Cyclacel Pharmaceuticals, Inc.
Form 424B5
January 21, 2010

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PROSPECTUS SUPPLEMENT **Filed Pursuant to Rule 424(b)(5)**
(To prospectus dated February 12, 2007) **Registration File No. 333-140034**

CYCLACEL PHARMACEUTICALS, INC.
2,350,000 Shares of Common Stock
Warrants to Purchase 705,000 Shares of Common Stock

We are offering up to 2,350,000 shares of our common stock and warrants to purchase up to 705,000 shares of our common stock. Of the 3,055,000 shares of our common stock, 2,350,000 shares are to be issued directly to the purchasers at the closing of the offering and the remaining 705,000 shares are issuable upon exercise of the warrants. The 2,350,000 shares of common stock and the warrants to purchase 705,000 shares of our common stock will be sold in units, with each unit consisting of one share of common stock and a five-year warrant to purchase 0.30 of one share of common stock at an exercise price of $2.85 per share of common stock. Each unit will be sold at a negotiated price of $2.50 per unit. Units will not be issued or certificated. The shares of common stock and warrants are immediately separable and will be issued separately. We refer to the shares of common stock issued or issuable hereunder upon exercise of the warrants, and the warrants to purchase common stock issued hereunder, collectively, as the securities. For a more detailed description of our common stock and warrants, see the section entitled Description of the Securities We are Offering beginning on page S-15 of this prospectus supplement.

Our common stock is listed on The NASDAQ Global Market under the symbol CYCC. On January 20, 2010, the last reported sale price of our common stock on the NASDAQ Global Market was $2.61.

We are offering these shares of common stock and warrants to purchase common stock on a best efforts basis primarily to institutional investors. We have retained Roth Capital Partners, LLC to act as placement agent in connection with this offering.

Investing in our securities involves significant risks. See Risk Factors beginning on page S-11 of this prospectus supplement and each of the Risk Factors beginning on page 12 of the accompanying prospectus.

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 supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

	Per Unit	Maximum Offering Amount
Public offering price	$ 2.50	$ 5,875,000
Placement agent s fees	$0.125	$ 293,750
Proceeds, before expenses, to us	$2.375	$ 5,581,250

We estimate the total expenses of this offering, excluding the placement agent s fees, will be approximately $136,750. Because there is no minimum offering amount required as a condition to closing in this offering, the actual offering amount, the placement agent s fees and net proceeds to us, if any, in this offering may be substantially less than the total maximum offering amounts set forth above. We are not required to sell any specific number or dollar amount of the units offered in this offering, but the placement agent will use its best efforts to arrange for the sale of all of the units offered.

Roth Capital Partners

The date of this prospectus supplement is January 21, 2010.

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Prospectus Supplement

Prospectus

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You should rely only on the information contained in this prospectus supplement, the accompanying prospectus or information incorporated by reference herein. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the date on the front of those documents or that any document incorporated by reference is accurate as of any date other than its filing date. You should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

This prospectus supplement is part of a registration statement that we have filed with the Securities and Exchange Commission utilizing a shelf registration process. Under this shelf registration process, we are offering to sell our common stock and warrants to purchase our common stock, which we refer herein collectively as the securities, using this prospectus supplement and the accompanying prospectus. In this prospectus supplement, we provide you with specific information about the securities that we are selling in this offering. Both this prospectus supplement and the accompanying prospectus include important information about us, our securities being offered and other information you should know before investing. This prospectus supplement also adds, updates and changes information contained in the accompanying prospectus. You should read this prospectus supplement and the accompanying prospectus as well as additional information described under Incorporation of Certain Documents by Reference on page 47 of the accompanying prospectus before investing in our securities.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus supplement and in the accompanying prospectus and in the documents we incorporate by reference. After you read this summary, you should read and consider carefully the more detailed information and financial statements and related notes that we include in and/or incorporate by reference into this prospectus supplement and the accompanying prospectus, especially the section entitled Risk Factors. If you invest in our securities, you are assuming a high degree of risk.

Our Company

We are a diversified biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Our strategy is focused on leading edge therapeutic management of cancer patients based on our clinical development pipeline, led by sapacitabine, and the medicines marketed by our subsidiary, ALIGN Pharmaceuticals, LLC, or ALIGN. Our core area of expertise is in cell cycle biology, or the processes by which cells divide and multiply. We have concentrated since our inception on the discovery and development of orally available anticancer agents that target the cell cycle with the aim of eradicating cancer cells to slow the progression or shrink the size of tumors, enhancing quality of life and improving survival rates of cancer patients. We market directly in the United States Xclair® Cream for dermatoses, such as radiation dermatitis, and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia or dry mouth.

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.

The Company has 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 CYC116.

We were founded by Professor Sir David Lane, a recognized leader in the field of tumor suppressor biology who discovered the p53 protein, which operates as one of the body s own anticancer drugs by regulating the function of 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 cell division, or mitosis phase, of the cell cycle. Our expertise in cell cycle biology is at the center of our business strategy to build a diversified biopharmaceutical business focused in oncology, hematology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

We are advancing three of our anticancer drug candidates, seliciclib, sapacitabine and CYC116, through in-house development activities. We are also progressing further novel drug series which are at

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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.

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

Hematological Cancers

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

In December 2007, at the American Society of Hematology, or 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.

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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 one 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 21 days, B. 300 mg twice daily for seven days every 21 days and C. 400 mg twice daily for three days per week for two weeks every 21 days, 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 twenty percent in first relapse. We completed enrollment of 60 AML patients in this study in October 2008. In December 2009, at the 51st Annual Meeting of the American Society of Hematology, or ASH, we reported one-year survival data.

The primary endpoint of one-year survival was 35% on Arm A, 30% on Arm C and 10% on Arm B. The median overall survival was 212 days on Arm C (range of 13 to over 654 days), 197 days on Arm A (range of 26 to over 610 days) and 100 days on Arm B (range of 6 to over 646 days). Overall response rate, 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 10.0% on Arm C and Arm A and 20.0% 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 one-year survival rate of 30%, ORR of 35% with durable CRs. The 7-day dosing schedule in Arm A was selected for further clinical development in elderly patients with AML preceded by AHD based on a one-year survival rate of 35%, ORR of 45% with durable hematological improvement.

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

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 one-year survival rate of three dosing schedules of sapacitabine. Secondary objectives are to assess the number of patients who have achieved CR or CRp, PR, hematological improvement and their corresponding durations, transfusion requirements, number of hospitalization days and safety. The study uses a selection design with the objective of identifying a dosing schedule which produces a better one year survival rate for each stratum in the event that all three dosing schedules are active.

