012	Period from August 13, 1996 (inception) to September 30, 2012
<b>Cash flows from operating activities:</b>				
Net loss	\$ (11,585)	\$ (8,422)	\$	(261,971)
Adjustments to reconcile net loss to net cash used in operating activities:				
Accretion of interest on notes payable, net of amortization of debt premium				100
Amortization of investment premiums, net				(2,297)
Change in valuation of Economic Rights			(27)	(27)
Change in valuation of other liabilities measured at fair value	(643)	(51)		(6,378)
Depreciation and amortization	250	45		12,600
Amortization of intangible assets				886
Fixed asset impairment				221
Unrealized foreign exchange loss	(29)			7,747
Deferred revenue				(98)
Compensation for warrants issued to non-employees				1,215
Shares issued for IP rights				446
(Gain) loss on disposal of property, plant and equipment			(62)	38
Goodwill and intangibles impairment				7,934
Stock based compensation	677	287		19,310
Provision for restructuring				1,779
Amortization of issuance costs of Preferred Ordinary C shares				2,517
Transaction costs on sale of Economic Rights			33	33
Gain on termination of distribution agreement			(1,192)	(1,192)
Changes in operating assets and liabilities:				
Prepaid expenses, inventory and other current assets	450	25		(33)
Accounts payable, accrued liabilities and other current liabilities	162	(220)		(5,533)
<b>Net cash used in operating activities</b>	<b>(10,718)</b>	<b>(9,584)</b>		<b>(222,703)</b>
<b>Investing activities:</b>				
Purchase of ALIGN				(3,763)
Purchase of property, plant and equipment	(6)	(12)		(8,849)
Proceeds from sale of property, plant and equipment			62	225
Purchase of short-term investments				(156,657)
Redemptions of short-term investments, net of maturities				162,729
Net cash provided by (used in) investing activities	(6)	50		(6,315)
<b>Financing activities:</b>				
Payment of capital lease obligations				(3,719)
Proceeds from issuance of ordinary and preferred ordinary shares, net of issuance costs				121,678
	9,258	2,886		94,557

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Proceeds from issuance of common stock, warrants and economic rights, net of issuance costs

Net proceeds from stock options and warrants exercised	3	48	221
Payment of preferred stock dividend	(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			17,915
Costs associated with stock purchase			(1,951)
Net cash (used in) provided by financing activities	8,897	2,934	246,393
Effect of exchange rate changes on cash and cash equivalents	7	(12)	462
Net increase (decrease) in cash and cash equivalents	(1,820)	(6,612)	17,837
Cash and cash equivalents at beginning of period	29,495	24,449	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 27,675</b>	<b>\$ 17,837</b>	<b>\$ 17,837</b>

**Supplemental disclosure of cash flows information:**

Cash received during the period for:

Interest	20	10	11,756
Taxes	688	556	18,763

Cash paid during the period for:

Interest			(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

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

Table of Contents

**CYCLACEL PHARMACEUTICALS, INC.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION**

*Nature of Operations*

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 development pipeline of novel drug candidates.

Cyclacel's clinical development priorities are focused on sapacitabine, an orally available, cell cycle modulating nucleoside analogue.

Sapacitabine is being evaluated in the SEAMLESS Phase 3 trial being conducted under a Special Protocol Assessment (SPA) agreement with the US Food and Drug Administration (FDA) for the front-line treatment of acute myeloid leukemia (AML) in the elderly and in Phase 2 studies for AML, myelodysplastic syndromes (MDS), non-small cell lung cancer (NSCLC) and chronic lymphocytic leukemia. Sapacitabine is also being evaluated in a Phase 1/2 study in combination with seliciclib, our second clinical candidate.

The Company has ongoing clinical programs with seliciclib in NSCLC and nasopharyngeal cancer (NPC) and once data becomes available and is reviewed, the Company will determine the feasibility of pursuing further development and/or partnering these assets.

In addition, until September 30, 2012 the Company marketed directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia pursuant to a distribution agreement with Sinclair Pharmaceuticals Limited (Sinclair). On August 10, 2012, the Company entered into an agreement with Sinclair to terminate these distribution agreements, effective September 30, 2012. See *Recent Developments* below and *Note 3 Discontinued Operations* for further details.

As a development stage enterprise, substantially all efforts of the Company to date have been devoted to performing research and development, conducting clinical trials, developing and acquiring intellectual property, raising capital and recruiting and training personnel. The Company currently anticipates that its cash and cash equivalents of approximately \$17.8 million as of September 30, 2012 are sufficient to meet its anticipated short-term working capital needs and to fund its on-going sapacitabine clinical trials for at least the next twelve months. However, the Company cannot be certain that it will be able to raise sufficient funds to complete the development and commercialize any of its product candidates currently in clinical development, should they succeed.

