

Cyclacel Pharmaceuticals, Inc.
Form 424B3
July 14, 2006
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PROSPECTUS

9,000,001 Shares

CYCLACEL PHARMACEUTICALS, INC.

Common Stock, \$0.001 Par Value

This prospectus relates to the disposition from time to time of up to 9,000,001 shares of our common stock, held by the selling stockholders described in the section entitled “Selling Stockholders” on page [20] of this prospectus. The selling stockholders may offer and sell any of the shares of common stock from time to time at fixed prices, at market prices or at negotiated prices, and may engage a broker, dealer or underwriter to sell the shares. For additional information on the possible methods of sale that may be used by the selling stockholders, you should refer to the section entitled “Plan of Distribution” on page 22 of this prospectus. We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders, although we may receive proceeds upon the exercise of certain warrants. We are contractually obligated to pay all expenses of registration incurred in connection with this offering, except any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares.

Our common stock is listed on the Nasdaq National Market under the symbol “CYCC.” On July 13, 2006, the last reported sale price for our common stock was \$6.50 per share.

You should consider carefully the risks that we have described in “Risk Factors” beginning on page 7 before deciding whether to invest in our common stock.

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

The date of this prospectus is July 14, 2006.

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You should read this prospectus and the information incorporated by reference carefully before you invest. Such documents contain important information you should consider when making your investment decision. See “Incorporation of Documents by Reference” on page 23. You should rely only on the information provided in this prospectus or documents incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information.

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PROSPECTUS SUMMARY

The following is only a summary. We urge you to read the entire prospectus, including the more detailed financial statements, notes to the financial statements and other information incorporated by reference from our other filings with the SEC. Investing in our common stock involves risk. Therefore, carefully consider the information provided under the heading “Risk Factors” beginning on page 7.

Our Company

We are a clinical-stage biopharmaceutical company dedicated to the discovery, development and eventual commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. We describe drugs, compounds or molecules as mechanism-targeted if they are designed to affect identified biological processes through known mechanisms and novel if they have been recently discovered using advanced technologies. 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 (AK) 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. We have a further seven novel drug series, five for cancer, one for HIV/AIDS and one for Type 2 Diabetes. In addition, we have partnered with Genzyme Corporation certain preclinical stage CDK inhibitors for nephrology or inflammatory kidney disease applications. 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, orally available CDK inhibitor that has been in multi-center Phase II clinical trials for cancer. Seliciclib has been dosed to approximately 233 subjects. 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. These included two non-small cell lung cancer patients with stable disease for 14 and over 18 months whose cancer had previously progressed on four different chemotherapy combinations and a patient with hepatocellular or liver cancer who experienced a partial response after failing four different treatment regimens.

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

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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 breast cancer. Interim data from two Phase II open label studies of a total of 54 patients with non-small cell lung cancer 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 trial of seliciclib as monotherapy for the treatment of hematological cancers has been closed for accrual and we expect to report final data within 2006.

Based on our observation of tolerability and antitumor activity of seliciclib in the clinical trials conducted to date, the oral availability of seliciclib, the recommendation of a non-small cell lung cancer expert panel, and regulatory and marketing considerations, we intend to evaluate seliciclib as stand-alone therapy in patients with non-small cell lung cancer and plan to commence a multi-center Phase IIb randomized clinical trial in the United States in early 2006. 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, and 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. We in-licensed sapacitabine from Sankyo Co., Ltd. Like CDK inhibitors, nucleosides work through cell cycle inhibition, though they do so at a different phase of the cell cycle. A number of nucleoside drugs, such as gemcitabine, are in wide use as conventional chemotherapies. Preclinical results from independent investigators reported that sapacitabine was superior to gemcitabine and 5-FU, another widely used chemotherapy, both in terms of extending survival and blocking metastases to the liver in animal models of cancer. Two Phase I studies of sapacitabine have been completed by Sankyo in the United States, 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 advanced malignancies with approximately 30 patients enrolled to date. Preliminary results from this trial were reported at the meeting of the American Society of Clinical Oncology in May 2005. The primary toxicity was reversible myelosuppression. Sapacitabine will enter an additional Phase I clinical trial in advanced leukemias and myelodysplastic syndromes in the first quarter of 2006. We currently expect to start Phase II evaluation in 2006. 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 expect to file an Investigational New Drug application, or IND, in 2006 and commence Phase I clinical development soon thereafter. We have retained worldwide rights to commercialize CYC116.