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

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

In December 2009, we announced that we held a Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss a randomized Phase 3 study design for our oral sapacitabine capsules in AML and separately in MDS. Based on the FDA s confirmation that the proposed study design would be acceptable for a Special Protocol Assessment (SPA), we plan to submit a SPA request during the first quarter of 2010. We expect to start enrolling patients in such a pivotal study within 2010. The SPA process allows for official FDA evaluation of clinical protocols of a Phase 3 clinical trial intended to form the primary basis for an efficacy claim. A SPA provides trial sponsors with a binding 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 agreement 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.

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 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.

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, one 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.

EU Orphan Designation

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

Seliciclib

Our second drug candidate, seliciclib, is a novel, first-in-class, orally available, CDK inhibitor. The compound selectively inhibits a spectrum of enzyme targets -CDK2/E, CDK2/A, CDK7 and CDK9- that are central to the process of cell division and cell cycle control. 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 400 patients in several Phase 1 and 2 studies and has shown signs of anti-cancer activity. We have retained worldwide rights to commercialize seliciclib.

Phase 1 clinical trials in patients with refractory solid tumors

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

Seliciclib was shown in a further Phase 1 study sponsored and conducted by independent investigators to have clinical antitumor activity in patients with nasopharyngeal cancer, measured as a

decrease in the size of primary tumor and involved lymph nodes, as well as an increase in tumor cell deaths by biomarker analyses.

Phase 2 clinical trials in patients with NSCLC or breast cancer

Four Phase 2 trials have been conducted in cancer patients to evaluate the tolerability and antitumor activities of seliciclib alone or in combination with standard chemotherapies used in the treatment of advanced NSCLC or breast cancer. Interim data from two Phase 2 open-label studies of a total of 52 patients with NSCLC, suggest that seliciclib treatment did not aggravate the known toxicities of standard first and second-line chemotherapies nor appear to cause unexpected toxicities, although these trials were not designed to provide statistically significant comparisons. The combination of seliciclib with a standard dose of capecitabine was not well tolerated in patients with advanced breast cancer.

Seliciclib is currently being investigated in the Phase 2b APPRAISE study as a treatment for patients with advanced NSCLC. APPRAISE is a double-blinded, randomized study of single agent seliciclib versus best supportive care in patients with NSCLC treated with at least two prior systemic therapies. APPRAISE is led by Chandra P. Belani, M.D. at Milton S. Hershey Medical Center, Penn State University and Alan B. Sandler, M.D. at Vanderbilt-Ingram Cancer Center. The study s main objective is to learn the anti-tumor activity of seliciclib as a single agent in refractory NSCLC and help determine further development strategies. The study design is randomized discontinuation. All patients receive seliciclib at a dose of 1200 mg twice a day for three days for at least three cycles of two weeks each. Patients who achieve stable disease after three cycles will be randomized to continue on seliciclib or receive placebo with best supportive care. Patients in the placebo arm who progress will be given the option to cross-over and again receive seliciclib. The primary efficacy endpoint of APPRAISE is doubling progression free survival or PFS measured in the randomized portion of the study.

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

Phase 2 clinical trials in patients with NPC

In November 2007, we commenced a Phase 2 multicenter, international, blinded randomized study of oral 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.

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In May 2009, at the American Society of Clinical Oncology, or 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 supports further clinical development of oral seliciclib in NPC.

CYC116

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

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 over 600 novel 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 compounds which inhibit 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 no resources will be allocated in accordance with our revised operating plan announced in September 2008.

For example, extensive preclinical data published by independent investigators evidence activity by our CDK inhibitors, including seliciclib, in various autoimmune and inflammatory diseases including lupus nephritis, pulmonary kidney disease, idiopathic pulmonary fibrosis 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.

Commercial products

In October 2007, we acquired exclusive rights to sell and distribute three products in the United States, through our ALIGN Pharmaceuticals subsidiary, used primarily to manage the effects of radiation or chemotherapy in cancer patients. All three products, Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges, are approved in the United States under FDA 510(k) or medical device registrations and were launched in the United States in January 2006.

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Xclair® Cream

Xclair is an aqueous cream containing sodium hyaluronate, or hyaluronic acid, glycyrrhetinic acid and telmesteine. Xclair is approved by FDA for the relief of symptoms associated with dermatoses or inflammation of the skin. Cancer patients suffer dermatoses as a result of radiation treatment, a condition called radiation dermatitis, and pharmacological treatment, such as the acneiform dermatoses caused by epidermal growth factor receptor, or EGFR, inhibitor drugs such as cetuximab and erlotinib, and the hand-and-foot syndrome caused by drugs such as capecitabine and sorafenib.

Numoisyn® Lozenges & Numoisyn® Liquid

Numoisyn Lozenges are taken by mouth and contain malic acid and sorbitol to stimulate normal salivation. Numoisyn Lozenges are approved by FDA for the treatment of xerostomia, or dry mouth, and for temporary relief of dry mouth due to damaged salivary function in patients with some residual secretory function and taste perception. Numoisyn Lozenges have been demonstrated to be safe and effective for long-term use and are well tolerated by patients. Numoisyn Liquid is an oral solution that contains linseed extract which in turn contains mucins that provide superior viscosity, similar to that of natural saliva, and reduced friction compared to water or carboxymethylcellulose-based solutions. Numoisyn Liquid is approved by FDA for the relief of symptoms of xerostomia, or dry mouth, by enhancing swallowing, improving speech mechanics, and lubricating the oral cavity like natural saliva. Numoisyn Liquid may be used to replace natural saliva when salivary glands are damaged or not functioning. Xerostomia is caused by chemotherapy, radiotherapy, Sjogren s syndrome, an autoimmune disease, or oral inflammation.

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 marketing, 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.