*Basis of Presentation*

The condensed consolidated balance sheet as of September 30, 2012, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2012 and 2011, the condensed consolidated statement of cash flows for the nine months ended September 30, 2012 and 2011 and the condensed consolidated statement of operations, comprehensive loss and cash flows for the period from August 13, 1996 (inception) to September 30, 2012, and all related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2011 is derived from the audited consolidated financial statements included in the 2011 Annual Report on Form 10-K filed with the Securities and Exchange Commission ( SEC ). The condensed consolidated financial statements are presented on the basis of accounting principles that are generally accepted in the United States ( GAAP ) for interim financial information and in accordance with the rules and regulations of the SEC. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States for a complete set of financial statements. In the opinion of management, all adjustments, which include normal recurring adjustments necessary to present fairly the condensed consolidated balance sheet as of September 30, 2012, and the results of operations, comprehensive loss for the three and nine months ended September 30, 2012 and 2011 and for the period from August 13, 1996 (inception) to September 30, 2012, and the consolidated statements of cash flows for the nine months ended September 30, 2012 and 2011 and for the period from August 13, 1996 (inception) to September 30, 2012, have been made. The interim results for the three months ended September 30, 2012 are not necessarily indicative of the results to be expected for the year ending December 31, 2012 or for any other year. Certain prior period amounts have been reclassified to conform to current period presentation. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2011, included in the Company s Annual Report on Form 10-K filed with the SEC.

Table of Contents

**Recent Developments**

Reverse Stock Split

On August 24, 2012, the Company effected a 1-for-7 reverse stock split of its shares of common stock in order to increase the per share trading price of the Company's shares of common stock to satisfy the \$1.00 minimum bid price requirement for continued listing on the NASDAQ Global Market. The Company received notification from NASDAQ that as of September 11, 2012, the Company evidenced a closing bid price of its common stock price in excess of the \$1.00 minimum requirement for at least 10 consecutive trading days. Accordingly, the Company has regained compliance with Listing Rule 5450(a)(1). All share and per share information presented in this Form 10-Q gives effect to the reverse stock split.

Termination and Settlement Agreement

On August 10, 2012, the Company entered into an agreement with Sinclair to terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid. The termination agreement includes a minimum royalty arrangement based on future net revenues, under which Sinclair will pay the Company a minimum of approximately \$1.0 million in quarterly installments over the three years ending on September 30, 2015. The operating results associated with the promotion and sale of Xclair®, Numoisyn® Liquid and Numoisyn® Lozenges are classified within Income (loss) from discontinued operations, net of tax in the consolidated statements of operations for all periods presented, and the associated assets and liabilities are classified within current assets of discontinued operations, long-term assets of discontinued operations, and current liabilities of discontinued operations, as appropriate, in the condensed consolidated balance sheets for all applicable periods presented. See *Note 3 Discontinued Operations* for further details.

Preferred Stock Dividend

On September 12, 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 third quarter of 2012 that would have otherwise been payable on November 1, 2012.



Table of Contents

**Subsequent Developments**

Stock Purchase Agreement

On December 14, 2012, the Company entered into a common stock purchase agreement with Aspire Capital Fund, LLC ( Aspire ). Upon execution of the Purchase Agreement, Aspire purchased 158,982 shares of common stock for an aggregate purchase price of \$1.0 million based the closing price of the Company s common stock December 13, 2012, the date upon which the business terms were agreed. Under the terms of the Purchase Agreement, Aspire has committed to purchase up to an additional 1,454,877 shares from time to time as directed by the Company over the next two years at prices derived from the market prices on or near the date of each sale. However, such commitment is limited to an additional \$19.0 million of share purchases. In consideration for entering into the Purchase Agreement, concurrent with the execution of the Purchase Agreement, the Company issued to 74,458 shares of its common stock to Aspire for no consideration.

Grant Award

In November 2012, the Company was awarded a grant of approximately \$1.9 million from the UK Government s Biomedical Catalyst to complete an Investigational New Drug ( IND ) directed preclinical development of CYC065, a novel orally available, second generation, CDK inhibitor.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Consolidation*

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries for the indicated periods. All significant intercompany transactions and balances have been eliminated.

*Use of Estimates*

The preparation of financial statements in accordance with United States 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 estimated levels of product returns, and inputs used to determine stock-based compensation expense and the fair value of financial instruments, such as Economic Rights and other liabilities measured at fair value. 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.

***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. Cash and cash equivalents includes cash, money market funds and commercial paper.

***Fair Value of Financial Instruments***

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, Economic Rights, and other liabilities measured at fair value. 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. Economic Rights and other liabilities measured at fair value employ applicable inputs as described in *Note 4 - Fair Value Measurements*.

Table of Contents

***Revenue Recognition***

*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. The Company had no such collaboration revenues for the three and nine months ended September 30, 2011 and 2012.

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 previously recognized are refundable if the relevant research effort is not successful. The Company had no such research and development revenue for the three and nine months ended September 30, 2011 and 2012.

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. All grants earned and received are not refundable. The Company had deferred grant revenue of approximately \$10,000, which is included in accrued liabilities and other current liabilities, as of September 30, 2012. The Company had no such deferred revenue at December 31, 2011.