To enhance its development efforts, we are making extensive use of biomarkers in all of the clinical programs to study the effects of our drugs in the blood and tissues of patients. Biomarkers are proteins or other substances whose presence in the blood and tissues can serve as an indicator of specific cell processes. For example, in the seliciclib clinical trials, we are working with a biomarker of apoptosis, a type of cell death. Although biomarkers are the focus of great interest within the scientific community and the FDA has issued for comment a draft guidance document that encourages submission of biomarker data, such data are not currently accepted by the FDA or other regulatory authorities as a basis for approval of drug candidates. We nonetheless believe that biomarkers serve a useful purpose in helping to evaluate at an early stage in clinical trials whether drug candidates cause their intended effects in patients through their assumed mechanisms and whether we should continue to invest in their development. Biomarker data from early clinical trials may also enable us to design

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subsequent trials more efficiently and to monitor patient compliance with trial protocols. Biomarkers may also be informative for designing improved next generation drugs working with similar mechanisms. 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.

We expect that in the future our drug programs will increasingly result from the application of a proprietary genes-to-drugs approach, originating through the use of genomic technology from our Polgen division to identify appropriate gene targets and progressing 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, our approach to drug discovery and development aims to improve on the ability to select promising drug targets at an early stage so as to decrease attrition rates during the later, more expensive stages of drug development, allowing us to progress through the drug discovery and development process more quickly and efficiently and thus enhancing the chances of successfully commercializing drugs. To this end, we have assembled a set of sophisticated discovery and development technologies, together with personnel who are highly skillful in making use of these technologies.

Our main research facility is located in Dundee, Scotland where structure-based drug design and development programs are carried out. We also have a second research facility located in Cambridge, England. This is the location of our Polgen division, which is focused on discovering the function of new cancer genes and validating their use as drug discovery targets. Our corporate headquarters are based in 150 John F. Kennedy Parkway, Suite 100, Short Hills, NJ 07078. Our telephone number is (973) 847-5955.

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The Offering

Common stock offered by the selling stockholders	Up to 9,000,001 shares, which includes 2,571,429 shares of common stock issuable upon exercise of outstanding warrants.
Use of proceeds	Proceeds from the sale of common stock covered by this prospectus will be received by the selling stockholders. We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus, although we may receive proceeds upon the exercise of certain warrants.
NASDAQ symbol	CYCC

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RISK FACTORS

Investing in our common stock is very risky. Please carefully consider the risk factors described below. Before making an investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus. Additional risks and uncertainties not presently known to us or that we deem currently immaterial may also impair our business operations. You should be able to bear a complete loss of your investment. See “Special Note Regarding Forward-Looking Statements.”

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.

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 March 31, 2006, our accumulated deficit was \$120.4 million. Our net loss for the three months ended March 31, 2006, the fiscal years ended December 31, 2005 and December 31, 2004, the fiscal nine months ended December 31, 2003, and the fiscal year ended March 31, 2003 was \$11.3 million, \$18.0 million, \$22.7 million, \$15.0 million, and \$15.5 million, respectively. Our net loss from inception through December 31, 2005 was \$109.0 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 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. For example, for the fiscal year ended December 31, 2005, our cash outflow to fund operations was approximately \$15.1 million. To meet these financing

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requirements, we may raise funds through public or private equity offerings, debt financings or strategic alliances. Raising additional funds by issuing equity or convertible debt securities may cause our 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. 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 patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues; and
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial 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.

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.

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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 yet 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 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 yet 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;
- seek regulatory approvals;
- build or access manufacturing and commercialization capabilities;
- commercialize and secure coverage, payment and reimbursement of our drug candidates, if any such candidates receive regulatory approval; 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;

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- 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.

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

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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 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 yet 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 itself 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

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

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

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

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

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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 yet been 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, elevation of liver enzymes and decrease in potassium levels have been observed in some patients receiving our lead drug candidate, seliciclib. 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 IIa clinical trials to test the safety and efficacy of seliciclib, in the treatment of non small cell lung cancer and hematological cancers. Independent investigators are conducting a Phase I clinical trial to test the safety of seliciclib in nasopharyngeal cancer and Phase I clinical trials to test the safety of sapacitabine in patients with advanced cancers.

We expect to report final results of these trials in 2006. We believe but cannot be certain that the independent investigators will publish their results in the near future. 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.

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.

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

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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, 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 Chiron, Eli Lilly and GlaxoSmithKline. A number of companies are pursuing discovery and research activities in each of the other areas that are the subject of our research and drug development programs. We believe that AstraZeneca, Merck, jointly with Vertex, Millennium and Nerviano Medical Sciences have commenced 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 Astex, Rigel and Sunesis, and may have started or are expected to start clinical trials within the next twelve months. We believe that Chiron, Eli Lilly, GlaxoSmithKline, Novartis and Novo Nordisk have reported selection of GSK-3 inhibitor candidates for development in type 2 diabetes, Alzheimer's and stroke indications and Boehringer Ingelheim and Onconova of Plk inhibitors 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.

