

ACADIA PHARMACEUTICALS INC

Form S-1

May 10, 2005

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As filed with the Securities and Exchange Commission on May 10, 2005

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

ACADIA PHARMACEUTICALS INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	2834 (Primary Standard Industrial Classification Code Number)	06-1376651 (I.R.S. Employer Identification Number)
3911 Sorrento Valley Boulevard, San Diego, CA 92121		
(858) 558-2871		

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Uli Hacksell, Ph.D.

Chief Executive Officer

ACADIA Pharmaceuticals Inc.

3911 Sorrento Valley Boulevard, San Diego, CA 92121

(858) 558-2871

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:

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Approximate date of commencement of proposed sale to the public:

As soon as practicable after the Registration Statement becomes effective.

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

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

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

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

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to Be Registered	Amount to Be Registered(1)	Proposed Maximum Offering Price per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, \$0.0001 par value	5,277,621	\$ 7.38	\$ 38,948,843	\$ 4,585
Common Stock, \$0.0001 par value, issuable upon exercise of warrants	1,319,402	\$ 7.38	\$ 9,737,187	\$ 1,146
Total	6,597,023		\$ 48,686,030	\$ 5,731

(1) Pursuant to Rule 415 under the Securities Act this registration statement also covers such additional shares as may hereafter be offered or issued to prevent dilution resulting from stock splits, dividends, recapitalizations or certain other capital adjustments.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457 under the Securities Act of 1933. The price per share is based on the average of the high and low prices reported on The Nasdaq National Market for shares of the Registrant's common stock on May 6, 2005.

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

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

SUBJECT TO COMPLETION, DATED MAY 9, 2005

Prospectus

6,597,023 Shares

Common Stock

The selling stockholders identified in this prospectus are offering for sale from time to time up to 6,597,023 shares of our common stock, \$0.0001 par value per share, which includes 5,277,621 shares of our common stock held by the selling stockholders and 1,319,402 shares of our common stock issuable to the selling stockholders upon the exercise of warrants. The selling stockholders have indicated that sales of their shares of common stock may be made by the methods described in the section entitled "Plan of Distribution" in this prospectus.

The selling stockholders acquired their shares from us in a private placement that closed on April 20, 2005 and is more fully described on page 68 of this prospectus under the heading "Selling Stockholders."

Our common stock is listed on The Nasdaq National Market under the symbol "ACAD". On May 6, 2005, the last reported sale price for our common stock was \$7.40. You are encouraged to obtain current market quotations for shares of our common stock.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 1.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

, 2005

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You should rely only on the information contained in this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with different information. No one is making offers to sell or seeking offers to buy these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus is accurate as of the date on the front of this prospectus only, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

References in this prospectus to ACADIA, the Company, we, us and our refer to ACADIA Pharmaceuticals Inc., together with our wholly-owned subsidiary, ACADIA Pharmaceuticals A/S.

ACADIA and R-SAT are our trademarks. This prospectus also includes trademarks and trade names owned by other parties, and these trademarks and trade names are the property of their respective owners. Use or display by us of other parties' trademarks, trade dress or products in this prospectus is not intended to, and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

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Our Corporate Information

We were originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. In 1997, we reincorporated in Delaware and changed our name to ACADIA Pharmaceuticals Inc. Our principal executive offices are located at 3911 Sorrento Valley Boulevard, San Diego, California 92121, and our telephone number at that address is (858) 558-2871. We also have chemistry research facilities located near Copenhagen, Denmark. Our website is located at www.acadia-pharm.com. We do not consider information contained on, or that can be accessed through, our website to be part of this prospectus.

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RISK FACTORS

You should consider carefully the following information about the risks described below, together with the other information contained in this prospectus and in our other public filings in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Business

We expect our net losses to continue for at least several years and are unable to predict the extent of future losses or when we will become profitable, if ever.

We have experienced significant net losses since our inception. As of December 31, 2004, we had an accumulated deficit of approximately \$94.3 million. We expect our annual net losses to increase over the next several years as we expand our research and development activities, incur significant preclinical and clinical development costs, and enhance our infrastructure.