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The Offering

Common stock offered by us	2,350,000 shares directly 705,000 shares issuable upon exercise of warrants
Warrants	Warrants to purchase 705,000 shares of common stock will be offered in this offering. The warrants will be exercisable beginning on the date that is six months after the date of original issuance and at any time up to the date that is five years after such date of issuance at an exercise price of $2.85 per share of common stock.
Common stock outstanding before this offering	29,043,080 shares
Common stock to be outstanding after this offering	31,393,080 shares
Use of proceeds	We intend to use the net proceeds this offering for general corporate purposes, including our internal discovery and development programs and the development of new technologies and general working capital. See Use of Proceeds on page S-13.
NASDAQ Global Market symbol	CYCC

Our common stock to be outstanding after this offering is based on 29,043,080 shares outstanding as of January 20, 2010, and excludes the following as of that date:

- 3,274,307 shares of common stock issuable upon the exercise of outstanding options, restricted stock and restricted common stock units at a weighted-average exercise price of $4.12 per share;
- 715,951 shares of common stock available for issuance under our 2006 Equity Incentive Plan;
- 8,386,863 shares of common stock issuable upon the exercise of outstanding warrants at a weighted-average exercise price of $4.13 per share, including the warrants to purchase 705,000 shares of common stock offered hereby; and
- 870,980 shares of common stock, subject to adjustment, that are issuable upon the conversion of 2,046,813 shares of convertible preferred stock that are issued and outstanding.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors beginning on page 12 of the accompanying prospectus, as well as the risks discussed under the caption Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2008, and in our Quarterly Report on Form 10-Q for the three-month period ended September 30, 2009, each of which is incorporated by reference into this prospectus supplement. If any of these risks actually occur, our business, financial condition and results of operations would suffer. In that case, the trading price of our common stock would likely decline and you might lose all or part of your investment in our common stock.

Investors in this offering will pay a much higher price than the book value of our stock.

If you purchase common stock and warrants to purchase common stock in this offering, you will incur immediate and substantial dilution in net tangible book value of $2.00 per share, after giving effect to the sale by us of 2,350,000 shares included in the units in this offering at the public offering price of $2.50 per share. Net tangible book value per share represents our total tangible assets less our total liabilities, divided by the aggregate number of shares of our common stock outstanding.

Our management will have broad discretion over the use of the net proceeds from this offering. You may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of the net proceeds from any offering by us and could use them for purposes other than those contemplated at the time of this offering. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity as part of your investment decision to assess whether the proceeds are being used appropriately. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for our company.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus supplement and the accompanying prospectus and the documents we have filed with the SEC that are incorporated by reference into this prospectus supplement and the accompanying prospectus contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, that involve risk and uncertainties. Any statements contained, or incorporated by reference, in this prospectus supplement and the accompanying prospectus that are not statements of historical fact may be forward-looking statements. When we use the words anticipates, plans, expects and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include, among others, the uncertainties associated with product research and development, the risk that clinical trials by us or our collaborators will not commence or proceed as planned, the risks and uncertainties associated with dependence upon the actions of our collaborators and of government regulatory agencies, the risk that our intellectual property rights may be infringed or challenged by third parties, the uncertainty of future profitability and other factors set forth more fully in this prospectus supplement and the accompanying prospectus, including those described under the caption Risk Factors beginning of page 7 of the accompanying prospectus.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as may be required by law, we do not intend to update any of the forward-looking statements for any reason after the date of this prospectus supplement to conform such statements to actual results or if new information becomes available.

All forward-looking statements attributable to us, or to persons acting on our behalf, are expressly qualified in their entirety by these cautionary statements.

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USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $5.4 million after deducting the placement agent s fees and estimated offering expenses. This amount does not include the proceeds which we may receive in connection with the exercise of the warrants. We intend to use the net proceeds of this offering for general corporate purposes, including our internal discovery and development programs and general working capital. Pending use of the net proceeds, we intend to invest these net proceeds in interest bearing investment grade securities.

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DILUTION

Our net tangible book value as of September 30, 2009, was approximately $7.9 million, or $0.32 per share of common stock. Net tangible book value per share is calculated by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the number of shares of common stock outstanding. After giving effect to the sale by us of the 2,350,000 shares of common stock included in the units offered in this offering, at a public offering price of $2.50 per share and after deducting the placement agent s fees and estimated offering expenses payable by us, our net tangible book value as of September 30, 2009, would have been approximately $13.4 million, or $0.50 per share of common stock. This represents an immediate increase in net tangible book value of $0.18 per share to our existing stockholders and an immediate and substantial dilution of $2.00 per share to new investors. The following table illustrates this per share dilution:

Offering price per share		$2.50
Net tangible book value per share as of September 30, 2009	$0.32	
Increase per share after the offering	$0.18	
Net tangible book value per share after this offering		$0.50
Dilution per share to new investors		$2.00

The foregoing table does not take into account further dilution to new investors that could occur upon the exercise of outstanding options and warrants having a per share exercise price less than the per share offering price to the public in this offering, including the warrants to purchase 705,000 shares of common stock offered hereby. As of September 30, 2009, there were 24,483,129 shares of common stock outstanding, which does not include:

- 3,538,933 shares of common stock issuable upon exercise of options outstanding as of September 30, 2009, at a weighted average exercise price of $4.14 per share.
- 7,044,363 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2009, at a weighted average exercise price of $4.47 per share.
- 141,700 shares of common stock issuable upon the vesting of restricted stock units outstanding as of September 30, 2009.
- 870,980 shares of common stock issuable upon conversion of the Convertible Preferred Stock outstanding as of September 30, 2009.

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DESCRIPTION OF THE SECURITIES WE ARE OFFERING

In this offering, we are offering a maximum of 2,350,000 units, consisting of 2,350,000 shares of common stock and warrants to purchase an aggregate of 705,000 shares of common stock. Each unit consists of one (i) share of common stock and (ii) one warrant to purchase 0.30 of one share of common stock, such warrant being exercisable at an exercise price of $2.85 per share. This prospectus supplement also relates to the offering of 705,000 shares of our common stock issuable upon exercise, if any, of the warrants.

Common Stock

A description of the common stock we are offering pursuant to this prospectus supplement is set forth under the heading Description of Common Stock, starting on page 25 of the prospectus. As of January 20, 2010, we had 29,043,080 shares of common stock outstanding.

Warrants

The warrants offered in this offering will be issued in registered form pursuant to a subscription agreement between each of the purchasers and us. You should review the forms of subscription agreement and warrant, which are attached thereto and which will be filed as exhibits to a Current Report on Form 8-K filed with the Securities and Exchange Commission in connection with this offering, for a complete description of the terms and conditions applicable to the warrants. The following is a brief summary of the warrants and is subject in all respects to the provisions contained in such warrants.

Terms Applicable to the Warrants

Exercisability. Holders may exercise the warrants beginning on the date that is six months after the date of original issuance and at any time up to the date that is five years after such date of issuance. The warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise, except in the case of a cashless exercise, as discussed below.

Exercise Price. Each warrant is exercisable for 0.30 of one share of common stock at an exercise price of $2.85 per share of common stock being purchased. The exercise price is subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock.