***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 developing the Company's product candidates, including upfront fees and milestones paid to parties from whom the Company licenses certain intellectual property, compensation and other expenses for research

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

and development personnel, supplies and development materials, costs for consultants and related contract research, facility costs, amortization of purchased technology and depreciation. Expenditures relating to research and development are expensed as incurred.

F-54

---

Table of Contents

***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 remeasurement of foreign-currency denominated intercompany loans that are of a long-term-investment nature, are recorded in other comprehensive income.

***Fair Value Measurements***

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, for quoted prices (unadjusted) in active markets for identical assets or liabilities, to Level 3, for unobservable inputs (see *Note 4 - Fair Value Measurements*). 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.

***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's management has established a full valuation allowance against its deferred tax assets based on the determination that it is not more likely than not that the Company will recognize the benefits of those assets.

The Company applies the guidance codified in ASC 740, *Income taxes* (ASC 740) related to accounting for uncertainty in income taxes. 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.

The Company records income tax benefits related to research and development tax credits, which will be claimed from H. M. Revenue & Customs, the United Kingdom's taxation and customs authority, with respect to qualifying research and development costs incurred in the same accounting 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 is described more fully in *Note 7 - Stock-Based Compensation Arrangements*. The Company accounts for these awards under ASC 718, *Compensation - Stock Compensation* ( ASC 718 ).

Table of Contents

ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on the 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 awards 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 the Company's share price, the anticipated exercise behavior of its employees, interest rates, and dividend yields. These variables are projected based on the Company's 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.

*Segments*

The Company has determined its reportable segments in accordance with ASC 280, *Segment Reporting* (ASC 280) and related disclosures about products, services, geographic areas and major customers. 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.

*Net Loss per Common Share*

The Company calculates net loss per common share in accordance with ASC Topic 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. All share and per share information presented gives effect to the reverse stock split, which occurred on August 24, 2012. 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.

	September 30, 2011	September 30, 2012
Stock options	447,025	480,415
Unvested restricted stock and restricted stock units	9,671	40,121
Convertible preferred stock	73,747	73,747
Contingently issuable common stock and common stock warrants associated with Economic Rights		435,187
Common stock warrants	834,800	1,973,431
Total shares excluded from calculation	1,365,243	3,002,901

Table of Contents**Comprehensive Income (Loss)**

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

**3. DISCONTINUED OPERATIONS**

On August 10, 2012, the Company entered into an agreement with Sinclair to terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid.

Product revenue, cost of goods sold and selling, general and administrative costs related to the promotion and sales of the of Xclair®, Numoisyn® Liquid and Numoisyn® Lozenges have been reclassified from operating results from continuing operations to income (loss) from discontinued operations in the consolidated statement of operations for all periods presented as follows:

	Three Months Ended		Nine Months Ended		Period from August 13, 1996 (inception) to September 30, 2012 (Unaudited)
	September 30,		September 30,		
	2011 (Unaudited)	2012 (Unaudited)	2011 (Unaudited)	2012 (Unaudited)	
Product revenue	\$ 164	\$ 302	\$ 524	\$ 583	\$ 3,604
Cost of goods sold	(95)	(110)	(273)	(293)	(2,045)
Selling, general and administrative	(237)	(121)	(755)	(578)	(9,266)
Goodwill and intangible impairment					(5,187)
Interest expense					(110)
Gain on termination of distribution agreements		1,192		1,192	1,192
<b>Income (loss) from discontinued operations, net of tax of \$0 for all periods presented</b>	(168)	1,263	(504)	904	(11,812)

The approximately \$0.9 million present value of the estimated \$1.0 million of minimum royalty payments the Company will receive over the next three years ending September 30, 2015 arising from the termination and settlement agreement and the recognition of approximately \$0.3 million associated with a \$0.3 million product returns provision liability for which an offsetting asset has been recorded based on our rights under the termination and settlement agreement result in a \$1.2 million gain on termination of the distribution agreements for the three and nine months ended September 30, 2012.



Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

The assets and liabilities associated with product promotion and sale have been classified within assets and liabilities of discontinued operations in the accompanying consolidated balance sheets:

F-57

---

Table of Contents

	December 31, 2011 (Unaudited)	September 30, 2012 (Unaudited)
<b>Current assets of discontinued operations:</b>		
Inventory	\$ 182	\$
Short term portion of minimum royalty arrangement receivable, net		423
Returns indemnification receivable		336
Accounts receivable	131	122
<b>Total current assets of discontinued operations</b>	<b>313</b>	<b>881</b>
<b>Long-term assets of discontinued operations:</b>		
Long-term portion of minimum royalty arrangement receivable, net		433
<b>Total assets of discontinued operations</b>	<b>313</b>	<b>1,314</b>
<b>Current liabilities of discontinued operations:</b>		
Accounts payable	\$ 46	\$
Returns provision	202	336
Accrued liabilities and other current liabilities	279	102
<b>Total current liabilities of discontinued operations</b>	<b>\$ 527</b>	<b>\$ 438</b>

**4. 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 considers counterparty credit risk in its assessment 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:



Table of Contents

	Level 1 \$000	Level 2 \$000	Level 3 \$000	Total \$000
<b>ASSETS</b>				
Cash equivalents	19,894			19,894
Total assets	19,894			19,894
<b>LIABILITIES</b>				
Other liabilities measured at fair value:				
Warrants liability			51	51
Scottish Enterprise agreement			20	20
Other liabilities measured at fair value			71	71
Total liabilities			71	71

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 September 30, 2012:

	Level 1 \$000	Level 2 \$000	Level 3 \$000	Total \$000
<b>ASSETS</b>				
Cash equivalents		14,592		
Total assets		14,592		
<b>LIABILITIES</b>				
Economic rights			1,070	1,070
Other liabilities measured at fair value:				
Warrants liability				
Scottish Enterprise agreement			20	20
Other liabilities measured at fair value			20	20
Total liabilities			1,090	1,090

The following table reconciles the beginning and ending balances of Level 3 inputs for the nine months ended September 30, 2012:

Table of Contents

	<b>Level 3 \$000</b>
Balance as of December 31, 2011	71
Sale of Economic Rights	1,097
Change in valuation of Economic Rights	(27)
Change in valuation of warrants liability	(51)
Balance as of September 30, 2012	1,090

***Economic Rights***

On March 22, 2012, the Company entered into a financing agreement with certain existing institutional stockholders. Under the terms of the agreement, investors received contractual rights to receive cash equal to 10% of any future litigation settlement related to the specified intellectual property, subject to a cap. In certain defined situations, the Company may have to issue either additional common shares or warrants (Collectively, the Economic Rights ).

The Economic Rights are accounted for as a derivative financial instrument under ASC 815, *Derivative financial instruments* ( ASC 815 ), and are measured at fair value. Changes in fair value are recognized in earnings. The fair value of the Economic Rights has been estimated using a decision-tree analysis method. This is an income-based method that incorporates the expected benefits, costs and probabilities of contingent outcomes under varying scenarios. Each scenario within the decision-tree is discounted to the present value using the company's credit adjusted risk-free rate and ascribed a weighted probability to determine the fair value.

The Company has concluded the fair value of this liability was approximately \$1.1 million as of September 30, 2012, respectively. The fair value of the Economic Rights increased approximately \$0.1 million and decreased \$27,000 for the three months and nine months ended September 30, 2012, respectively. Decreases and increases in the valuation of Economic Rights are recognized in the consolidated statement of operations as gains and losses, respectively.

The most significant inputs in estimating the fair value of this liability are:

(i) The Company's credit adjusted risk-free rate, which has been derived from the observable returns on debt for more developed pharmaceuticals companies, adjusted for the Company's risk profile.

(ii) The amount of the return to the investors, which will vary depending on:

a. The outcome of the litigation, including consideration of whether the litigation may be resolved in a jury trial or settled out of court;

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

b. The amount of the settlement or award, which the Company has estimated predominantly based on observable royalty rates arising from the settlement of other cases of intellectual property litigation; and

c. The form of the settlement or award.

(iii) The projected timing of the cash flows to the investors, which could vary between several months to several years depending upon whether the litigation is settled, when the court may decide the case, whether any appeal is made on any court decision and the form of any settlement or award.

F-60

---

Table of Contents

- (iv) The number of contingent warrants that could be issued, which is based on a formula.

The decision-tree analysis model used to calculate the fair value of the derivative requires the probability of alternative scenarios to be determined at a series of decision points. Each scenario may contain more than one decision point resulting in further scenarios. Therefore, the probability estimates made by management at each decision point are a significant input to the valuation model.

All of these inputs are unobservable inputs, which have an interrelated effect on the fair value of the derivative. It is not possible to evaluate the impact on the fair value of each factor in combination. However, generally the fair value of the derivative liability will increase, (i) the higher the value of the expected settlement or award, (ii) the lower the discount rate employed and (iii) the more likely it is that a settlement or award will be made. The fair value of the derivative liability will decrease if the timing of settlement is delayed, the expected settlement decreases, or anticipated litigation costs increase. The impact on the fair value of the derivative liability related to the probability of whether the litigation is settled prior to the court hearing or whether a settlement award is made by the court and the form of the settlement will depend on the other factors above and cannot be estimated in isolation.

The decision-tree analysis model has been performed by valuation specialists, based on inputs provided by the Company and other sources. At each reporting period, the inputs to the model will be evaluated to determine whether any adjustments are appropriate, and to reflect changes in the time value of the expected cash flows.

The Company used the following assumptions to calculate the value of the Economic Rights:

	<b>March 22, 2012</b>	<b>September 30, 2012</b>
Probability of unsuccessful/successful outcomes	25% - 75%	25% - 75%
Amount of award or settlement (1)	\$10.0 million - \$20.0 million	\$10.0 million - \$20.0 million
Discount rate	16%	16%
Timing of cash flows	0.75 2.27 years	0.25 1.77 years
Royalty rate	6%	6%
Litigation expenses	\$1.0 million \$3.0 million	\$1.0 million \$3.0 million

- (1) Assumptions take into consideration the cap on the amount that the Company would have to pay investors in the event of an award or settlement.