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our drug candidates. Our primary source of revenues for the year ended December 31, 2004 was from research and milestone payments under our collaboration agreements with Allergan. For the year ended December 31, 2004, we received 98 percent of our revenues from our collaborations with Allergan. We anticipate that collaborations with pharmaceutical companies will continue to be our primary source of revenues for the next several years, which provide us with research funding and potential milestone payments and royalties. We cannot be certain that the milestones required to trigger payments will be reached or that we will secure additional collaboration agreements. To obtain revenues from our drug candidates, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. We may never succeed in these activities, and may never generate revenues that are significant enough to achieve profitability.

Our most advanced clinical products are in clinical trials, which are long, expensive and unpredictable, and there is a high risk of failure.

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

All of our drug candidates are at an early stage of development and the historical rate of failures for drug candidates is extremely high. Our three Phase II-stage clinical programs are ACP-103 for treatment-induced dysfunctions in Parkinson's disease, ACP-103 as an adjunctive therapy for schizophrenia, and ACP-104 for the treatment of schizophrenia.

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In connection with clinical trials, we face risks that:

a drug candidate may not prove to be efficacious;

patients may die or suffer other adverse effects for reasons that may or may not be related to the drug candidate being tested;

the results may not confirm the positive results of earlier trials; and

the results may not meet the level of statistical significance required by the Food and Drug Administration, or FDA, or other regulatory agencies.

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If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our drug candidates and to generate product revenues. Even if we do successfully complete Phase I and Phase II clinical trials, those results are not necessarily predictive of results of future trials. Of the large number of drugs in development, only a small percentage result in the submission of a new drug application to the FDA and even fewer are approved for commercialization.

Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay our ability to generate product revenues.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;

reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

manufacturing sufficient quantities of a drug candidate;

obtaining approval of an Investigational New Drug Application, or IND, from the FDA;

obtaining institutional review board approval to conduct a clinical trial at a prospective site; and

insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;

failure to conduct clinical trials in accordance with regulatory requirements;

lower than anticipated retention rate of patients in clinical trials;

serious adverse events or side effects experienced by participants; and

insufficient supply or deficient quality of drug candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential drug candidate. If we experience delays in our clinical trials, the commercial prospects for our drug candidates will be harmed, and our ability to generate product revenues will be delayed.

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop products.

We have consumed substantial amounts of capital since our inception. For the year ended December 31, 2004, we used \$20.7 million in cash, cash equivalents and investment securities to fund our operating activities. Although we believe our existing cash resources and anticipated payments from existing agreements with our collaborators will be sufficient to fund our anticipated cash requirements through at least mid-2007, we will require significant additional financing in the future to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

progress in, and the costs of, our preclinical studies and clinical trials and other research and development programs;

the scope, prioritization and number of our research and development programs;

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the ability of our collaborators and us to reach the milestones, and other events or developments, triggering payments under our collaboration agreements or to otherwise make payments under these agreements;

the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;

the costs of securing manufacturing arrangements for clinical or commercial production; and

the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market our drug candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through strategic collaborations, private or public sales of our securities, debt financings, or by licensing all or a portion of our drug candidates or technology. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. Additional funding may significantly dilute existing stockholders.

We depend on collaborations with third parties to develop and commercialize selected drug candidates and to provide the majority of our revenues.

A key aspect of our strategy is to selectively enter into collaborations with third parties. We currently rely, and will continue to rely, on our collaborators for financial resources and for development, commercialization and regulatory expertise for selected drug candidates. For the year ended December 31, 2004, we received 98 percent of our revenues from our collaborations with Allergan. We expect that nearly all of our revenues for the foreseeable future will be generated by collaborations, although there is no guarantee that revenues from our collaborations will continue at current or past levels.

Our collaborators may fail to develop or effectively commercialize products using our drug candidates or technologies because they:

do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;

decide to pursue a competitive product developed outside of the collaboration; or

cannot obtain the necessary regulatory approvals.

The continuation of our collaborations is dependent on our collaborators' periodic renewal of the governing agreements. Allergan and Sepracor can terminate our existing collaborations before the full term of these collaborations under specific circumstances, including in some cases the right to terminate upon notice. We may not be able to renew these collaborations on acceptable terms, if at all. We also face competition in our search for new collaborators.