Cashless Exercise. If, at any time during the warrant exercisability period, 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.

Transferability. Subject to applicable laws and the restriction on transfer set forth in the subscription agreement, the warrants may not be transferred at the option of the holders 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.

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Exchange Listing. We do not plan on making an application to list 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.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder s ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

Waivers and Amendments. The provisions of each warrant may be amended and we may take any action prohibited by the warrant, or omit to perform any act required to be performed pursuant to the warrant, only with the written consent of the holder of that warrant.

Other Provisions. 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.

No fractional shares will be issued upon exercise of the warrants, but rather the number of shares of common stock to be issued shall be rounded up to the nearest whole number.

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PLAN OF DISTRIBUTION

We are offering the units through a placement agent. Subject to the terms and conditions contained in the placement agent agreement, dated January 21, 2010, Roth Capital Partners, LLC has agreed to act as the placement agent for the sale of up to 2,350,000 units. The placement agent is not purchasing or selling any shares or warrants by this prospectus supplement or the accompanying prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of units, but has agreed to use its best efforts to arrange for the sale of all units.

The placement agent agreement provides that the obligations of the placement agent and the investors are subject to certain conditions precedent, including the absence of any material adverse change in our business and the receipt of customary legal opinions, letters and certificates.

Confirmations and definitive prospectuses will be distributed to all investors who agree to purchase the units, informing investors of the closing date as to such units. We currently anticipate that closing of the sale of units will take place on or about January 25, 2010. Investors will also be informed of the date and manner in which they must transmit the purchase price for their units.

On the scheduled closing date, the following will occur:

we will receive funds in the amount of the aggregate purchase price for the units we sell; and

Roth Capital Partners, LLC will receive the placement agent s fee in accordance with the terms of the placement agent agreement.

We will pay the placement agent an aggregate cash commission equal to 5.0% of the gross proceeds from the sale of units. We will also reimburse the placement agent for legal expenses incurred by it in connection with this offering, subject to a cap of $40,000. In no event will the total amount of compensation paid to the placement agent and other securities brokers and dealers upon completion of this offering exceed 8.0% of the gross proceeds of this offering. The estimated offering expenses payable by us, in addition to the placement agent s fee of approximately $293,750, are approximately $136,750, which includes legal, accounting and printing costs, a financial advisory fee and various other fees associated with registering and listing the common stock. After deducting the payments to the placement agent described above and our estimated offering expenses, we expect the net proceeds from this offering to be approximately $5.4 million. We will pay Merriman Curhan Ford & Co. an advisory fee equal to 1% of the gross proceeds from the sale of the units.

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and liabilities arising from breaches of representations and warranties contained in the placement agent agreement. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

We, along with our executive officers and directors, have agreed to certain lock-up provisions with regard to future sales of our common stock and other securities convertible into or exercisable or exchangeable for common stock for a period of thirty (30) days after the offering as set forth in the placement agent agreement. In the subscription agreements to be entered into with the investors in the offering, we have agreed to similar lock-up provisions for a period of ten (10) business days after the offering. In addition, pursuant to those subscription agreements, we have granted to the investors in the offering certain participation rights with respect to sales of common stock and other securities convertible

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into or exercisable or exchangeable for common stock, made during the period ending 120 days after the offering.

The placement agent agreement and the form of subscription agreement are included as exhibits to our Current Report on Form 8-K that we will file with the SEC in connection with the consummation of this offering.

The transfer agent for our common stock to be issued in this offering is American Stock Transfer & Trust Company located at 59 Maiden Lane, Plaza Level, New York, New York 10038.

Our common stock is traded on the Nasdaq Global Market under the symbol CYCC.

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LEGAL MATTERS

The validity of the issuance of the securities offered by this prospectus supplement and the accompanying prospectus will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York. Lowenstein Sandler, P.C., Roseland, New Jersey, is acting as counsel for the placement agent in connection with various matters related to the securities offered hereby.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2008, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements as of December 31, 2008 are incorporated by reference in reliance on Ernst & Young LLP s reports, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement and accompanying prospectus constitute a part of a registration statement on Form S-3 that we filed on February 12, 2007 with the SEC under the Securities Act of 1933, as amended. We refer you to this registration statement for further information about us and the common stock and warrants to purchase our common stock offered hereby.

We file annual, quarterly and special reports and other information with the SEC (Commission File Number 0-50626). These filings contain important information that does not appear in this prospectus supplement or the accompanying prospectus. For further information about us, you may read and copy any reports, statements and other information filed by us at the SEC s Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549-0102. You may obtain further information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our SEC filings are also available on the SEC Internet site at http://www.sec.gov, which contains periodic reports and other information regarding issuers that file electronically.

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INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus and information we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended. The documents we are incorporating by reference as of their respective dates of filing are:

- our Annual Report on Form 10-K for the year ended December 31, 2008 (including information specifically incorporated by reference into our Form 10-K from our Proxy Statement for our 2009 Annual Meeting of Stockholders);
- our Quarterly Reports on Form 10-Q filed on May 15, 2009, August 13, 2009 and November 12, 2009;
- our Current Reports on Form 8-K filed on January 13, 2009, February 6, 2009, February 12, 2009, March 17, 2009, April 8, 2009, April 20, 2009, May 7, 2009, June 26, 2009, July 24, 2009, August 28, 2009, October 20, 2009, October 30, 2009, November 25, 2009, December 15, 2009, December 31, 2009, January 8, 2010, January 11, 2010 and January 13, 2010;
- our Proxy Statement for our 2009 Annual Meeting of Stockholders; and
- the description of our common stock contained in our registration statement on Form 8-A and any amendments or reports filed for the purpose of updating such description.

This prospectus supplement may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus supplement. To the extent that any statements contained in a document incorporated by reference are modified or superseded by any statements contained in this prospectus, such statements shall not be deemed incorporated in this prospectus except as so modified or superseded. Reports we file with the SEC after the date of this prospectus supplement may also contain information that updates, modifies or is contrary to information in this prospectus supplement or in documents incorporated by reference in this prospectus supplement. Investors should review these reports as they may disclose a change in our business, prospectus, financial condition or other affairs after the date of this prospectus supplement.

You may request, orally or in writing, a copy of these filings, which will be provided to you at no cost, by contacting our investor relations department our principal executive offices, which are located at 200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922, Attention: Investor Relations, Telephone: (908) 517-7330.