***Other Liabilities Measured at Fair Value***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. As of September 30, 2012, the fair value of the warrants is nil based on the high exercise price of the warrants relative to the Company's stock price at September 30, 2012 and the term of 1.38 years. The fair value of the warrant is remeasured each reporting period, with a gain or loss recognized in the consolidated statement of operations. Such gains or losses will continue to be reported until the warrants are exercised or expired. The Company used the Black-Scholes option-pricing model to value the warrants.



Table of Contents

The Company recognized the change in the value of warrants as a gain on the consolidated statement of operations of \$0.4 million and approximately \$1,000 for the three months ended September 30, 2011 and 2012, respectively. The Company recognized a gain of \$0.6 million and approximately \$51,000 for the nine months ended September 30, 2011 and 2012, respectively.

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 and \$6.5 million at September 30, 2012) 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, the amount potentially payable to SE would have been approximately £3.8 million (approximately \$5.9 million) and approximately £3.8 million (approximately \$6.2 million) at December 31, 2011 and September 30, 2012, respectively.

This arrangement is accounted for as a liability under ASC Topic 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 31, 2011 and September 30, 2012, respectively. 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. At both December 31, 2011 and September 30, 2012, the Company used a scenario analysis model to arrive at the fair value of the Scottish Enterprise Agreement and assumed a 30% probability of falling below a minimum staffing level and a 1% probability that the occurrence of such an event would not be cured within the prescribed time period. At each reporting period, the inputs used to determine the fair value of the liability will be evaluated to determine whether adjustments are appropriate. Changes in the value of this liability are recorded in the consolidated statement of operations.

Table of Contents**5. PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets consist of the following:

	December 31, 2011	(\$000s)	September 30, 2012
Research and development tax credit receivable	541		732
Prepayments	317		318
Other current assets	211		185
Total prepaid expenses and other current assets	1,069		1,235

**6. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES**

Accrued and other current liabilities consisted of the following:

	December 31, 2011	(\$000s)	September 30, 2012
Accrued research and development	3,471		3,335
Other current liabilities	712		792
	4,183		4,127

During the nine months ended September 30, 2012, the Company recorded out of period reversals of pre-clinical expense accruals of \$0.4 million as a decrease to accrued liabilities and other current liabilities on the consolidated balance sheets and as a decrease to research and development expenses on the consolidated statements of operations.

**7. STOCK BASED COMPENSATION**

All share and per share information presented gives effect to the reverse stock split, which occurred on August 24, 2012.

Stock based compensation has been in the consolidated statement of operations for the three and six months ended September 30, 2011 and 2012 as shown in the following table:

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

	For the three months ended September 30,		For the nine months ended September 30,	
	2011	2012	2011	2012
	(\$000s)			
Research and development	39	16	130	49
General and administrative	171	59	515	202
Income (loss) from discontinued operations, net of tax	11	1	32	36
Stock-based compensation costs before income taxes	221	76	677	287

At the Company's annual shareholder meeting on May 23, 2012, the stockholders approved and amended the number of shares reserved under the 2006 Plan to 10,000,000 shares of the Company's common stock, up from 5,200,000 shares. Stock option awards granted under the 2006 Plan have a maximum life of 10 years and generally vest over a four-year period from the date of grant.

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

Table of Contents

A summary of activity for the options under the Company's 2006 Plan for the nine months ended September 30, 2012 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$000s)
Options outstanding at December 31, 2011	502,253	\$ 26.11	6.44	140
Granted	33,571	\$ 3.29		
Exercised	(15,438)	\$ 3.06		
Expired				
Cancelled / forfeited	(39,970)	\$ 20.03		
Options outstanding at September 30, 2012	480,416	\$ 25.76	5.84	212
Unvested at September 30, 2012	77,607	\$ 9.00	8.67	36
Vested and exercisable at September 30, 2012	402,809	\$ 28.99	5.30	176

ASC 718 requires compensation expense associated with share-based awards to be recognized over the requisite service period, which for the Company is the period between the grant date and the date the award vests or becomes exercisable. Most of the awards granted by the Company (and still outstanding), vest ratably over four years, with 1/4 of the award vesting one year from the date of grant and 1/48 of the award vesting each month thereafter. However, certain awards made to executive officers vest over three to five years, depending on the terms of their employment with the Company. In addition, recent awards made to rank-in-file employees vest ratably over three to four years, with 1/36 to 1/48 of the award vesting each month.