If conflicts arise with our collaborators, they may act in their self interests, which may be adverse to our interests.

Conflicts may arise in our collaborations due to one or more of the following:

disputes with respect to payments that we believe are due under the applicable agreements;

disagreements with respect to ownership of intellectual property rights;

unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities;

delay of a collaborator's development or commercialization efforts with respect to our drug candidates; or

termination or non-renewal of the collaboration.

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Conflicts arising with our collaborators could harm our reputation, result in a loss of revenues, reduce our cash position and cause a decline in our stock price.

In addition, in each of our collaborations, we generally have agreed not to conduct independently, or with any third party, any research that is directly competitive with the research conducted under our collaborations. Our collaborations may have the effect of limiting the areas of research that we may pursue, either alone or with others. Our collaborators, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations.

We have collaborations with Allergan for the development of drug candidates related to neuropathic pain and ophthalmic diseases, including glaucoma. Allergan currently markets therapeutic products to treat glaucoma and is engaged in other research programs related to glaucoma and other ophthalmic products that are independent from our development program in this therapeutic area. Allergan is also pursuing other research programs related to pain management that are independent from our collaboration in this therapeutic area. Our collaboration with Sepracor includes an option to pursue a combination drug to treat sleep disorders. Sepracor currently markets a therapeutic product to treat sleep disorders and is engaged in other research programs related to this field that are independent from our development program in this therapeutic area. Competing products, either developed by our collaborators or to which our collaborators have rights, may result in the allocation of resources to competing products and their withdrawal of support for our drug candidates.

We rely on third parties to coordinate our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing drug candidates.

Although we design and manage our current preclinical studies and clinical trials, we currently do not have the ability to coordinate clinical trials for our drug candidates. In addition to our collaborators, we rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. In addition, we also rely on third parties to assist with our preclinical studies, including studies regarding biological activity, safety, absorption, metabolism and excretion of drug candidates.

Our preclinical development activities or clinical trials may be delayed, suspended or terminated if:

these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;

these third parties need to be replaced; or

the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons.

Failure to perform by these third parties may increase our development costs, delay our ability to obtain regulatory approval and prevent the commercialization of our drug candidates. We currently use several contract research organizations to perform services for our preclinical studies and clinical trials. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures.

Even if we successfully complete the clinical trials of our drug candidates, they may fail for other reasons.

Even if we successfully complete the clinical trials of our drug candidates, they may fail for other reasons, including the possibility that the drug candidates will:

fail to receive the regulatory clearances required to market them as drugs;

be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;

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be difficult or expensive to manufacture on a commercial scale;

have adverse side effects that make their use less desirable; or

fail to compete with drug candidates or other treatments commercialized by our competitors.

Our drug candidates may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

Even if our drug candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved drug candidate by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

our ability to provide acceptable evidence of safety and efficacy;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

availability of alternative treatments;

pricing and cost effectiveness, which may be subject to regulatory control;

effectiveness of our or our collaborators' sales and marketing strategy; and

our ability to obtain sufficient third-party insurance coverage or reimbursement.

If any drug candidate that we discover and develop does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product will not achieve market acceptance and we will not generate sufficient revenues to achieve or maintain profitability.

We do not know whether one of our drug candidates, ACP-104, will have the same adverse effects as clozapine, a currently available therapy.

One of our drug candidates under development is ACP-104 for the treatment of schizophrenia. ACP-104 is formed in the body from clozapine, a generic drug that is currently approved as a second-line therapy for schizophrenia in the United States. This means that clozapine will only be

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prescribed to a patient after a doctor determines that the patient has failed to progress under a first-line therapy consisting of antipsychotic drugs. Clozapine is associated with the occurrence of a rare and potentially fatal blood disorder leading to a complete loss of white blood cells, known as agranulocytosis, in approximately one percent of patients treated with clozapine. As a result, patients being treated with clozapine are subject to weekly or bi-weekly blood monitoring. In addition, one of the other side effects of clozapine is the occurrence of seizures, which is found in approximately five percent of users. ACP-104 may have the same adverse effects of clozapine or other significant adverse effects and, if successfully developed, may also only be approved as a second-line therapy. These factors could substantially limit the commercial potential of ACP-104 and may substantially restrict its potential market.