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PROSPECTUS
CYCLACEL PHARMACEUTICALS, INC.
$75,000,000
COMMON STOCK
PREFERRED STOCK
WARRANTS
DEBT SECURITIES

We may, from time to time, issue up to $75,000,000 aggregate principal amount of common stock, preferred stock, warrants and/or debt securities. We will specify in an accompanying prospectus supplement the terms of the securities. We may sell these securities to or through underwriters and also to other purchasers or through agents. We will set forth the names of any underwriters or agents in the accompanying prospectus supplement.

Our common stock is quoted on the Nasdaq Global Market under the symbol CYCC. On February 9, 2007, the last reported sale price of our common stock was $8.12 per share. Our preferred stock is quoted on the Nasdaq Capital Market under the symbol CYCCP. On February 9, 2007, the last reported sale price of our preferred stock was $5.30 per share.

Investing in our securities involves risks.
See Risk Factors on page 7.

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.

This prospectus may not be used to consummate sales of securities unless it is accompanied by a prospectus supplement.

The date of this prospectus is February 12, 2007.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. Under this shelf process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of $75,000,000. We have provided to you in this prospectus a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. In any applicable prospectus supplements, we may add to, update or change any of the information contained in this prospectus.

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PROSPECTUS SUMMARY

The following is only a summary. We urge you to read the entire prospectus, including the more detailed consolidated financial statements, notes to the consolidated financial statements and other information included herein or incorporated by reference from our other filings with the SEC. Investing in our securities involves risks. Therefore, please carefully consider the information provided under the heading Risk Factors starting on page 7.

Our Business

We are a development-stage biopharmaceutical company dedicated to the discovery, development and eventual commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Our core area of expertise is in cell cycle biology, or the processes by which cells divide and multiply. We focus primarily on the discovery and development of orally available anticancer agents that target the cell cycle with the aim of slowing the progression or shrinking the size of tumors, and enhancing quality of life and improving survival rates of cancer patients. We have been focused on the cell cycle since our inception. We were founded in 1996 by Professor Sir David Lane, a recognized leader in the field of tumor suppressor biology who discovered the p53 protein, which operates as one of the body s own anticancer drugs by inhibiting cell cycle targets. In 1999, we were joined by Professor David Glover, a recognized leader in the mechanism of mitosis or cell division who discovered, among other cell cycle targets, the mitotic kinases, Polo and Aurora, enzymes that act in the mitosis phase of the cell cycle. Our expertise in cell cycle biology is at the center of our business strategy.

We are generating several families of anticancer drugs that act on the cell cycle including cyclin dependent kinase (CDK) and Aurora kinase inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop CDK inhibitor drugs, we believe that our lead drug candidate, seliciclib, is the only orally available CDK inhibitor drug candidate currently in Phase II trials.

We are advancing three of our anticancer drug candidates, seliciclib, sapacitabine and CYC116 through in-house research and development activities. In addition we are progressing further novel drug series, principally for cancer, which are at earlier stages. Taken together, our pipeline covers all four phases of the cell cycle, which we believe will improve the chances of successfully developing and commercializing novel drugs that work on their own or in combination with approved conventional chemotherapies or with other targeted drugs to treat human cancers.

Our lead 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. 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 240 patients in several Phase I and II uncontrolled studies and has shown early signs of anti-cancer activity.

We have completed two Phase I trials that enrolled 24 healthy volunteers and three Phase I 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.

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Seliciclib was shown in a further Phase I 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. Four Phase II 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 non-small cell lung cancer, or NSCLC, or breast cancer. Interim data from two Phase II open-label studies of a total of 54 patients with NSCLC, suggest that seliciclib treatment did not aggravate the known toxicities of standard first and second-line chemotherapies nor appear to cause unexpected toxicities, although these trials were not designed to provide statistically significant comparisons. The combination of seliciclib with standard dose of capecitabine was not well tolerated in patients with advanced breast cancer. The Phase II open-label trials of seliciclib have been closed and we expect to report final data within the first quarter of 2007.

Based on our observations of tolerability and antitumor activity of seliciclib in the clinical trials conducted to date, the oral availability of seliciclib, the recommendation of a NSCLC expert panel, and regulatory and marketing considerations, seliciclib is currently being evaluated in the APPRAISE trial, a Phase IIb randomized double-blinded study to evaluate the safety and efficacy of the drug as a third line treatment in patients with NSCLC. The trial, which is expected to enroll approximately 200 patients, is using a randomized discontinuation trial design. We have retained worldwide rights to commercialize seliciclib.

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

Two Phase I studies of sapacitabine have been completed in the United States by Sankyo, from which we in-licensed sapacitabine, evaluating 87 patients in refractory solid tumors. A Phase Ib dose escalation clinical trial is currently in progress in the United States for the treatment of patients with refractory solid tumors or lymphomas. Preliminary results from this study were reported at the 18 th 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 with five with NSCLC, two with breast cancer, two with ovarian cancer and one each with colorectal cancer, adenocarcinoma of unknown primary, gastrointestinal stroma tumor and parotid acinar carcinoma. The primary toxicity was reversible myelosuppression.

Sapacitabine is also currently being evaluated in a Phase I clinical trial in advanced leukemias and myelodysplastic syndromes, or MDS. The Phase I study is being conducted by Dr. Hagop Kantarjian, Professor of Medicine and Chairman of the Leukemia Department at M.D. Anderson Cancer Center in Houston, Texas. The study s primary objective is to determine the maximum tolerated dose, or MTD, of sapacitabine administered twice daily, or b.i.d., by mouth for

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seven consecutive days every 21 days. As of November 2006, 26 patients were enrolled and 25 patients have received at least one dose of sapacitabine. Preliminary interim data are available on 22 patients, of which nine had de novo acute myelogenous leukemia, or AML; seven had AML preceded by MDS; three had MDS-refractory anemia with excess blasts, or MDS-RAEB; and one each had treatment-related AML, acute lymphocytic leukemia, or ALL and chronic lymphocytic leukemia or CLL. The median age is 62 ranging from 39 to 91. Twenty-one patients received prior chemotherapy and one elderly patient (aged 91) did not receive any prior chemotherapy. The median number of prior chemotherapy regimens is two, ranging from one to four. Fifteen patients were previously treated with Ara-C-containing regimens of which nine had de novo AML and six had AML preceded by MDS. Six patients were previously treated with decitabine of which three had MDS-RAEB, and one each had de novo AML, AML preceded by MDS, and treatment-related AML. One patient treated at the dose level of 275 mg b.i.d. experienced a dose limiting toxicity, or DLT consisting of Grade 3 diarrhea and Grade 3 neutropenic colitis, which resolved after cessation of dosing and medical treatment. No DLTs were reported in the remaining five patients treated at 275 mg b.i.d. Dose escalation continues and the MTD has not been reached at the dose level of 325 mg b.i.d., which is approximately four times the recommended Phase II dose for solid tumor patients. To date, the best response to sapacitabine was reduction in bone marrow blast counts to 5% or less, which was observed in seven patients of which three had de novo AML, two had AML preceded by MDS, and two had MDS-RAEB. We expect to start Phase II evaluation of sapacitabine in 2007. We have retained worldwide rights to commercialize sapacitabine with the exception of Japan where Sankyo has a right of first refusal to market the drug under terms to be negotiated.