The Company estimates the grant date fair value of stock option awards using the Black-Scholes option-pricing model with the following assumptions for stock option grants to employees and directors for the nine months ended September 30, 2011 and 2012:

	For the nine months ended September 30,	
	2011	2012
Expected term	5 6 yrs.	6 yrs.
Risk free interest rate	1.47 2.29%	0.95%
Expected volatility	93 99%	98%
Expected dividend yield over expected term		
Resulting weighted average grant fair value	\$8.05	\$2.52

Table of Contents

There were 28,500 and 33,571 options granted during the nine months ended September 30, 2011 and 2012, respectively. For grants made during the nine months ended September 30, 2011 and 2012, the expected term assumption was estimated using past history of early exercise behavior and estimated expectations of future exercise behavior. Starting with the December 2010 annual grants to the Company's employees, the Company began to rely exclusively on its historical volatility as an input to the option pricing model as the Company's management believes that this rate will be representative of future volatility over the expected term of the options. Prior to December 2010, because the Company had been publicly traded for a limited period, the expected volatility assumption was based on the historical volatility of peer companies over the expected term of the option awards.

ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. This analysis is evaluated quarterly and the forfeiture rate adjusted as necessary. Ultimately, the actual expense recognized over the requisite service period is based on only those shares that vest.

Estimates of pre-vesting option forfeitures are based on the Company's experience. For outstanding options, the Company uses a forfeiture rate of 0-30% depending on when and to whom the options are granted. The Company adjusts its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and may impact the amount of compensation expense to be recognized in future periods.

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

During the nine months ended September 30, 2011, 948 stock options were exercised resulting in approximately \$3,000 of cash proceeds to the Company. During the nine months ended September 30, 2012, there were 15,438 stock options exercised totaling approximately \$48,000 in proceeds. As the Company presently has tax loss carry forwards from prior periods and expects to incur tax losses during the year ended December 31, 2012, the Company is not able to benefit from the deduction for exercised stock options in the current reporting period.

*Restricted Stock*

In November 2008, the Company issued 7,143 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. Summarized information for the restricted stock grant for the nine months ended September 30, 2012 is as follows:

	<b>Restricted Stock</b>	<b>Weighted Average Grant Date Value Per Share</b>
Non-vested at December 31, 2011	1,632	\$ 3.08
Vested	(1,341)	\$ 3.08
Non-vested at September 30, 2012	291	\$ 3.08



Table of Contents*Restricted Stock Units*

In November 2008 and December 2011, respectively, the Company issued 13,100 and 34,000 restricted stock units to senior executives. Each unit entitles the holder to receive a share of the Company's common stock.

During the first quarter of 2012, the Company issued approximately 12,281 restricted stock units to employees as part of its annual grant.

The 2008 grants vest over four years and the 2011 and 2012 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. Summarized information for restricted stock grants for the nine months ended September 30, 2012 is as follows:

	<b>Restricted Stock Units</b>	<b>Weighted Average Grant Date Value Per Share</b>	
Non-vested at December 31, 2011	36,463	\$	5.60
Granted	12,281	\$	3.85
Forfeited	(6,904)	\$	4.99
Vested	(2,010)	\$	3.08
Non-vested at September 30, 2012	39,830	\$	5.32

**8. COMMITMENTS AND CONTINGENCIES***Licensing 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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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 upon twelve months' notice after a launch of a sapacitabine-based product. The license also may be terminated 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 rate due from the Company to Daiichi Sankyo on future net sales of sapacitabine be increased between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.

F-66

---



Table of Contents

*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 for Celgene's sale of ISTODAX® to CTCL, and, more recently, peripheral T-cell lymphoma (PTCL) and seeking damages for Celgene's infringement as well as injunctive relief. A Scheduling Order was entered February 2, 2012, at which time the court set significant dates, the remaining of which are the following: 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.

**9. STOCKHOLDERS EQUITY**

All share and per share information presented gives effect to the reverse stock split, which occurred on August 24, 2012.

*Preferred stock*

As of September 30, 2012, 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 0.06079 shares of common stock for each share of Preferred Stock based on a price of \$164.50. The Company has reserved 73,747 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at September 30, 2012.

During 2010, 833,671 shares of Preferred Stock were converted into 236,514 shares of the Company's common stock. Since inception through September 30, 2012, holders have voluntarily converted 1,776,858 shares of Preferred Stock into common stock. The converted shares of Preferred Stock have been retired and canceled and shall upon cancellation be restored to the status of authorized but unissued shares of preferred stock, subject to reissuance by the Board of Directors as shares of Preferred Stock of one or more series.

Table of Contents

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded \$246.75, 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.

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

Year from November 1, 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.

On March 6, 2012, June 22, 2012, and September 12, 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 first, second, and third quarters of 2012, respectively, that would have otherwise been payable on May 1, 2012, August 1, 2012 and November 1, 2012, respectively.

***Common Stock***

*March 2012 Sale of Common Stock and Economic Rights*

On March 22, 2012, the Company entered into a purchase agreement with certain existing institutional stockholders, raising approximately \$2.9 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 669,726 shares of the Company's common stock at a price of \$4.53, which is equal to the 10-day average closing price of the Company's common stock for the period ending on March 21, 2012. In addition to the common stock, investors received contractual rights to receive cash equal to 10% of any future litigation settlement related to the specified intellectual property, subject to a cap. In certain defined situations, the Company may have to issue either additional shares or warrants. The shares issued at closing are subject to a lock-up period of one year from the date of issuance. See Note 4 - Fair Value Measurements for further details.