If we are unable to attract, retain and motivate key management and scientific staff, our drug development programs and our research and discovery efforts may be delayed and we may be unable to successfully develop or commercialize our drug candidates.

Our success depends on our ability to attract, retain and motivate highly qualified management and scientific personnel. In particular, our drug discovery and development programs depend on our ability to attract and retain highly skilled chemists, biologists, pharmacologists and development personnel, especially in the fields of central nervous system disorders, including neuropsychiatric and pain disorders. In addition, we will need to hire additional personnel as we continue to expand our clinical development and other research and development activities. We face competition for experienced scientists and other technical personnel from

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numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area. If we are unable to attract and retain the necessary personnel, this will significantly impede the achievement of our research and development objectives and our ability to meet the demands of our collaborators in a timely fashion.

Although we have employment agreements with key members of management, all of our employees are at will employees, which means that any employee may quit at any time and we may terminate any employee at any time. We do not carry key person insurance covering members of senior management.

We do not know whether our drug discovery platform will lead to the discovery or development of commercially viable drug candidates.

Our drug discovery platform uses new and unproven methods to identify and develop drug candidates. We have never successfully completed clinical development of any of our drug candidates, and there are no drugs on the market that have been discovered using our drug discovery platform.

Much of our research focuses on small molecule drugs for the treatment of central nervous system disorders. Due to our limited resources, we may have to forego potential opportunities with respect to discovering drug candidates to treat diseases or conditions in other areas. If we are not able to use our technologies to discover and develop drug candidates that can be commercialized, we may not achieve profitability. In the future, we may find it necessary to license the technology of others or acquire additional drug candidates to augment the results of our internal discovery activities. If we are unable to identify new drug candidates using our drug discovery platform, we may be unable to establish or maintain a clinical development pipeline or generate product revenues.

We may not be able to continue or fully exploit our collaborations with outside scientific and clinical advisors, which could impair the progress of our clinical trials and our research and development efforts.

We work with scientific and clinical advisors at academic and other institutions who are experts in the field of central nervous system disorders. They assist us in our research and development efforts and advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. Although our scientific and clinical advisors and collaborators generally agree not to engage in competing work, if a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the clinical development of our drug candidates.

We will need to increase the size of our organization, and we may encounter difficulties managing our growth, which could adversely affect our results of operations.

We will need to expand and effectively manage our operations and facilities in order to advance our drug development programs, achieve milestones under our collaboration agreements, facilitate additional collaborations and pursue other development activities. It is possible that our human resources and infrastructure may be inadequate to support our future growth. To manage our growth, we will be required to continue to improve our operational, financial and management controls, reporting systems and procedures in at least two countries and to attract and retain sufficient numbers of talented employees. In addition, we may have to develop sales, marketing and distribution capabilities if we decide to market any drug that we may successfully develop without partnering with third parties. We may not successfully manage the expansion of our operations and, accordingly, may not achieve our research, development and commercialization goals.

We face financial and administrative challenges in coordinating the operations of our European activities with our activities in California, which could have on adverse impact on our operations.

Our subsidiary in Denmark, ACADIA Pharmaceuticals A/S, employs approximately 33 percent of our total personnel and is engaged in research and development activities, with primary responsibility for combinatorial,

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medicinal and analytical chemistry. Our principal executive offices, however, are located in San Diego. The additional administrative expense required to follow and coordinate activities in both Europe and California could divert management resources from other important endeavors and, in turn, delay any development and commercialization efforts. In addition, currency fluctuations involving our Danish operations may cause foreign currency translation gains and losses. These exchange-rate fluctuations could have a negative effect on our operations. We do not engage in currency hedging transactions.

We face financial and administrative challenges in opening our new chemistry research facility in Malmo, Sweden, which could have on adverse impact on our operations.