We have selected CYC116 as a lead development candidate from our Aurora kinase inhibitor program. In this program, several compounds have demonstrated efficacy by oral administration in hematological and solid tumor models with a mechanism consistent with inhibition of the target. We submitted in December 2006 an Investigational New Drug, or IND application, with the Food and Drug Administration, or FDA, to begin clinical trials of CYC116, an orally-active inhibitor of Aurora kinases A & B and VEGFR2, for the treatment of cancer. Aurora kinases are a family of serine/threonine protein kinases that are only expressed in actively dividing cells and are crucial for the process of cell division, or mitosis. These proteins, which have been found to be over-expressed in many types of cancer, have generated significant scientific and commercial interest as cancer drug targets. Aurora kinases were discovered by Professor David Glover, Chief Scientist of Cyclacel s Polgen Division. VEGFR2 is a receptor protein that is part of an important and validated pathway in angiogenesis, or blood vessel formation. We have retained worldwide rights to commercialize CYC116.

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

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

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

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RISK FACTORS

The following factors should be considered carefully in evaluating whether to purchase shares of Cyclacel common stock. These factors should be considered in conjunction with any other information included or incorporated by reference herein, including in conjunction with forward-looking statements made herein. See Where You Can Find More Information on page 47.

RISKS RELATED TO OUR BUSINESS

We are at an early stage of development as a company and we do not have, and may never have, any products that generate 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. Since beginning operations in 1997, we have not generated any product revenues. We currently have no products for sale and we cannot guarantee that we will ever have any marketable products. We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the Food and Drug Administration, or 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. Seliciclib and sapacitabine, our most advanced drug candidates for the treatment of cancer, are currently our only drug candidates in clinical trials and we cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that they 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, if any, will be derived from sales of drugs that we do not expect to 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 1997 due to costs incurred in connection with our research and development activities and general and administrative costs associated with our operations, and we may never achieve profitability. As of September 30, 2006, our accumulated deficit was $132.7 million. Our net loss from inception through September 30, 2006 was $170.9 million. Our initial drug candidates are in the early stages of clinical testing and we must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of our drugs. We expect to incur continued losses for several years, as we continue our research and development of our initial drug candidates, seek regulatory approvals and commercialize any approved drugs. If our initial drug candidates are unsuccessful in clinical trials or we are unable to obtain regulatory approvals, or if our drugs are unsuccessful in the market, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, you could lose all or part of your investment.

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

We have funded all of our operations and capital expenditures with proceeds from the issuance of public equity securities, private placements of our securities, interest on investments, government grants and research and development tax credits. In order to conduct the lengthy and expensive research, preclinical testing and clinical trials necessary to complete the development and marketing of our drug candidates, we will require substantial additional funds. Based on our current operating plans, we expect our existing resources to be sufficient to fund our planned operations for at least the next 12 months. To meet these financing requirements, we may raise funds through public or private

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equity offerings, debt financings or strategic alliances. Raising additional funds by issuing equity or convertible debt securities will cause our shareholders to experience substantial dilution in their ownership interests and new investors may have rights superior to the rights of our other stockholders. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities and options. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights to our drug discovery and other technologies, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. Additional funding may not be available to us on favorable terms, or at all. If we are unable to obtain additional funds, we may be forced to delay or terminate our clinical trials and the development and marketing of our drug candidates.

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

Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We estimate that clinical trials of our most advanced drug candidates will continue for several years, but may take significantly longer to complete. The designs used in some of our trials have not been used widely by other pharmaceutical companies. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future drug candidates, including but not limited to:

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

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

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

Adverse or inconclusive results from our clinical trials may substantially delay, or halt entirely, any further development of our drug candidates. Many companies have failed to demonstrate the safety or effectiveness of drug candidates in later stage clinical trials notwithstanding favorable results in early stage clinical trials. Previously unforeseen and unacceptable side effects could interrupt, delay or halt clinical trials of our drug candidates and could result in the FDA or other regulatory authorities denying approval of our drug candidates. We will need to

demonstrate safety and efficacy for specific indications of use, and monitor safety and compliance with clinical trial protocols throughout the development process. To date, long-term safety and efficacy has not been

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demonstrated in clinical trials for any of our drug candidates. Toxicity and severe adverse effects as defined in trial protocols have been noted in preclinical and clinical trials involving certain of our drug candidates. For example, elevations of liver enzymes and decrease in potassium levels have been observed in some patients receiving our lead drug candidate, seliciclib and neutropenia was observed in patients receiving sapacitabine. In addition, we may pursue clinical trials for seliciclib in more than one indication. There is a risk that severe toxicity observed in a trial for one indication could result in the delay or suspension of all trials involving the same drug candidate. We are currently conducting Phase IIb clinical trials to test the safety and efficacy of seliciclib in the treatment of non small cell lung cancer. Independent investigators are conducting Phase I clinical trials to test the safety of sapacitabine in patients with advanced cancers. If these trials or any future trials are unsuccessful, our business and reputation could be harmed and our share price could be negatively affected.

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

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

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

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

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

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

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

We are making extensive use of biomarkers in an effort to facilitate our drug development and to optimize our clinical trials. Biomarkers are proteins or other substances whose presence in the blood can serve as an indicator of specific cell processes. We believe that these biological markers serve a useful purpose in helping us to evaluate whether our drug candidates are having their intended effects through their assumed mechanisms, and thus enable us to identify more promising drug candidates at

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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.

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

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

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

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs associated with establishing sales and marketing capabilities;
- the costs of acquiring or investing in businesses, products and technologies;
- the effect of competing technological and market developments; and
- the payment, other terms and timing of any strategic alliance, licensing or other arrangements that we may establish.