Table of Contents*Common Stock Warrants*

The following table summarizes information about warrants outstanding at September 30, 2012:

<b>Issued in Connection With</b>	<b>Expiration Date</b>	<b>Common Shares Issuable</b>	<b>Weighted Average Exercise Price</b>
April 2006 stock issuance	2013	367,347	\$ 49.00
February 2007 stock issuance	2014	151,773	\$ 59.08
December 2007 CEFF	2013	14,285	\$ 9.80
July 2009 Series II stock issuance	2014	98,893	\$ 7.00
January 2010 stock issuance	2015	101,785	\$ 22.82
January 2010 stock issuance	2015	100,714	\$ 19.95
October 2010 stock issuance	2015	594,513	\$ 13.44
July 2011 stock issuance	2015	544,117	\$ 9.52
<b>Total</b>		<b>1,973,427</b>	<b>\$ 22.96</b>

There were no exercises of warrants during the three and nine months ended September 30, 2011 and 2012.

Table of Contents

**1,689,317 Shares**

**Cyclacel Pharmaceuticals, Inc.**

**Common Stock**

**PROSPECTUS**

**, 2012**

---

Table of Contents**PART II INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distributions**

Securities and Exchange Commission Registration Fee*	\$	1,426
Legal Fees and Expenses		75,000
Accounting Fees and Expenses		30,000
Miscellaneous Expenses		3,574
<b>Total</b>	<b>\$</b>	<b>110,000</b>

---

\* All expenses except the registration fee are estimates.

**Item 14. Indemnification of Directors and Officers**

Our amended and restated certificate of incorporation, as amended, and amended and restated bylaws, as amended, provide that each person who was or is made a party or is threatened to be made a party to or is otherwise involved (including, without limitation, as a witness) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was a director or an officer of Cyclacel Pharmaceuticals, Inc. or is or was serving at our request as a director, officer, or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan, whether the basis of such proceeding is alleged action in an official capacity as a director, officer or trustee or in any other capacity while serving as a director, officer or trustee, shall be indemnified and held harmless by us to the fullest extent authorized by the Delaware General Corporation Law against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such.

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Pursuant to Section 102(b)(7) of the Delaware General Corporation Law, our amended and restated certificate of incorporation eliminates the liability of a director to us or our stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

- from any breach of the director's duty of loyalty to us or our stockholders;

II-1

---

Table of Contents

- from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- under Section 174 of the Delaware General Corporation Law; and
- from any transaction from which the director derived an improper personal benefit.

We carry insurance policies insuring our directors and officers against certain liabilities that they may incur in their capacity as directors and officers. In addition, we expect to enter into indemnification agreements with each of our directors and executive officers prior to completion of the offering.

The Company has entered into indemnification agreements with each of its directors and executive officers. Pursuant to the indemnification agreements, the Company agrees to hold harmless and indemnify its directors and executive officers to the fullest extent authorized or permitted by the provisions of the Company's amended and restated certificate of incorporation, amended and restated by-laws and the DGCL, including for any amounts that such director or officer becomes obligated to pay because of any claim to which such director or officer is made or threatened to be made a party, witness or participant, by reason of such director's or officer's service as a director, officer, employee or other agent of the Company.

There are certain exceptions from the Company's obligation to indemnify its directors and executive officers pursuant to the indemnification agreements, including for short-swing profit claims under Section 16(b) of the Securities Exchange Act of 1934, as amended, losses that are as a result of conduct that is established by a final judgment as knowingly fraudulent or deliberately dishonest or that constituted willful misconduct, or that constituted a breach of the duty of loyalty to the Company or resulted in any improper personal profit or advantage, where payment is actually made to a director or officer under an insurance policy, indemnity clause, bylaw or agreement, except in respect of any excess beyond payment under such insurance, clause, bylaw or agreement, for indemnification which is not lawful, or in connection with any proceeding initiated by such director or officer, or any proceeding against the Company or its directors, officers, employees or other agents, unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the board of directors of the Company, (iii) such indemnification is provided by the Company, in its sole discretion, pursuant to the powers vested in the Company under the DGCL, or (iv) the proceeding is initiated to enforce a claim for indemnification pursuant to the indemnification agreement.

All agreements and obligations of the Company contained in the indemnification agreements shall continue during the period when the director or officer who is a party to an indemnification agreement is a director, officer, employee or other agent of the Company (or is or is serving at the request of the Company as a director, officer, employee or other agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise) and shall continue thereafter so long as such director or officer shall be subject to any possible claim or threatened, pending or completed action, suit or proceeding, whether civil, criminal, arbitrational, administrative or investigative. In addition, the indemnification agreements provide for partial indemnification and advance of expenses.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to our directors, officers or controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission this indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable.





Table of Contents**Item 15. Recent Sales of Unregistered Securities**

On December 14, 2012, the Company entered into a Common Stock Purchase Agreement (the **Purchase Agreement**) with Aspire Capital Fund, LLC, an Illinois limited liability company (**Aspire Capital**), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$20 million of shares of the Company's common stock (the **Purchase Shares**) over the two-year term of the Purchase Agreement.

Upon execution of the Purchase Agreement, the Company issued 74,548 shares of its common stock to Aspire Capital in consideration for entering into the Purchase Agreement (the **Commitment Shares**) and sold 158,982 shares to Aspire Capital for an aggregate purchase price of \$1,000,000 (the **Initial Shares**). The Purchase Shares may be sold by the Company to Aspire Capital on any business day the Company selects in two ways: (1) through a regular purchase of up to 100,000 shares at a known price based on the market price of our common stock prior to the time of each sale, and (2) through a VWAP purchase of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lesser of the closing sale price or 96% of the volume weighted average price for such purchase date.

The issuance of the Commitment Shares, the Initial Shares and all other shares of common stock that may be issued from time to time to Aspire Capital under the Purchase Agreement is exempt from registration under the Securities Act of 1933, as amended (the **Securities Act**), pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

**Item 16. 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).
1.5	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).

3.1 Amended and Restated Certificate of Incorporation of Cyclacel Pharmaceuticals, Inc. (previously filed as Exhibit

II-3

---

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

### Table of Contents

- 3.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on November 5, 2004, 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 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on October 4, 2010, and incorporated herein by reference).
- 4.7 Amended and Restated Warrant to purchase Common Stock, dated as of November 24, 2009, issued by the Company to Kingsbridge Capital Limited. (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on November 25, 2009, and incorporated herein by reference).
- 4.8 Form of Series I Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on July 24, 2009, and incorporated herein by reference).
- 4.9 Form of Series II Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on July 24, 2009, and incorporated herein by reference).
- 4.10 Form of Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 11, 2010, and incorporated herein by reference).
- 4.11 Form of Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 21, 2010, and incorporated herein by reference).
- 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).

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

### Table of Contents

- 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 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).
- 10.6 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).
- 10.7 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).
- 10.8 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 May 24, 2012, and incorporated herein by reference).
- 10.9 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).
- 10.10 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).
- 10.11 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).
- 10.12 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).
- 10.13 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).
- 10.14 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 January 11, 2010, 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 21, 2010, and incorporated herein by reference).
- 10.16 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).
- 10.17 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

## Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form S-1

incorporated herein by reference).

- 10.18 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).
- 10.19 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).

Table of Contents

- 10.20# 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).
- 10.21# 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).
- 10.22## Purchase Agreement dated March 22, 2012, by and between the Registrant and certain existing institutional investors.
- 10.23 Common Stock Purchase Agreement, dated as of December 14, 2012, by and between the Company and Aspire Capital Fund, LLC (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 17, 2012, and incorporated herein by reference).
- Registration Rights Agreement, dated as of December 14, 2012, by and between the Company and Aspire Capital Fund, LLC (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 17, 2012, and incorporated herein by reference).
- 21\* Subsidiaries of Cyclacel Pharmaceuticals, Inc.
- 23.1\* Consent of Independent Registered Public Accounting Firm.
- 23.2\* Consent of Independent Registered Public Accounting Firm.

---

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.
- ## Certain portions of this exhibit are subject to an application for confidential treatment filed with the Securities and Exchange Commission pursuant to the Securities and Exchange Act of 1934, as amended, and has not yet been filed.
- \* Filed herewith.
- \*\* Furnished herewith.



Table of Contents

**Item 17. Undertakings**

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales of securities are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser,

(A) Each prospectus filed by a registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(5) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Table of Contents

(b) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the claim has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized in the city of Berkley Heights, State of New Jersey, on December 26, 2012.

**CYCLACEL PHARMACEUTICALS, INC.**

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

**Power of Attorney**

Each person whose signature appears below constitutes and appoints each of Spiro Rombotis and Paul McBarron his attorney-in-fact and agent, with the full power of substitution and resubstitution and full power to act without the other, for them in any and all capacities, to sign any and all amendments, including post-effective amendments, and any registration statement relating to the same offering as this registration that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, to this registration statement, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, or their substitute or substitutes, may do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Spiro Rombotis Spiro Rombotis	President & Chief Executive Officer (Principal Executive Officer) and Director	December 26, 2012
/s/ Paul McBarron Paul McBarron	Chief Operating Officer, Chief Financial Officer, and Executive Vice President, Finance (Principal Financial and Accounting Officer) and Director	December 26, 2012
* Dr. David U Prichard	Chairman	December 26, 2012
* Dr. Christopher Henney	Vice Chairman	December 26, 2012
* Dr. Nicholas Bacopoulos	Director	December 26, 2012
* Sir John Banham	Director	December 26, 2012



Table of Contents

Gregory Hradsky	*	Director	December 26, 2012
Lloyd Sems	*	Director	December 26, 2012

---

\* By executing his name hereto, Spiro Rombotis is signing this document on behalf of the persons indicated above pursuant to the powers of attorney executed by such persons and filed with the Securities and Exchange Commission.