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:

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- 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.

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

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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. We will only be able to protect our drug candidates and our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

Our ability to obtain patents is uncertain because legal means afford only limited protections and may not adequately protect our rights or permit it to gain or keep any competitive advantage. Some legal principles remain unresolved and the breadth or interpretation of claims allowed in patents in the United States, the European Union or elsewhere can still be difficult to ascertain or predict. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States, the European Union or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent

protection.

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

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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.

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; 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.

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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 use, 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 use then we may 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety, and intended utilization of our product candidates, the conduct and results of future clinical trials, plans regarding regulatory filings, future research and clinical trials and plans regarding partnering activities. Factors that may cause actual results to differ materially include the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials, the risk that we will not obtain approval to market our products, the risks associated with reliance on outside financing to meet capital requirements, and the risks associated with reliance on collaborative partners for further clinical trials, development and commercialization of product candidates. You are urged to consider statements that include the words “may,” “will,” “would,” “could,” “should,” “believes,” “estimates,” “projects,” “potential,” “expects,” “plans,” “continues,” “forecast,” “designed,” “goal,” or the negative of those words or other comparable words to be uncertain and forward-looking. These factors and others are more fully discussed under “Risk Factors” above and in the other reports we file with the SEC.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares of our common stock by the selling stockholders. We may receive proceeds upon the exercise of the warrants described below.

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SELLING STOCKHOLDERS

The following table sets forth information with respect to the number of shares of common stock beneficially owned by the selling stockholders named below and as adjusted to give effect to the sale of the shares offered hereby. The shares beneficially owned have been determined in accordance with rules promulgated by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. The calculation of the shares beneficially owned takes into account the limitation on more than 4.99% beneficial ownership contained in the terms of the warrants (as discussed below in note 1. The information in the table below is current as of June 9, 2006. All information contained in the table below is based upon information provided to us by the selling stockholders and we have not independently verified this information. The selling stockholders are not making any representation that any shares covered by the prospectus will be offered for sale. The selling stockholders may from time to time offer and sell pursuant to this prospectus any or all of the common stock being registered.

For purposes of this table, beneficial ownership is determined in accordance with SEC rules, and includes voting power and investment power with respect to shares and shares owned pursuant to warrants exercisable within 60 days. The “Number of Shares Beneficially Owned After Offering” column assumes the sale of all shares offered.

As explained below under “Plan of Distribution,” we have agreed with the selling stockholders to bear certain expenses (other than broker discounts and commissions, if any) in connection with the registration statement, which includes this prospectus.

Name of Selling Stockholder	Number of Shares Beneficially Owned Prior to Offering ⁽¹⁾	Number of Shares Offered	Number of Shares Beneficially Owned After Offering
Atlas Master Fund, Ltd.	42,036	58,850 ⁽²⁾	0
Visium Long Bias Fund, LP	30,562	42,787 ⁽³⁾	0
Visium Balanced Fund, LP	101,632	142,285 ⁽⁴⁾	0
Visium Balanced Offshore Fund, Ltd.	151,892	212,648 ⁽⁵⁾	0
Visium Long Bias Offshore Fund, Ltd.	102,449	143,429 ⁽⁶⁾	0
SF Capital Partners Ltd.	421,429	590,001 ⁽⁷⁾	0
Capital Ventures International	428,571	599,999 ⁽⁸⁾	0
Magnetar Capital Master Fund, Ltd.	1,071,429	1,500,001 ⁽⁹⁾	0
Federated Kaufman Fund A Portfolio of Federated Equity Funds	2,142,857	3,000,000 ⁽¹⁰⁾	0
Deerfield Special Situations Fund International Limited	381,715	534,401 ⁽¹¹⁾	0
Deerfield Special Situations Fund, L.P.	189,714	265,600 ⁽¹²⁾	0
Deerfield International Limited	287,000	401,800 ⁽¹³⁾	0
Deerfield Partners, L.P.	213,000	298,200 ⁽¹⁴⁾	0
Joseph Klein III 5% Charitable Remainder Unitrust	7,143	10,000 ⁽¹⁵⁾	0
Baker Biotech Fund I, L.P.	91,615	128,261 ⁽¹⁶⁾	0
Baker Biotech Fund I, L.P.	84,677	118,548 ⁽¹⁷⁾	0
Baker Brothers Life Sciences, L.P.	526,461	737,045 ⁽¹⁸⁾	0

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14159, L.P.	11,533	16,146 ⁽¹⁹⁾	0
Red Abbey Venture Partners, LP	142,857	200,000 ⁽²⁰⁾	0
TOTAL	6,428,572	9,000,001 ⁽²¹⁾	0

(1)The amounts indicated do not include the shares of common stock underlying the warrants, an aggregate of 2,571,429 shares, included in this offering that are held by the selling stockholders, as the warrants are not exercisable until October 26, 2006 which date is not within 60 days of June 9, 2006.