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

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

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

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

Although we are not currently party to any collaboration arrangement or strategic alliance that is material to our business, in the future we expect to be dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our drug candidates particularly after the Phase II stage of clinical testing. These arrangements may place the development of our drug candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

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

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

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

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 to expand our operations to include manufacturing capacities. Any performance failure on the part of future manufacturers could delay late stage clinical development or regulatory approval of our drug candidates or commercialization of our drugs, producing additional losses and depriving us of potential product revenues.

If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities. To date, our drug candidates have been manufactured in small quantities for preclinical testing and

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clinical trials and we may not be able to successfully increase the manufacturing capacity, whether in collaboration with third party manufacturers or on our own, for any of our drug candidates in a timely or economic manner, or at all. For example, the manufacture of our drug candidate sapacitabine and CYC116 require several steps and it is not known if scale up to commercial production is feasible. Significant scale-up of manufacturing may require additional validation studies, which the FDA and other regulatory bodies must review and approve. If we are unable to successfully increase the manufacturing capacity for a drug candidate whether for late stage clinical trials or for commercial sale, the drug development, regulatory approval or commercial launch of any related drugs may be delayed or there may be a shortage in supply. Even if any third party manufacturer makes improvements in the manufacturing process for our drug candidates, we may not own, or may have to share, the intellectual property rights to such innovation.

We currently have no marketing or sales staff. If we are unable to conclude strategic alliances with marketing partners or if we are unable to develop our own sales and marketing capabilities, we may not be successful in commercializing any drugs we may develop.

Our strategy is to develop compounds through the Phase II stage of clinical testing and market or co-promote certain of our drugs on our own. We have no 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 ourselves or through a strategic alliance, product revenues will suffer, we will incur significant additional losses and our share price will be negatively affected.

If we evolve from a company primarily involved in discovery and development to one also involved in the commercialization of drugs, we may encounter difficulties in managing our growth and expanding our operations successfully.

If we advance our drug candidates through clinical trials, we will need to expand our development and regulatory capabilities and develop manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Our ability to manage our operations and any growth will require us to make appropriate changes and upgrades (as necessary) to our operational, financial and management controls, reporting systems and procedures where we may operate. Any inability to manage growth could delay the execution of our business plan or disrupt our operations.

The failure to attract and retain skilled personnel could impair our drug development and commercialization efforts.

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

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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, or NDA, from the FDA. We have not received an NDA approval from the FDA for any of our drug candidates.

Obtaining an NDA approval is expensive and is a complex, lengthy and uncertain process. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, an NDA may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In addition, failure to comply with FDA and other applicable foreign and U.S. regulatory requirements may subject it to administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve either pending NDAs, or supplements to approved NDAs.

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

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

Following regulatory approval of any drug candidate, we would be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential drugs.

If one of our drug candidates is approved by the FDA or by another regulatory authority, we would be 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, and could include withdrawal of the drug from the market.

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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, it might not be permitted to market our drugs and our business could suffer.

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

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

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

We are engaged in a rapidly changing and highly competitive field. We are seeking to develop and market products that will compete with other products and drugs that currently exist or are being developed. We compete with companies that are developing small molecule drugs, as well as companies that have developed drugs or are developing alternative drug candidates for cancer or other serious disorders where there is abnormal cell proliferation. We believe that other companies are currently developing drugs targeting cancer that may compete with our drug candidates, including Astex, AstraZeneca, Eisai, Kyowa Hakko, Onconova, Pfizer, Roche, Schering AG, and Sunesis. Although Aventis, a predecessor of Sanofi-Aventis, had previously announced that it has ceased Phase II development of alvocidib or flavopiridol, a CDK inhibitor, we believe that the National Cancer Institute s Cancer Therapy Evaluation Program is continuing to enroll patients in a Phase II trial and that Sanofi-Aventis has reinitiated development of alvocidib in Phase III clinical trials in patients with chronic leukemia. Several pharmaceutical and biotechnology companies have nucleoside analogs on the market or in clinical trials for oncology indications, including Clavis Pharmaceuticals, Eli Lilly, Genzyme, GlaxoSmithKline and Supergen. 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 Astex, AstraZeneca, Merck, jointly with Vertex, Millennium Nerviano Medical Sciences and Serono have commenced Phase II or Phase I clinical trials of Aurora kinase inhibitors in patients with advanced cancers. Several companies have reported selection of Aurora kinase inhibitor candidates for development, including Entremed and Sunesis, and may have started or are expected to start clinical trials within the next twelve months. We believe that Boehringer Ingelheim and Onconova have entered clinical development with Plk inhibitor candidates for 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 drug candidates.

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

The commercial success of our drug candidates depends upon their market acceptance among physicians, patients, healthcare providers and payors and the medical community.

If our drug candidates are approved by the FDA or by another regulatory authority, the resulting drugs, if any, may not gain market acceptance among physicians, healthcare providers and payors, patients and the medical community. The degree of market acceptance of any of our approved drugs will depend on a variety of factors, including:

timing of market introduction, number and clinical profile of competitive drugs;

our ability to provide acceptable evidence of safety and efficacy;

relative convenience and ease of administration;

cost-effectiveness;

availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors;

prevalence and severity of adverse side effects; and

other potential advantages over alternative treatment methods.

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

There is uncertainty related to coverage, reimbursement and payment by healthcare providers and payors for newly approved drugs. The inability or failure to obtain coverage could affect our ability to market our future drugs and decrease our ability to generate revenue.

The availability and levels of coverage and reimbursement of newly approved drugs by healthcare providers and payors is subject to significant uncertainty. The commercial success of our drug candidates in both the U.S. and international markets is substantially dependent on whether third party coverage and reimbursement is available. The U.S. Centers for Medicare and Medicaid Services, health maintenance organizations and other third party payors in the United States, the European Union and other jurisdictions are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs and, as a result, they may not cover or provide adequate payment for our potential drugs. Our drug candidates may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our drug candidates to be marketed on a competitive basis.

In some countries, pricing of prescription drugs is subject to government control. In such countries, pricing negotiations with governmental authorities can take three to 12 months or longer following application to the competent authorities. To obtain reimbursement or pricing approval in such countries may require conducting an additional clinical trial comparing the cost-effectiveness of the drug to other alternatives. In the United States, the Medicare Part D drug benefit to be implemented in 2006 will limit drug coverage through formularies and other cost and utilization management programs, while Medicare Part B limits drug payments to a certain percentage of average price or through restrictive payment policies of least costly alternatives and inherent reasonableness. Our business could be materially harmed if coverage, reimbursement or pricing is unavailable or set at unsatisfactory levels.

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We may be exposed to product liability claims that may damage our reputation and 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.