We have announced that we have entered into a lease for a chemistry research and development facility in Malmo, which is located near our current facilities in the Copenhagen region. We will incur additional costs in setting up and adjusting to operations in a new country with a new Swedish subsidiary. In addition, we may not be able to retain all of our current European employees when we establish our new facility in Malmo. In addition, like our current Danish operations, currency fluctuations involving our Swedish operations may cause foreign currency translation gains and losses. These exchange-rate fluctuations could have a negative effect on our operations. As mentioned above, we do not engage in currency hedging transactions.

We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.

Our quarterly operating results have fluctuated in the past and are likely to do so in the future. Some of the factors that could cause our operating results to fluctuate from period to period include:

the status of development of ACP-103 and ACP-104 and the preclinical and clinical development of our other drug candidates;

whether we generate revenues by achieving specified research or commercialization milestones under any agreements or otherwise receive potential payments under these agreements;

the incurrence of preclinical or clinical expenses that could fluctuate significantly from period to period;

the initiation, termination or reduction in the scope of our collaborations during these periods or any disputes regarding these collaborations;

the timing of our satisfaction of applicable regulatory requirements;

the rate of expansion of our clinical development and other internal research and development efforts;

the effect of competing technologies and products and market developments; and

general and industry specific economic conditions.

We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Relying on third-party manufacturers may result in delays in our clinical trials and product introductions.

We have no manufacturing facilities and have no experience in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our drug candidates for clinical trials. If any of our drug candidates are approved by the FDA or other regulatory agencies for commercial sale, we may need to contract with a third party to manufacture them in larger quantities. We currently use third-party manufacturers to produce ACP-103 and ACP-104 for us. While we believe that there are alternative sources available to manufacture our drug candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but do not expect them to be material.

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Our manufacturers are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or obtaining regulatory approval of drug candidates or the ultimate launch of our products into the market. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant premarket approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our profitability or our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

We will incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance and other matters.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002, or SOA, and rules adopted or proposed by the SEC and by the Nasdaq Stock Market, will result in increased costs to us as we evaluate the implications of any new rules and respond to their requirements. Although we are not required to issue an evaluation of our internal control over financial reporting under Section 404 of SOA until March 2006, at the earliest, preparations for the issuance of this report have already resulted in increased costs to us, which will increase further. If we are not able to issue an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. The new rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees and as executive officers. We cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs to comply with these rules and regulations.

Changes in stock option accounting treatment may adversely affect our results of operations.

Changes in stock option accounting treatment commencing January 1, 2006 will require us to account for employee stock options as compensation expense in our financial statements. In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123 (revised 2004), Share-Based Payment, or SFAS 123(R), which requires that compensation costs relating to share-based payment transactions be recognized in financial statements. We are required to implement SFAS 123(R) in our first quarter of 2006. We are currently evaluating the requirements of SFAS 123(R) and we have not yet fully determined the impact on our consolidated financial statements. However, implementation of SFAS 123(R) could materially and adversely affect our reported results of operations and our timing to achieve profitability.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may not be able to generate product revenue.

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. In order to market any products that may be approved by the FDA, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these

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services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

If we engage in any acquisition, we will incur a variety of costs and may never realize the anticipated benefits of the acquisition.

We may attempt to acquire businesses, technologies, services or products or license in technologies that we believe are a strategic fit with our business. We have limited experience in identifying acquisition targets, successfully completing proposed acquisitions and integrating any acquired businesses, technologies, services or products into our current infrastructure. The process of integrating any acquired business, technology, service or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. As a result, we will incur a variety of costs in connection with an acquisition and may never realize its anticipated benefits.

Earthquake damage to our facilities could delay our research and development efforts and adversely affect our business.

Our headquarters and research and development facilities in San Diego are located in a seismic zone, and there is the possibility of an earthquake, which could be disruptive to our operations and result in delays in our research and development efforts. In the event of an earthquake, if our facilities or the equipment in our facilities is significantly damaged or destroyed for any reason, we may not be able to rebuild or relocate our facilities or replace any damaged equipment in a timely manner and our business, financial condition and results of operations could be materially and adversely affected. We do not have insurance for damages resulting from earthquakes.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our commercial success depends on obtaining and maintaining proprietary rights to our drug candidates and technologies and their uses, as well as successfully defending these rights against third-party challenges. We will only be able to protect our drug candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or effectively protected trade secrets cover them. Although we have filed several patent applications with respect to ACP-104 and ACP-103, we have not been issued any patents with respect to ACP-104, and have been issued only two patents with respect to ACP-103.

Our ability to obtain patent protection for our products and technologies is uncertain due to a number of factors, including:

we may not have been the first to make the inventions covered by our pending patent applications or issued patents;

we may not have been the first to file patent applications for our drug candidates or the technologies we rely upon;

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others may independently develop similar or alternative technologies or duplicate any of our technologies;

our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;

any or all of our pending patent applications may not result in issued patents;

we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;

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any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;

our proprietary technologies may not be patentable;

others may design around our patent claims to produce competitive products which fall outside of the scope of our patents; or

others may identify prior art which could invalidate our patents.

Even if we have or obtain patents covering our drug candidates or technologies, we may still be barred from making, using and selling our drug candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, genes, gene products or therapeutic products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to genes, nucleic acids, polypeptides, chemical compounds or therapeutic products, and some of these may encompass reagents utilized in the identification of candidate drug compounds or compounds that we desire to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of central nervous system disorders and the other fields in which we are developing products. These could materially affect our ability to develop our drug candidates or sell our products. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our drug candidates or technologies may infringe. These patent applications may have priority over patent applications filed by us.

We regularly conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our proprietary compounds or that could limit the rights we have claimed in our patents and patent applications. In particular, we are aware of claims that have been allowed by, and are pending before, the United States Patent and Trademark Office that, if issued as currently drafted, would encompass the chemical structure of ACP-103. While we do not believe that these pending claims would be valid if issued in their current form, there can be no assurance that a court would find these claims invalid or that the text or substance of these claims will not be modified upon further prosecution of the application. If valid, these claims could limit our rights with respect to ACP-103.

Disputes may arise regarding the ownership or inventorship of our inventions. It is difficult to determine how such disputes would be resolved. Others may challenge the validity of our patents. If our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information will be impaired. In addition, technology that we may license in may become important to some aspects of our business. We generally will not control the patent prosecution, maintenance or enforcement of in-licensed technology.

We have limited proprietary rights to one of our drug candidates, ACP-104, which may limit our ability to prevent competitors from exploiting that compound.

One of our drug candidates, ACP-104, is a publicly available compound, and we will have limited proprietary rights in this candidate. Other companies may obtain patents or regulatory approvals to use the same drug for treatments other than to treat the indications for which we have

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filed for patent protection. We are aware of an issued patent not owned by us that claims the use of N-desmethylozapine, which is the chemical name for ACP-104, to induce analgesia. ACP-104, which we are developing for treatment of schizophrenia, is formed in the body from clozapine and its structure was known prior to our filing of patent applications relating to its use to treat certain conditions. Accordingly, we will not be able to obtain composition of matter patents for ACP-104. We have filed a method of use patent application for ACP-104, but a competitor could use ACP-104, and patent

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its method of use, for a treatment not covered by our patent application. In addition, while we have filed a patent application directed to methods of synthesis of ACP-104, those claims will not prevent a potential competitor from making ACP-104.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain trade secret protection could adversely affect our competitive position. In addition, we have not entered into any noncompete agreements with any of our employees other than Dr. Brann.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our drug candidates, technologies or activities infringe the intellectual property rights of others. In particular, there are many patents relating to specific genes, nucleic acids, polypeptides or the uses thereof to identify drug candidates. Some of these may encompass genes or polypeptides that we utilize in our drug development activities. If our drug development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented genes or polypeptides for the identification or development of drug compounds. There are also many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from making, using or selling the patented compounds. We may need to resort to litigation to enforce a patent issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against our company or our collaborators could lead to:

payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;

injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell products; or

we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all.

As a result, we could be prevented from commercializing current or future products.

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The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. For example, some of our patent applications will cover gene sequences and products and the uses of those gene sequences and products. Public disclosures and patent applications related to the Human Genome Project and other genomics efforts may limit the scope of our claims or make unpatentable subsequent patent applications. No consisten