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- (2)Includes 16,814 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (3)Includes 12,225 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (4)Includes 40,653 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (5)Includes 60,756 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (6)Includes 40,980 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (7)Includes 168,572 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (8)Includes 171,428 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (9)Includes 428,572 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (10)Includes 857,143 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (11)Includes 152,686 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (12)Includes 75,886 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (13)Includes 114,800 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (14)Includes 85,200 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (15)Includes 2,857 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (16)Includes 36,646 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (17)Includes 33,871 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (18)Includes 210,584 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (19)Includes 4,613 shares of common stock underlying warrants that are exercisable as of October 26, 2006.
- (20)Includes 57,143 shares of common stock underlying warrants that are exercisable as of October 26, 2006.

(21)Includes 2,571,429 shares of common stock underlying warrants that are exercisable as of October 26, 2006.

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PLAN OF DISTRIBUTION

The selling stockholders may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits Investors;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the Investor of shares, from the Investor) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed a

supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

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We are required to pay all fees and expenses incident to the registration of the shares of common stock, including up to \$5,000 of fees and disbursements of counsel to the selling stockholders. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. The selling stockholders have agreed to indemnify us in certain circumstances against certain liabilities, including liabilities under the Securities Act.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling stockholder. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling stockholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholders.

LEGAL MATTERS

The validity of the common stock offered in this prospectus will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York. Members of Mintz Levin do not own any shares of common stock of Cyclacel.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in both our Current Report on Form 8-K dated May 16, 2006 and filed with the Securities and Exchange Commission on May 16, 2006 and in our Amendment No. 1 to the Current Report on Form 8-K/A dated June 9, 2006 and filed with the Securities and Exchange Commission on June 9, 2006, as set forth in their report dated March 27, 2006, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance upon Ernst & Young LLP’s report, given on their authority as experts in accounting and auditing.

INCORPORATION OF 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 with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934. The documents we are incorporating by reference as of their respective dates of filing are:

- Part III of the Annual Report on Form 10-K for the year ended December 31, 2005, filed on March 23, 2006;
- Amendment No. 1 to the Annual Report on Form 10-K/A for the year ended December 31, 2005, filed on May 1, 2006;
- Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, filed on May 16, 2006;
- Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2006, filed on July 7, 2006;
- Current Reports on Form 8-K, filed on March 30, 2006, April 14, 2006, April 19, 2006, April 28, 2006, May 16, 2006, May 18, 2006, June 21, 2006, June 29, 2006, July 7, 2006 and July 10, 2006;

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- Current Reports on Form 8-K/A filed on June 9, 2006 and July 7, 2006;
- The description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on March 8, 2004, including any amendments or reports filed for the purpose of updating that description; and
- The description of our convertible exchangeable preferred stock contained in our Registration Statement on Form 8-A filed with the SEC on October 27, 2004, including any amendments or reports filed for the purpose of updating that description.

All documents we file with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus but before the termination of the offering by this prospectus shall be deemed to be incorporated herein by reference and to be a part hereof from the date of the filing of those documents.

Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for all purposes to the extent that a statement contained in this prospectus, or in any other subsequently filed document which is also incorporated or deemed to be incorporated by reference, modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost, by contacting:

Investor Relations
150 John F. Kennedy Parkway, Suite 100
Short Hills, NJ 07078
Telephone: (732) 225-8910

WHERE YOU CAN FIND MORE INFORMATION

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We are a public company and file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. Our SEC filings are also available to the public at the SEC's web site at "<http://www.sec.gov>." In addition, our stock is listed for trading on the Nasdaq National Market. You can read and copy reports and other information concerning us at the offices of the National Association of Securities Dealers, Inc. located at 1735 K Street, Washington, D.C. 20006.

This prospectus is only part of a Registration Statement on Form S-3 that we have filed with the SEC under the Securities Act of 1933 and therefore omits certain information contained in the Registration Statement. We have also filed exhibits and schedules with the Registration Statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may:

- inspect a copy of the Registration Statement, including the exhibits and schedules, without charge at the public reference room,
- obtain a copy from the SEC upon payment of the fees prescribed by the SEC, or
- obtain a copy from the SEC web site.

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9,000,001 Shares of Common Stock

CYCLACEL PHARMACEUTICALS, INC.

Prospectus

July 14, 2006