Once we have commercially available drugs based on our drug candidates, we will be exposed to the risk of product liability claims. This risk exists even with respect to those drugs 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 intend to secure limited product liability insurance coverage, but may not be able to obtain such insurance on acceptable terms with adequate coverage, or at 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 create adverse publicity, all of which would impair our ability to generate sales of the litigated product as well as our other potential drugs.

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

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

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

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

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

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

Our ability to obtain patents is uncertain because legal means afford only limited protections and may not adequately protect our rights or permit it to gain or keep any competitive advantage. Some

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

Even if patents are issued regarding our drug candidates or methods of using them, those patents can be challenged by our competitors who may argue such patents are invalid and/or unenforceable. Patents also will not protect our drug candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The U.S. Federal Food, Drug and Cosmetic, or FD&C, Act and FDA regulations and policies and equivalents in other jurisdictions provide incentives to manufacturers to challenge patent validity or create modified, noninfringing versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage manufacturers to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor.

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

If we infringe intellectual property rights of third parties, we may increase our costs or be prevented 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 our research explores. 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. 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. In addition, the production, manufacture, commercialization or use of our product candidates may infringe existing patents of which we are not aware. Numerous third-party United States and foreign issued patents and pending applications exist in the area of kinases, including CDK, Aurora and Plk for which we have research programs. Because patent applications can take several years to issue, there may be pending applications that may result in issued patents that cover our technologies or product candidates. 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. If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that the owner asserts that we infringe its patents. In one case we have opposed a European patent relating to human aurora kinase. We are also aware of

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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 certain of our aurora kinase inhibitors once clinical trials are completed.

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

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder;
- be required to pay substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a competitor s patent or other proprietary rights; or
- be required to redesign the formulation of a drug candidate so it does not infringe, which may not be possible or could require substantial funds and time.

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

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

Intellectual property rights of third parties could adversely affect our ability to commercialize our drug candidates.

If patents issued to third parties contain valid claims that cover our compounds or their manufacture or uses relevant to our development plans, 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, could cover various aspects of our developmental programs, including in some cases our lead drug candidate, seliciclib, particular uses of that compound, sapacitabine or other therapeutic candidates, or gene sequences and techniques that we use in the course of our research and development. Based on our review of the published applications, we believe that it is unlikely that a valid claim would be issued that covered seliciclib. In addition, we understand that other applications exist relating to potential uses of seliciclib and sapacitabine that are not part of our current clinical programs for these compounds. 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. If a patent is issued that covers our compounds or their manufacture or uses related to our development plans then we may

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not be in a position to commercialize the related drug candidate unless we successfully pursue litigation to have that patent invalidated or enter into a licensing arrangement with the patent holder. Any such litigation would be time consuming and costly, and our outcome would not be guaranteed, and we cannot be certain that we would be able to enter into a licensing arrangement with the patent holder on commercially reasonable terms. In either case, our business prospects could be materially adversely affected.

The number of shares of common stock which are being 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 those security holders determine to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

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

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

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

As a newly public company, we face and will continue to face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. Compliance with the Sarbanes Oxley Act of 2002, as well as other rules of the SEC, the Public Company Accounting Oversight Board and The Nasdaq Global Market has resulted in a significant initial cost to us as well as an ongoing increase in our legal, audit and financial compliance costs. As a public company, we are subject to Section 404 of the Sarbanes Oxley Act relating to internal control over financial reporting. We have commenced a formal process to evaluate our internal controls for purposes of Section 404, and we cannot assure that our internal control over financial reporting will prove to be effective.

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 commenced a formal process to evaluate our internal control over financial reporting. Given the status of our efforts, coupled with the fact that guidance from regulatory authorities in the area of internal controls continues to evolve, substantial uncertainty exists regarding our 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.

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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 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.

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 5,000,000 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.

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

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

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

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

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

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

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

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

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

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

- additions to or departures of our key personnel;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements concerning our competitors or the biotechnology industry in general;

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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 convertible preferred stock, and future issuances of our common stock upon conversion of our convertible preferred stock and upon the payment of make-whole dividends, if any, could negatively affect our stock price.

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

In addition, if we exercise our rights to pay make-whole dividends in common stock rather than in cash upon conversion of our convertible preferred stock to common stock, then the sale of such shares of common stock or the perception that such sales may occur could cause the market price of our stock to fall. Additionally, after our convertible preferred stock offering, the holders of our convertible preferred stock had the right to convert each share of convertible preferred stock into approximately 0.42553 shares of our common stock. Such conversion rate is subject to certain antidilution adjustments that, upon the occurrence of certain events, will increase the number of shares of common stock that each holder of convertible preferred stock will receive upon conversion into common stock. Such antidilution price adjustments may apply in the case of any strategic alternative that we pursue which may result in further dilution to the holders of outstanding common stock. The conversion of our convertible preferred stock into common stock and the payment of any make-whole dividends in shares of common stock in lieu of cash, may result in substantial dilution to the interests of our holders of common stock.

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

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

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

We may elect to automatically convert the convertible preferred stock on or prior to maturity if our common stock price has exceeded 150% of the conversion price for at least 20 trading days during

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a 30-day trading period ending within five trading days prior to the notice of automatic conversion. You should be aware that there is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred and the automatic conversion date.

We do not intend to pay cash dividends on its 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.

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SPECIAL 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 te substance used in connection with 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.

Please also see the discussion of risks and uncertainties under the heading Risk Factors starting on page 7.

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 Coley 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.

USE OF PROCEEDS

Unless we indicate otherwise in the applicable prospectus supplement, we currently intend to use the net proceeds from this offering for general corporate purposes, including our internal discovery and development programs and the development of new technologies, general working capital and possible future acquisitions.

We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds from this offering. Pending application of the net proceeds as described above, we intend to invest the net proceeds of the offering in short-term, investment-grade, interest-bearing securities.

We may set forth additional information on the use of net proceeds from the sale of securities we offer under this prospectus in a prospectus supplement relating to the specific offering.

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THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize all the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include information in the prospectus supplement, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

common stock;

preferred stock;

warrants to purchase common stock; and/or

debt securities.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

DESCRIPTION OF COMMON STOCK

We are authorized to issue 100,000,000 shares of common stock, $0.001 par value per share. As of February 9, 2007, approximately 16,157,991 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 Securities and Exchange Commission.

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.

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.

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

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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.

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

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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.

DESCRIPTION OF PREFERRED STOCK

Preferred Stock

We have the authority to issue up to 5,000,000 shares of preferred stock. As of February 9, 2007, 2,046,813 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.

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. 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: