

ACADIA PHARMACEUTICALS INC

Form 10-K

March 05, 2008

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**Form 10-K**

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2007

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-50768

**ACADIA PHARMACEUTICALS INC.**

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

**Delaware**  
(State or Other Jurisdiction of

**06-1376651**  
(I.R.S. Employer

**Incorporation or Organization)**

**Identification Number)**

**3911 Sorrento Valley Boulevard**

**San Diego, California**  
(Address of Principal Executive Offices)

**92121**  
(Zip Code)

**Registrant's telephone number, including area code:**

**(858) 558-2871**

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Name of each exchange on which registered
<b>Common Stock, par value \$0.0001 per share</b>	<b>The NASDAQ Global Market</b>

**Securities registered pursuant to Section 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934:

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☒

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

As of June 29, 2007, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$401 million, based on the closing price of the registrant's common stock on the NASDAQ Global Market on June 29, 2007 of \$13.67 per share.

As of February 29, 2008, 37,059,232 shares of registrant's common stock, \$0.0001 par value, were outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission by April 29, 2008 are incorporated by reference into Part III of this report.

**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**TABLE OF CONTENTS**

**FORM 10-K**

**For the Year Ended December 31, 2007**

**INDEX**

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1. <u>Business.</u>	1
Item 1A. <u>Risk Factors.</u>	19
Item 1B. <u>Unresolved Staff Comments.</u>	35
Item 2. <u>Properties.</u>	35
Item 3. <u>Legal Proceedings.</u>	35
Item 4. <u>Submission of Matters to a Vote of Security Holders.</u>	35
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</u>	36
Item 6. <u>Selected Financial Data.</u>	37
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	38
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk.</u>	48
Item 8. <u>Financial Statements and Supplementary Data.</u>	48
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.</u>	49
Item 9A. <u>Controls and Procedures.</u>	49
Item 9B. <u>Other Information.</u>	50
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance.</u>	51
Item 11. <u>Executive Compensation.</u>	51
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</u>	51
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence.</u>	51
Item 14. <u>Principal Accounting Fees and Services.</u>	51
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits, Financial Statement Schedules.</u>	52

---

**Table of Contents**

**PART I**

**FORWARD-LOOKING STATEMENTS**

This report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plans, in estimates, could, should, would, continue, seeks, aims, projects, predicts, pro forma, anticipates, potential or other similar use in the negative), or by discussions of future matters such as the development of drug candidates or products, technology enhancements, possible changes in legislation, and other statements that are not historical. These statements include but are not limited to statements under the captions Business, Risk Factors, and Management's Discussion and Analysis of Financial Condition and Results of Operations as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the caption Risk Factors and elsewhere in this report could substantially harm our business, results of operations and financial condition. If any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report.

**Item 1. Business.**

**Overview**

We are a biopharmaceutical company focused on the discovery, development, and commercialization of small molecule drugs for the treatment of central nervous system disorders. We currently have six clinical programs and several additional programs in discovery and development. In our most advanced program, we are conducting Phase III studies with pimavanserin for the treatment of Parkinson's disease psychosis. We have reported positive results from a Phase II trial in our program with pimavanserin as a co-therapy in schizophrenia. We also have completed enrollment of a Phase IIb trial in our program with ACP-104 as a stand-alone treatment for schizophrenia. In addition, we have completed a proof-of-concept clinical study with pimavanserin for the treatment of sleep maintenance insomnia in healthy older adults. We have retained worldwide commercialization rights for our programs with pimavanserin and ACP-104. Additionally, we have a neuropathic pain program in Phase II development and a glaucoma program in Phase I studies in collaboration with Allergan, Inc. All of the drug candidates in our product pipeline emanate from discoveries made using our proprietary drug discovery platform.

Our pipeline addresses diseases that are not well served by currently available therapies and represent large potential commercial opportunities. We believe that our drug candidates offer innovative therapeutic approaches and may provide significant advantages relative to current therapies. Our clinical programs consist of the following:

*Pimavanserin for the treatment of Parkinson's disease psychosis.* Parkinson's disease psychosis is a debilitating psychiatric disorder that occurs in up to 40 percent of patients with Parkinson's disease and is associated with increased caregiver burden, nursing home placement, and increased mortality. Currently, there

## **Table of Contents**

are no therapies approved to treat Parkinson's disease psychosis in the United States. We believe that pimavanserin may effectively treat psychosis in patients with Parkinson's disease while allowing for optimal motor control, thereby significantly improving the quality of life for these patients. We are currently conducting the first pivotal trial and are preparing to initiate a second pivotal trial in this Phase III program.

*Pimavanserin as a co-therapy for schizophrenia.* Current drugs used to treat schizophrenia have substantial limitations, including inadequate efficacy and severe side effects. We believe that co-therapy with pimavanserin may result in enhanced efficacy and fewer side effects relative to existing treatments, thereby providing an improved therapy for patients with schizophrenia. We have reported positive results from a Phase II trial, which demonstrated several advantages of co-therapy with pimavanserin and a sub-maximal dose of risperidone, a commonly prescribed antipsychotic drug, including enhanced efficacy, a faster onset of antipsychotic action, and an improved side effect profile.

*ACP-104 for the treatment of schizophrenia.* Currently prescribed treatments do not effectively address or may exacerbate cognitive disturbances associated with schizophrenia. We believe that ACP-104 represents a promising new approach to schizophrenia therapy that combines the potential for a superior atypical antipsychotic efficacy profile with enhanced cognition. We have completed enrollment in a Phase IIb clinical trial designed to evaluate the safety and efficacy of ACP-104 in patients with schizophrenia. We expect to report top-line results from this trial in the second quarter of 2008.

*Pimavanserin for the treatment of sleep maintenance insomnia.* Frequent awakenings and difficulty returning to sleep are common sleep disturbances in older adults and patients with neurological and psychiatric disorders. We believe pimavanserin provides the opportunity to treat these symptoms of sleep maintenance insomnia without inducing sleep or impairing daytime functioning. We have completed a proof-of-concept clinical study that demonstrated that pimavanserin induced a statistically significant and dose-related increase in deep, or slow wave, sleep in healthy older adults.

*Neuropathic pain.* We have discovered a new class of compounds in collaboration with Allergan that we believe may represent a significant breakthrough in the treatment of neuropathic pain. Allergan is currently conducting Phase II development in this program.

*Glaucoma.* We have discovered and, in collaboration with Allergan, are developing a small molecule drug candidate for the treatment of glaucoma. Allergan is conducting Phase I testing in this program.

We have built an integrated drug discovery platform that we use to rapidly discover new compounds that may serve as potential treatments for significant unmet medical needs. Our proprietary technologies include target-based and chemistry-based technologies that we integrate with our discovery and development capabilities. We believe that the breadth of our discovery and development programs and the rapid pace at which we have discovered drug candidates provide strong validation of our proprietary platform and a basis for expanding our pipeline.

We have assembled a management team with significant industry experience to lead the discovery, development, and commercialization of our drug candidates. Members of our management team have contributed to the discovery, development, and approval of multiple drug candidates. We complement our management team with a network of scientific and clinical advisors that includes recognized experts in the fields of schizophrenia, Parkinson's disease, and other central nervous system disorders.

We were originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. In 1997, we reincorporated in Delaware. ACADIA and R-SAT are our registered trademarks. Our logos and trademarks are the property of ACADIA Pharmaceuticals Inc. All other brand names or trademarks appearing in this report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this report is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

## **Table of Contents**

We maintain a website at [www.acadia-pharm.com](http://www.acadia-pharm.com). We make available free of charge on our website our periodic and current reports as soon as reasonably practicable after such reports are filed with the Securities and Exchange Commission, or SEC. Information contained on, or accessible through, our website is not part of this report or our other filings with the SEC.

### **Our Strategy**

Our goal is to become a leader in the discovery, development, and commercialization of novel small molecule drugs for the treatment of central nervous system disorders and other areas of unmet medical need. Key elements of our strategy are to:

***Develop and commercialize our lead drug candidates.*** We are focused on advancing the development of our lead clinical programs with pimavanserin and ACP-104. We intend to complete development of our Phase III program with pimavanserin for the treatment of Parkinson's disease psychosis and, if successful, participate in the commercialization of pimavanserin for this indication in the United States. We also intend to continue to advance our programs with each of pimavanserin and ACP-104 for the treatment of schizophrenia through clinical development and to commercialization through, or in collaboration with, partners.

***Selectively establish strategic collaborations to advance and maximize the commercial potential of our pipeline.*** We will continue to pursue strategic collaborations to leverage the development and commercialization expertise of our partners. In therapeutic areas such as schizophrenia that involve a more extensive development program or address large primary care markets, we intend to complete late-stage clinical development and commercialization of our drug candidates through, or in collaboration with, partners. We plan to retain selected commercialization rights to certain of our products in areas where we feel they can be sold by a specialty sales force that calls on a focused group of physicians.

***Expand our pipeline of drug candidates for the treatment of central nervous system and related disorders.*** We plan to continue using our drug discovery platform and expertise to expand our pipeline of drug candidates for the treatment of central nervous system and related disorders. We believe that these disorders represent significant market opportunities. We believe that our diversified pipeline of programs will mitigate the risks inherent in drug discovery and development and increase the likelihood of commercial success.

***Maintain our technology leadership position and continue to build our development capabilities.*** We believe we are a leader in the discovery of small molecule drugs for central nervous system disorders. We intend to continue to maintain our proprietary discovery technologies and capabilities. We also intend to continue to expand our development capabilities as our drug candidates advance in clinical development.

***Leverage our proprietary drug discovery platform outside of our core focus.*** In addition to our focus on central nervous system disorders, we are leveraging our proprietary drug discovery platform to identify novel drug candidates in therapeutic areas outside of our core focus that we may develop in partnerships or independently.

***Opportunistically in-license or acquire complementary technologies and drug candidates.*** Although all of the drug candidates currently in our pipeline emanate from discoveries made using our proprietary platform, in the future, we may elect to in-license or acquire complementary technologies or augment our internal pipeline with drug candidates or products.

**Table of Contents****Our Programs**

Our pipeline includes six clinical programs, two IND-track development programs, where we have selected a drug candidate for development and are seeking to complete required testing in preparation for future clinical trials, and four preclinical programs, where we have not yet selected a drug candidate for development. Our programs address diseases that are not well served by currently available therapies and represent large potential commercial market opportunities. We believe that our drug candidates offer innovative therapeutic approaches and may provide significant advantages relative to current therapies. The following table summarizes our programs:

<b>Program</b>	<b>Stage of Development</b>	<b>Commercialization Rights</b>
Pimavanserin for Parkinson's disease psychosis	Phase III	ACADIA
Pimavanserin as a co-therapy for schizophrenia	Phase II	ACADIA
ACP-104 for schizophrenia	Phase II	ACADIA
Pimavanserin for sleep maintenance insomnia	Phase II	ACADIA
AGN-XX and AGN-YY for neuropathic pain	Phase II	Allergan
AC-262271 for glaucoma	Phase I	Allergan
ACP-105 for endocrine indications	IND-track development	ACADIA
ACP-106 for neuropsychiatry and sleep indications	IND-track development	ACADIA
Serotonin program for neuropsychiatry and sleep indications	Preclinical	ACADIA
Pro-cognitive antipsychotic (PCAP) program for schizophrenia	Preclinical	ACADIA
Muscarinic program for neuropsychiatry and other indications	Preclinical	ACADIA
Cannabinoid CB1 program for obesity	Preclinical	ACADIA

**Our Clinical Programs*****Parkinson's Disease Psychosis****Disease and Market Overview*

Parkinson's disease is a chronic and progressive neurological disorder that results from the degeneration of neurons in a region of the brain that controls movement. This degeneration creates a shortage of an important brain signaling chemical, or neurotransmitter, known as dopamine, rendering patients unable to initiate their movements in a normal manner. Parkinson's disease is characterized by a number of symptoms including tremors, limb stiffness, slowness of movements, and difficulties with posture and balance. The severity of Parkinson's disease symptoms tends to worsen over time.



---

## **Table of Contents**

According to the National Parkinson Foundation, over 1.5 million people in the United States suffer from this disease. Parkinson's disease is more prevalent in people over 60 years of age, and the incidence of this disease is expected to increase as the average age of the population increases. Parkinson's disease patients are currently treated with dopamine replacement therapies such as levodopa, commonly referred to as L-dopa, which is metabolized to dopamine, and dopamine agonists, which are molecules that mimic the action of dopamine. These therapies are relatively effective in controlling the symptoms of the disease in most patients and the use of these agents normally is required throughout the course of the disease.

Studies have suggested that up to 40 percent of patients with Parkinson's disease will develop psychotic symptoms, commonly consisting of visual hallucinations and delusions. The development of psychosis in patients with Parkinson's disease often disrupts their ability to perform many of the activities of daily living that keeps them independent and active. As a result, Parkinson's disease psychosis is associated with increased caregiver burden, nursing home placement, and increased mortality.

The U.S. Food and Drug Administration, or FDA, has not approved any therapy for Parkinson's disease psychosis. Physicians may attempt to address this disorder initially by decreasing the dose of the dopamine replacement drugs, which are administered to patients to manage the motoric symptoms of Parkinson's disease. However, this approach is generally not effective in alleviating psychotic symptoms in most patients and is often associated with the significant worsening of motor function in these patients. Despite substantial limitations, currently marketed antipsychotic drugs, including Seroquel, are also used off-label to treat patients with Parkinson's disease psychosis. Because antipsychotic agents worsen the preexisting brain dopamine deficit, these drugs are generally not well tolerated by patients with Parkinson's disease at doses required to achieve antipsychotic effects.

One antipsychotic therapy that has demonstrated efficacy in reducing psychosis in patients with Parkinson's disease without further impairing motor function is low-dose treatment with the generic drug clozapine. Our studies suggest that this unique clinical utility of clozapine arises from its potent blocking of a key serotonin receptor, a protein that responds to the neurotransmitter serotonin, known as the 5-HT<sub>2A</sub> receptor. The use of low-dose clozapine has been approved in Europe for the treatment of psychotic disorders in Parkinson's disease. However, patients being treated with clozapine require frequent blood monitoring because clozapine is associated with the occurrence of a rare blood disorder leading to the complete loss of blood cells, known as agranulocytosis. Currently, there is a large unmet medical need for new therapies that will effectively treat psychosis in patients with Parkinson's disease without impairing motor function.

### *Pimavanserin for the Treatment of Parkinson's Disease Psychosis*

#### *Overview*

Pimavanserin is a small molecule drug candidate that we discovered and are developing to treat patients with Parkinson's disease psychosis. Pimavanserin can be taken orally and is a novel, potent, and selective 5-HT<sub>2A</sub> inverse agonist, meaning that it blocks the activity of the 5-HT<sub>2A</sub> receptor. We believe that pimavanserin may effectively treat Parkinson's disease psychosis without impairing motor function, thereby significantly improving the quality of life for patients with Parkinson's disease.

#### *Development Status*

We are currently conducting the first pivotal trial in our Phase III development program with pimavanserin for Parkinson's disease psychosis. This multi-center, double-blind, placebo-controlled Phase III trial is designed to evaluate the safety and efficacy of pimavanserin in approximately 240 patients. Patients in the trial are randomized to three different study arms, which include two different doses of pimavanserin and one placebo arm. Patients receive oral doses of either pimavanserin or placebo once daily for six weeks in addition to stable doses of their existing dopamine replacement therapy. The primary endpoint of the trial is antipsychotic efficacy.

## **Table of Contents**

as measured using the Scale for the Assessment of Positive Symptoms, or SAPS. Motoric tolerability is an important secondary endpoint in the trial and is measured using the Uniform Parkinson's Disease Rating Scale, or UPDRS.

We are also preparing to initiate a second pivotal trial in our Phase III program with pimavanserin for Parkinson's disease psychosis. This study will be of a similar size, duration and nature as our first pivotal trial. In addition to these two pivotal trials, we are currently conducting an open-label extension study pursuant to which patients who have completed either of the pivotal trials will have the opportunity to enroll if, in the opinion of the physician, the patient may benefit from continued treatment with pimavanserin.

In 2006, we announced top-line results from a multi-center, double-blind, placebo-controlled Phase II clinical trial designed to evaluate the efficacy, safety, and tolerability of pimavanserin in 60 patients with Parkinson's disease psychosis. The trial met the primary endpoint, which was to demonstrate that administration of pimavanserin did not result in deterioration of the motoric function of these patients as measured by the UPDRS. Pimavanserin also showed antipsychotic effects in secondary endpoints using two different rating scales, including SAPS. Pimavanserin was safe and well tolerated in the study. In connection with this Phase II trial, we continue to conduct an open-label extension study, pursuant to which 24 patients with Parkinson's disease psychosis have been treated with pimavanserin for at least one year, 12 of whom have been treated for at least two years.

## ***Schizophrenia***

### ***Disease and Market Overview***

Schizophrenia is a chronic, debilitating mental illness characterized by disturbances in thinking, emotional reaction, and behavior. These disturbances may include positive symptoms, such as hallucinations and delusions, and a range of negative symptoms, including loss of interest, emotional withdrawal, and cognitive disturbances. Schizophrenia is associated with persistent impairment of a patient's social functioning and productivity. It is believed that cognitive disturbances prevent patients with schizophrenia from readjusting to society. As a result, patients with schizophrenia are normally required to be under medical care for their entire lives.

According to the National Institute of Mental Health, or NIMH, approximately one percent of the population develops schizophrenia during their lifetime and more than two million people in the United States suffer from this disease. Worldwide sales of drugs used to treat schizophrenia and other psychoses approached \$16 billion in 2006. Despite their commercial success, current drugs used to treat schizophrenia have substantial limitations, including inadequate efficacy and severe side effects.

The first-generation, or typical, antipsychotics that were introduced in the late-1950s block dopamine receptors. While these drugs are effective against positive symptoms of schizophrenia in many patients, they also induce disabling motor disturbances, including akathisia, an extremely distressful condition characterized by feelings of inner restlessness and an urge to move. Typical antipsychotics fail to address or worsen most of the negative symptoms of schizophrenia and their use has decreased in the United States and Europe.

Most schizophrenia patients in the United States today are treated with second-generation, or atypical, antipsychotics, which induce fewer motor disturbances than typical antipsychotic agents, but still fail to address most of the negative symptoms of schizophrenia. In addition, currently prescribed treatments do not effectively address or may exacerbate cognitive disturbances associated with schizophrenia. Clozapine, more so than other atypical antipsychotics, appears to have the ability to partially address cognitive disturbances in some patients. It is believed that the efficacy of atypical antipsychotics is due to their interactions with dopamine and 5-HT<sub>2A</sub> receptors. The side effects induced by the atypical agents may include weight gain, non-insulin dependent (type II) diabetes, cardiovascular side effects, and motor disturbances, including akathisia. We believe that these side effects arise either from non-essential receptor interactions or from excessive dopamine blockade.

## **Table of Contents**

The limitations of currently available antipsychotics result in poor patient compliance. A study conducted by the NIMH, which was published in *The New England Journal of Medicine* in September 2006, found that 74 percent of patients taking typical or atypical antipsychotics discontinued treatment within 18 months because of side effects or lack of efficacy. We believe there is a large unmet medical need for new therapies that have a broadened efficacy profile that extends beyond the positive symptoms, such as effects on the negative symptoms and cognitive deficits, and induce fewer side effects.

We have two development programs that we believe offer innovative therapeutic solutions to major unmet medical needs in schizophrenia.

### *Pimavanserin as a Co-Therapy for Schizophrenia*

#### *Overview*

We are developing pimavanserin as a co-therapy to be used together with other antipsychotic drugs to treat schizophrenia. We believe that co-therapy with pimavanserin may result in enhanced efficacy and fewer side effects relative to existing treatments, thereby providing an improved therapy for patients with schizophrenia and related psychiatric disorders. Pimavanserin can be taken orally and is a novel, potent, and selective 5-HT<sub>2A</sub> inverse agonist. By adding pimavanserin to a low dose of an antipsychotic drug, we believe that the optimal relationship between 5-HT<sub>2A</sub> blockade and partial dopamine receptor blockade can be achieved with a range of existing antipsychotic drugs.

#### *Development Status*

In 2007, we reported positive results from a multi-center, double-blind, placebo-controlled Phase II clinical trial designed to evaluate the ability of pimavanserin when used as a co-therapy together with low doses of either risperidone, an atypical antipsychotic drug, or haloperidol, a typical antipsychotic drug, to treat patients with schizophrenia. We enrolled a total of 423 patients with schizophrenia in the Phase II trial. The results of the trial demonstrated several advantages of co-therapy with pimavanserin and a sub-maximal dose of risperidone. These advantages included enhanced efficacy (comparable efficacy to high-dose risperidone plus placebo), a faster onset of antipsychotic action, and an improved side effect profile, including less weight gain.

We also have completed two earlier clinical trials in our program with pimavanserin as a co-therapy for schizophrenia. In 2005, we reported top-line results of a double-blind, placebo-controlled Phase II clinical trial designed to evaluate the ability of pimavanserin to treat haloperidol-induced akathisia in patients with schizophrenia. In 2004, we reported results of a clinical study designed to assess the ability of pimavanserin to reduce side effects associated with drug treatment with haloperidol in healthy volunteers.

### *ACP-104 as a Stand-Alone Treatment for Schizophrenia*

#### *Overview*

ACP-104 is a small molecule drug candidate that we are developing as a stand-alone treatment for patients with schizophrenia. We believe that ACP-104 may provide an effective antipsychotic therapy with the added advantage of improving cognitive function in patients with schizophrenia. It is known that large amounts of ACP-104, or N-desmethylclozapine, are formed in the body after administration of clozapine. That is, clozapine is metabolized to ACP-104. We discovered that ACP-104 has a unique ability to stimulate m<sub>1</sub> muscarinic receptors, which are widely known to play an important role in cognition. Since clozapine itself blocks the m<sub>1</sub> muscarinic receptor, patients need to extensively metabolize clozapine into ACP-104 to stimulate this receptor and thereby overcome the blocking action of clozapine. Like clozapine, ACP-104 also interacts with 5-HT<sub>2A</sub> and dopamine receptors. Our research indicates that ACP-104 is a partial agonist that causes weak activation of dopamine D<sub>2</sub> and D<sub>3</sub> receptors, whereas clozapine and most other antipsychotic drugs block these dopamine receptors. These partial agonist properties of ACP-104 may lead to less motoric side effects than seen with most other antipsychotic drugs.

## **Table of Contents**

### *Development Status*

We have completed enrollment in a multi-center, double-blind, placebo-controlled Phase IIb trial designed to evaluate the safety and efficacy of ACP-104 in patients with schizophrenia who are experiencing an acute psychotic episode. A total of 248 patients were enrolled in the trial. Patients were randomized to one of three study arms, which included two different doses of ACP-104 and one placebo arm, for six weeks. The primary endpoint of the trial is antipsychotic efficacy as measured using the Positive and Negative Syndrome Scale, or PANSS, an industry standard rating scale commonly used in schizophrenia trials. We expect to report top-line results from this trial during the second quarter of 2008.

We have completed four initial studies of ACP-104 involving a total of 83 patients with schizophrenia. These studies included a single ascending-dose study, a 14-day multiple ascending-dose study, a single-dose positron emission tomography, or PET, study, and a food-effect study. The results of these studies demonstrated that ACP-104 was well tolerated, initial signals of antipsychotic effects, as indicated by clinically meaningful reductions in PANSS scores, were observed within the tolerated dose range of ACP-104, and no food effect was observed.

We have also analyzed data on clozapine and ACP-104 plasma levels relative to clinical response from two clinical trials that included 92 patients with schizophrenia treated with clozapine for up to six months. We demonstrated in this analysis that the plasma drug ratio of ACP-104 to clozapine positively predicts improvement in cognitive functioning and quality-of-life parameters in these patients. This analysis indicated that a higher ratio of ACP-104 relative to clozapine resulted in a better response by these patients in a wide range of standard cognitive functioning and quality of life clinical measures. The results of this analysis and our preclinical tests suggest that due to its ability to stimulate m1 muscarinic receptors, ACP-104 is responsible for the cognitive benefits of clozapine.

### *Sleep Maintenance Insomnia*

#### *Disease and Market Overview*

Chronic insomnia, a sleep disorder lasting a month or more, is estimated to affect about 10 percent of the U.S. adult population. A significant portion of insomnia patients complain of frequent awakenings during the night and difficulty returning to sleep, which may be referred to as sleep maintenance insomnia. Patients with sleep maintenance insomnia may experience a number of problems, including a lack of energy, difficulty concentrating, irritability, and impairment of daytime functioning. The prevalence of sleep disorders appears to increase with advancing age. In particular, slow wave sleep, which is the deepest and most restorative sleep, normally decreases with age, and this may contribute to an increase in sleep maintenance insomnia. There is also an increased incidence of sleep maintenance insomnia in patients with neurological and psychiatric disorders.

Sales of prescription drugs used to treat insomnia in major markets were estimated at approximately \$3.9 billion in 2006. Most of the currently marketed therapies for insomnia are sedatives that are designed primarily to address sleep onset and have limitations in treating the symptoms of sleep maintenance insomnia. Most of these therapies work by interacting with gamma-aminobutyric acid, or GABA, receptors in the brain and may be associated with side effects including the risk of developing tolerance to the drug and the potential for causing lethargy upon awakening, referred to as a hangover effect. In addition, drugs that work by activating the GABA receptors are designated by the Drug Enforcement Administration as controlled substances due to their potential for abuse. We believe that there is a large unmet medical need for new therapies that can treat the symptoms of sleep maintenance insomnia without impairing daytime functioning.

#### *Pimavanserin for Sleep Maintenance Insomnia*

##### *Overview*

We believe that pimavanserin and other 5-HT<sub>2A</sub> inverse agonists generated in our serotonin program may provide sleep maintenance insomnia patients with a novel type of sleep therapy without the limitations of most of the current sleep-inducing agents.

## **Table of Contents**

### *Development Status*

In 2006, we announced positive top-line results from a proof-of-concept clinical study designed to assess the effect of pimavanserin on slow wave sleep in 45 healthy volunteers ranging in age from 40 to 64. The results of the study demonstrated that pimavanserin induced a statistically significant and dose-related increase in slow wave sleep. In addition, pimavanserin had a positive impact on measures for sleep maintenance, including decreases in the number of awakenings after sleep onset and in the time awake after sleep onset, referred to as WASO. Pimavanserin also did not alter latency to sleep onset and did not impair daytime functioning. Pimavanserin was safe and well tolerated in the study.

### *Neuropathic Pain*

#### *Disease and Market Overview*

Neuropathic pain is a common form of pain that is thought to involve an alteration in nervous system function or a reorganization of nervous system structure. Neuropathic pain can be associated with nerve damage caused by trauma, diseases such as diabetes, shingles, irritable bowel syndrome, late-stage cancer or the toxic effects of chemotherapy. In many patients, damage to sensory nerves is accompanied by varying degrees of pain. The experience can range from mildly increased sensitivity to touch or temperature to excruciating pain. This kind of pain is extremely difficult to manage clinically because it fails to respond to most medications currently used to treat other forms of pain. According to Pharmaprojects, a healthcare publication, each year approximately 26 million people worldwide suffer from some form of neuropathic pain.

Drugs such as opioid painkillers and non-steroidal anti-inflammatory agents that are effective in treating inflammatory and acute pain usually are not effective in treating neuropathic pain. Opioid painkillers also have significant adverse side effects that limit their usefulness, including respiratory depression, nausea, vomiting, dizziness, sedation, mental clouding, constipation, urinary retention, and severe itching. In addition, prolonged chronic use of opioid painkillers can lead to the need for increasing dosage and potentially to addiction. Neurontin, the first product to be approved by the FDA for the treatment of neuropathic pain, is now generic. Currently, the leading drugs approved for neuropathic pain indications include Lyrica, the successor to Neurontin, and Cymbalta. Lyrica had worldwide sales of \$1.8 billion in 2007. Cymbalta, indicated for treatment of diabetic peripheral neuropathic pain as well as treatment of major depressive disorder, had worldwide sales of \$2.1 billion in 2007. We believe that there is a large unmet medical need for new therapies with improved efficacy and side effect profiles.

#### *Our Drug Candidates for Neuropathic Pain*

In collaboration with Allergan, we have discovered and are developing a new class of small molecule drug candidates that we believe provide the potential for a significant breakthrough in the treatment of neuropathic pain. Using our proprietary drug discovery platform, we identified a previously unappreciated target for neuropathic pain, which is an alpha adrenergic receptor. We have discovered and are developing orally active, small molecule drug candidates that selectively activate this target. Our novel alpha adrenergic agonists provide highly effective pain relief in a wide range of preclinical models, without the side effects of current pain therapies, including sedation and cardiovascular and respiratory effects. Allergan has demonstrated that these drug candidates are highly potent and efficacious when administered orally in relevant animal models and are more efficacious than Neurontin in preclinical models at approximately 300-fold lower doses. Allergan is currently conducting Phase II development in this program.

### *Glaucoma*

#### *Disease and Market Overview*

Glaucoma is an eye disease that, if left untreated, can lead to degeneration of the optic nerve and blindness. Glaucoma is a leading cause of blindness in the United States. A prevalent symptom of glaucoma is increased fluid pressure within the eye, or intraocular pressure. Currently, physicians treat glaucoma with multiple classes of therapeutics to optimize therapy and minimize side effects.

## **Table of Contents**

### ***AC-262271 for Treatment of Glaucoma***

We have discovered and, in collaboration with Allergan, are developing AC-262271, a small molecule drug candidate for the treatment of glaucoma. Using our proprietary drug discovery platform, we identified a subtype of the muscarinic receptors that controls intraocular pressure and discovered lead compounds that selectively activate this target. In a primate model of glaucoma, AC-262271 demonstrated efficacy and a long duration of action. Allergan is conducting Phase I studies with AC-262271.

### **Our IND-Track Development and Preclinical Programs**

In addition to our clinical programs, we have two programs in IND-track development, where we have selected a drug candidate for development and are seeking to complete required development testing in preparation for future clinical trials. We also have four programs that are in preclinical testing where we have not yet selected a drug candidate for development. The following summarizes our IND-track development and preclinical programs.

### ***ACP-105 for Treatment of Endocrine Indications***

We have discovered and are developing ACP-105, a non-steroidal and selective androgen receptor agonist. ACP-105 is part of a class of molecules referred to as selective androgen receptor modulators, or SARMs. SARMs may advance the standard of treatment for a variety of disorders including muscle-wasting conditions and osteoporosis, with fewer side effects as compared to current treatments based on testosterone replacement. ACP-105 has exhibited promising pharmacological properties and a favorable safety profile in preclinical testing. In addition, ACP-105 has reversed endocrine and bone-related markers of testosterone deficiency in preclinical animal testing. Unlike testosterone, ACP-105 had little effect on the prostate, thereby demonstrating tissue specificity in its actions. We have initiated development of ACP-105 and we intend to seek a partner to advance the further development of this program.

### ***ACP-106 for Neuropsychiatry and Sleep Indications and Our Serotonin Preclinical Program***

We have used our serotonin program to generate new drug candidates to treat neuropsychiatric and related central nervous system disturbances as well as sleep maintenance insomnia. We discovered pimavanserin, a potent and selective 5-HT<sub>2A</sub> inverse agonist, in this program. In addition to pimavanserin, we have discovered a large number of compounds having diverse pharmacological, chemical and pharmaceutical properties that interact with the 5-HT<sub>2A</sub> receptor. These novel 5-HT<sub>2A</sub> inverse agonists may serve as back-up or follow-on molecules for pimavanserin.

We have nominated ACP-106, a potent and selective 5-HT<sub>2A</sub> inverse agonist, as a clinical candidate. ACP-106 belongs to a class of molecules that is structurally different than pimavanserin. We have initiated development of ACP-106 and intend to complete required testing in preparation for potential clinical trials. We believe that ACP-106 and other compounds in our serotonin preclinical program provide us with a strong foundation and may enable us to more broadly pursue a range of potential therapeutic indications suitable with this mechanism of action.

### ***PCAP Preclinical Program***

We have discovered a series of novel lead compounds that provide the potential for a new class of pro-cognitive antipsychotic drugs. These compounds differ structurally from ACP-104, but like ACP-104, they combine muscarinic m<sub>1</sub> agonism with actions on both dopamine and serotonin receptors. These novel compounds demonstrate robust effects in animal models of psychosis and pro-cognitive effects in preclinical models of cognition. We are currently seeking to identify a clinical candidate for further development in this program.

## **Table of Contents**

### ***Muscarinic Preclinical Program***

Our muscarinic program is designed to deliver new drug candidates to treat psychosis, cognitive disturbances in patients with schizophrenia and dementia, neuropathic pain, and other indications. We have identified novel sites for muscarinic receptor/drug interactions that yield selective muscarinic agonists. Such compounds have not shown the side effects typical of non-selective muscarinic agents, but show robust effects in animal models of psychosis, cognition, and neuropathic pain.

This program includes our muscarinic agonists that selectively target the m1 muscarinic receptor and may represent a novel approach to the treatment of cognition in patients with schizophrenia. We have discovered over 300 potent muscarinic agonists that selectively target the m1 muscarinic receptor. These muscarinic agonist compounds inhibit behaviors associated with psychotic states and enhance cognitive function in preclinical models.

### ***Cannabinoid CB1 Preclinical Program***

We have discovered structurally novel lead compounds that potently and selectively block the cannabinoid CB1 receptor. The CB1 receptor is predominantly expressed in the central nervous system and has a key role in regulating appetite and other reward-based behaviors. Blockade of CB1 receptors may lead to novel treatments for obesity and substance abuse. CB1 receptor antagonists may also be useful in the treatment of disorders associated with cognitive deficits. We have discovered proprietary compounds that are potent and selective for the CB1 receptor, are active following oral dosing in preclinical animal models, and are well tolerated at high doses.

## **Our Drug Discovery Platform and Capabilities**

### ***Overview***

We have established drug discovery and technical expertise in the areas of molecular biology, ultra-high throughput screening, molecular and behavioral pharmacology, and combinatorial, medicinal and analytical chemistry. We have integrated our discovery and development capabilities with our proprietary technologies in a seamless fashion. In addition, we collaborate with world-renowned scientists, clinicians, and academic institutions. We believe that our expertise combined with our proprietary drug discovery platform has allowed us to discover drug candidates more efficiently than traditional approaches.

All of our drug candidates that are currently in clinical trials and earlier stages of discovery and development emanate from discoveries made using our proprietary drug discovery platform. We have demonstrated that our platform can be used to rapidly identify drug-like, small molecule chemistries for a wide range of drug targets. We believe that the breadth of our discovery and development programs and the rapid pace at which we have discovered drug candidates provide strong validation of our proprietary platform and a basis for expanding our pipeline.

### ***Our Drug Discovery Approach***

Our drug discovery approach is designed to introduce chemistry at an early stage in the drug discovery process and enable selection of the most attractive, drug-like chemistries for desired targets that we validate with past clinical experience. A key to our discovery approach is our set of proprietary functional test systems, or assays, that we have developed focused on members of three important gene families, G-protein coupled receptors, or GPCRs, nuclear receptors, or NRs, and tyrosine kinase linked receptors, or RTKs. We believe that these gene families represent the most relevant and feasible targets for small molecule drug discovery. We use our proprietary assays to validate drug targets and to discover novel small molecule drug candidates that are specific for these targets using two complementary approaches.

## **Table of Contents**

Our first approach is to validate potential drug targets. We profile our collection of reference drugs, primarily consisting of currently and formerly marketed central nervous system drugs, over a range of targets in our functional assays to link clinical and physiological effects of drugs with specific drug targets. Using our reference-drug approach, we are able to identify key drug targets that are validated with past clinical experience as well as the targets that we believe are responsible for various side effects of these drugs. Our discoveries of pimavanserin and ACP-104 resulted from the successful application of our reference-drug approach.

Our second approach is to broadly screen a number of targets for the most attractive small molecule chemistries. These chemistries may be prioritized and used as starting points for our drug discovery programs. Using this approach, we discovered that one of our target-specific chemistries demonstrated activity in preclinical models of neuropathic pain, providing the starting point for our collaborative neuropathic pain clinical program. Similarly, one of our selective muscarinic agonists was active in a glaucoma model without showing classical side effects, providing the starting point for our collaborative glaucoma development program.

### ***Key Components of Our Drug Discovery Platform***

Key components of our drug discovery platform are discussed below:

#### ***Our Target-Based Discovery Technologies***

##### ***Overview***

The human genome project has provided information about the genetic structure of essentially all of the potential drug targets in the human genome. This knowledge, when combined with our proprietary technologies, allows for the efficient testing of the effects of chemical compounds on a wide range of potential drug targets. Within the human genome there are families of genes that include the most frequent targets of drugs. We focus our drug discovery efforts on those families of targets that are most likely to be affected by small molecule drugs.

##### ***R-SAT and Other Functional Assay Technologies***

Our proprietary receptor selection and amplification technology, which we refer to as R-SAT, is a valuable component of our drug discovery platform. R-SAT is a cell-based assay system where genes are transferred to cultured cells. The functional activity of the gene products, or potential drug targets, are then evaluated through signal transduction pathways that lead to cellular growth. The growth signals are reported using marker gene technologies. Thus, effects of drugs on potential drug targets can be efficiently detected as changes in color or fluorescence. R-SAT enables the efficient screening of large compound libraries for identification of new chemistries at given targets, as well as detailed pharmacological testing of compounds at a wide range of targets. In addition to R-SAT, we have developed other proprietary tools that evaluate compound interaction with these targets. One of these technologies measures the physical interaction of GPCRs and RTKs with signaling proteins.

##### ***Proprietary Receptor Assay Platforms***

Our scientists have cloned the genes for the majority of the targets in the G-protein coupled receptor, nuclear receptor and tyrosine kinase gene families. These represent some of the largest families of genes targeted by known drugs. Our R-SAT assay system has enabled the building of functional assays for a large number of these genes. We also have developed assays for several additional targets in other relevant gene families.

##### ***Our Chemistry-Based Discovery Technologies***

Our drug discovery approach aims to identify small molecules that can serve as chemical starting points, or leads, for optimization efforts providing novel, potent and selective drug candidates for targets that are most likely to be affected by small molecule drugs. To enable our screening operation to identify high quality leads,



## **Table of Contents**

we have assembled a large proprietary chemical library of diverse compounds. This diverse compound library consists of about 800,000 small organic molecules. We have also developed proprietary synthetic methods for library construction and lead optimization. In addition, our reference drug library provides us with the opportunity to validate targets and is another key component of our drug discovery platform. This reference drug library includes a wide range of the known central nervous system active drugs.

### ***Drug Discovery Opportunities***

Our proprietary drug discovery platform has generated a range of novel chemistries that we believe will continue to provide us with starting points for additional programs. Using these target-specific chemistries, we have established a portfolio of proprietary drug discovery assets and projects in multiple therapeutic areas. In each of these areas, we have identified novel chemistries for different drug targets that we believe play an important role in these major diseases. Our discovery projects aim to answer specific scientific questions using relatively limited synthetic chemistry and biological efforts. When all key criteria have been fulfilled, these earlier-stage discovery projects may be advanced into preclinical programs.

### **Collaboration Agreements**

We have established three separate collaboration agreements with Allergan and a technology license agreement with Aventis to leverage our drug discovery platform and related assets and to commercialize selected drug candidates. Our collaborations have included upfront payments at initiation of the collaboration, which may be in the form of an equity investment, research support during the term, milestone payments upon successful completion of specified development objectives, and royalties based upon sales, if any, of drugs developed under the collaboration. Our current agreements are as follows:

#### ***Allergan***

In March 2003, we entered into a collaboration agreement with Allergan to discover, develop, and commercialize new therapeutics for ophthalmic and other indications. The agreement originally provided for a three-year research term, which has been extended by the parties through March 2009. As of December 31, 2007, we had received an aggregate of \$14.5 million under the agreement, consisting of an upfront payment, and research funding and related fees. During the extended research term, Allergan is entitled to exclusively license specified chemistry and related assets for development and commercialization. If we grant Allergan such an exclusive license, we would be eligible to receive license fees and milestone payments upon the successful achievement of agreed upon clinical and regulatory objectives as well as royalties on future product sales, if any, worldwide. Assuming the license and successful development of a product in the area of eye care, we could receive up to approximately \$13.5 million in aggregate license fees and milestone payments per product under the agreement, excluding product royalties.

In July 1999, we entered into a collaboration agreement with Allergan to discover, develop and commercialize selective muscarinic drugs for the treatment of glaucoma based on our compounds. Under this agreement, we provided our chemistry and discovery expertise to enable Allergan to select a compound for development. We granted Allergan exclusive worldwide rights to commercialize products based on this compound for the treatment of ocular disease, which program is currently in Phase I testing. As of December 31, 2007, we had received an aggregate of \$9.3 million in payments under the agreement, consisting of upfront fees, research funding and milestone payments. We are eligible to receive additional milestone payments of up to \$15 million in the aggregate as well as royalties on future product sales worldwide, if any. Allergan may terminate this agreement upon 90 days' notice. However, if terminated, Allergan's rights to the selected compound would revert to us.

In September 1997, we entered into a collaboration agreement with Allergan focused primarily on the discovery and development of new therapeutics for neuropathic pain, which program is currently in Phase II testing, and ophthalmic indications. This agreement was amended in conjunction with the execution and

## **Table of Contents**

subsequent amendments of the March 2003 collaboration agreement, and provides for the continued development of drug candidates for one target area. We are restricted from conducting competing research in that target area. Pursuant to the agreement, we granted Allergan exclusive worldwide rights to commercialize products resulting from the collaboration. We had received an aggregate of \$10.5 million in research funding and milestone payments through December 31, 2007. We are eligible to receive additional milestone payments of up to \$10.0 million in the aggregate as well as royalties on future product sales worldwide, if any. In connection with the execution of the collaboration agreement in 1997, Allergan made a \$6.0 million equity investment in us.

The general terms of our collaboration agreements with Allergan continue until the later of the expiration of the last to expire patent covering a drug candidate licensed under the collaboration and at least 10 years from the date of first commercial sale of a drug candidate. In addition, each of our Allergan collaboration agreements includes a research term that is shorter but may be renewed if agreed to by the parties.

### ***Aventis***

In July 2002, we entered into an agreement with Aventis under which we have licensed a portion of our technology for their use in a specified area that we are not pursuing presently.

## **Intellectual Property**

We currently hold 20 issued U.S. patents and 123 issued foreign patents. All of these patents originated from us. In addition, we have 104 provisional and utility U.S. patent applications and 316 foreign patent applications.

Patents or other proprietary rights are an essential element of our business. Our strategy is to file patent applications in the United States and any other country that represents an important potential commercial market to us. In addition, we seek to protect our technology, inventions and improvements to inventions that are important to the development of our business. Our patent applications claim proprietary technology, including methods of screening and chemical synthetic methods, novel drug targets and novel compounds identified using our technology.

We also rely upon trade secret rights to protect other technologies that may be used to discover and validate targets and that may be used to identify and develop novel drugs. We protect our trade secrets in part through confidentiality and proprietary information agreements. We have entered into a license agreement, dated as of November 30, 2006, for certain intellectual property rights from the Ipsen Group in order to expand and strengthen the intellectual property portfolio for our serotonin platform. We are a party to various other license agreements that give us rights to use certain technologies in our research and development.

### ***Pimavanserin***

Two U.S. patents have been issued to us that provide generic coverage for pimavanserin. We have 26 issued foreign patents that generally cover pimavanserin, including patents in 21 European countries, Australia, Hong Kong, New Zealand, Singapore and South Africa. We continue to prosecute patent applications directed to pimavanserin and to methods of treating various diseases using pimavanserin, either alone or in combination with other agents, worldwide.

### ***ACP-104***

ACP-104 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 directed to the form of ACP-104 known prior to the filing of our patent applications. We have filed patent applications with claims that are directed to the use of ACP-104 as a treatment for neuropsychiatric

## **Table of Contents**

diseases, either alone or in combination with various other agents. In addition, we have filed patent applications directed to methods of synthesis of ACP-104 and various crystalline polymorphs thereof. We are aware of an issued patent, not owned by us, that claims the use of ACP-104 as an analgesic.

### ***Our Drug Discovery Platform***

Our core R-SAT technology is protected by four issued U.S. patents and 20 foreign patents.

### ***Other Drug Candidates***

We have nine issued U.S. patents with claims for compounds that affect muscarinic receptor activity. We also have three issued U.S. patents for compounds (other than pimavanserin) from our serotonin program. We continue to pursue patent applications in these areas in other countries.

### **Competition**

We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. We compete or will compete, as applicable, with existing and new products being developed by our competitors. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target. In each of our clinical programs, we intend to complete clinical trials designed to evaluate the potential advantages of our drug candidates as compared to the current standard of care.

Even if we and our collaborators are successful in developing our drug candidates, the resulting products would compete with a variety of established drugs in the areas of Parkinson's disease, schizophrenia, sleep maintenance insomnia, neuropathic pain, and glaucoma. For example, our potential product for the treatment of Parkinson's disease psychosis will compete with off-label use of antipsychotic drugs, including Seroquel, marketed by Astra-Zeneca, and clozapine, a generic drug.

Our potential products for the treatment of schizophrenia would compete with Zyprexa, marketed by Eli Lilly, Risperdal, marketed by Johnson & Johnson, Abilify, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical, Seroquel, and clozapine. Zyprexa is the market leader with worldwide sales of \$4.8 billion in 2007. While proven effective in schizophrenia and bipolar mania, it produces a variety of adverse events including weight gain, orthostatic hypertension, and other side effects.

Our potential products for the treatment of sleep maintenance insomnia would compete with Ambien and Ambien CR, marketed by Sanofi-Aventis, Lunesta, marketed by Sepracor, Sonata, marketed by King Pharmaceuticals, Inc., Rozerem, marketed by Takeda Pharmaceuticals North America, Inc., and various benzodiazepines. Ambien is the current market leader with worldwide sales of approximately \$1.8 billion in 2007.

Our potential products for the treatment of neuropathic pain would compete with Neurontin and Lyrica, each marketed by Pfizer, and Cymbalta, marketed by Eli Lilly, as well as with a variety of generic or proprietary opioids. In 2003, Neurontin was the first product to be approved by the FDA for the treatment of neuropathic pain. Currently, the leading drugs approved for neuropathic pain indications include Lyrica, the successor to Neurontin, and Cymbalta. Lyrica had worldwide sales of \$1.8 billion in 2007. Cymbalta, indicated for treatment of diabetic peripheral neuropathic pain as well as treatment of major depressive disorder, had worldwide sales of \$2.1 billion in 2007.

Our potential products for the treatment of glaucoma would compete with Xalatan, marketed by Pfizer, and Lumigan and Alphagan, marketed by Allergan. Xalatan is the leading drug for glaucoma treatment and had worldwide sales in excess of \$1.6 billion in 2007. It is an effective anti-glaucoma agent but frequently causes an increased pigmentation of the iris that may lead to a change of iris color. Other side effects of Xalatan include blurred vision and burning and stinging sensations in the eye.

## **Table of Contents**

In addition, the companies described above and other competitors may have a variety of drugs in development or awaiting FDA approval that could reach the market and become established before we have a product to sell. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Some of our competitors are using functional genomics technologies or other methods to identify and validate drug targets and to discover novel small molecule drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

identifying and validating targets;

screening compounds against targets;

preclinical and clinical trials of potential pharmaceutical products; and

obtaining FDA and other regulatory clearances.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

capital resources;

research and development resources;

manufacturing capabilities; and

sales and marketing.

Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development. We face competition from other companies, academic institutions, governmental agencies and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific and management personnel and for licenses to additional technologies. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, and more affordable or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Developments by others may render our drug candidates or our technologies obsolete. Our failure to compete effectively could have a material adverse affect on our business.

## **Government Regulation**

The manufacturing and marketing of our potential products and our ongoing research and development activities are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Before marketing in the United States, any new drug developed by us must undergo rigorous preclinical testing, clinical trials and an extensive regulatory clearance process implemented by the FDA under the federal Food, Drug, and Cosmetic Act, as amended. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. None of our drug candidates has been approved for sale in the United States or any foreign market. The regulatory review and approval process, which includes preclinical testing and clinical trials of each drug candidate, is lengthy, expensive and uncertain.

In the United States, drug candidates are tested in animals until adequate proof of safety is established. Clinical trials for new drug candidates are typically conducted in three sequential phases that may overlap. Phase I trials involve the initial introduction of the drug candidate into healthy human volunteers. The emphasis of Phase I trials is on testing for safety or adverse effects, dosage, tolerance, metabolism, distribution, excretion

and clinical pharmacology. Phase II involves studies in a limited patient population to determine the initial efficacy of the compound for specific targeted indications, to determine dosage tolerance and optimal dosage and

## **Table of Contents**

to identify possible adverse side effects and safety risks. Once a compound shows evidence of effectiveness and is found to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to more fully evaluate clinical outcomes. Before commencing clinical investigations in humans, we or our collaborators must submit to the FDA an Investigational New Drug Application, or IND.

Regulatory authorities may require additional data before allowing the clinical studies to commence or proceed from one phase to another, and could demand that the studies be discontinued or suspended at any time if there are significant safety issues. We have in the past and may in the future rely on some of our collaborators to file INDs and generally direct the regulatory approval process for many of our potential products. Clinical testing must also meet requirements for institutional review board oversight, informed consent and good clinical practices.

To establish a new drug candidate's safety and efficacy, the FDA requires companies seeking approval to market a drug product to submit extensive preclinical and clinical data, along with other information, for each indication. The data and information are submitted to the FDA in the form of a New Drug Application, or NDA. Generating the required data and information for an NDA takes many years and requires the expenditure of substantial resources. Information generated in this process is susceptible to varying interpretations that could delay, limit or prevent regulatory approval at any stage of the process. The failure to demonstrate adequately the quality, safety and efficacy of a drug candidate under development would delay or prevent regulatory approval of the drug candidate. We cannot assure you that, even if clinical trials are completed, either our collaborators or we will submit applications for required authorizations to manufacture and/or market potential products or that any such application will be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all. Under applicable laws and FDA regulations, each NDA submitted for FDA approval is usually given an internal administrative review within 60 days following submission of the NDA. If deemed sufficiently complete to permit a substantive review, the FDA will file the NDA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. The FDA has established internal goals of six months for priority review for NDAs that cover drug candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists, and 10 months for the standard review of non-priority NDAs. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, may not be an actual approval but an action letter that describes additional work that must be done before the NDA can be approved. The FDA's review of an NDA may involve review and recommendations by an independent FDA advisory committee.

Before receiving FDA approval to market a potential product, we or our collaborators must demonstrate through adequate and well-controlled clinical studies that the potential product is safe and effective on the patient population that will be treated. If regulatory approval of a potential product is granted, this approval will be limited to those disease states and conditions for which the product is approved. Marketing or promoting a drug for an unapproved indication is generally prohibited. Furthermore, FDA approval may entail ongoing requirements for post-marketing studies. Even if approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continuing review and periodic inspections by the FDA. Discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including labeling changes, costly recalls or withdrawal of the product from the market.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or during clinical trials of our potential products. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates. Further, such unacceptable toxicity or side effects could ultimately prevent a potential product's approval by the FDA or foreign regulatory authorities for any or all targeted indications or limit any labeling claims, even if the product is approved.

## **Table of Contents**

We and our collaborators and contract manufacturers also are required to comply with the applicable FDA current good manufacturing practice regulations. Good manufacturing practice regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our potential products. The FDA may conclude that we or our collaborators or contract manufacturers are not in compliance with applicable good manufacturing practice requirements and other FDA regulatory requirements.

If the product is approved, we must also comply with post-marketing requirements, including, but not limited to, compliance with the Prescription Drug Marketing Act and post-marketing safety surveillance. In addition, we are subject to state regulation including, but not limited to, implementation of corporate compliance programs and gift reporting to healthcare professionals.

Outside of the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community, or EC, registration procedures are available to companies wishing to market a product in more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA marketing approval discussed above.

### **Drugs for Serious or Life-Threatening Illnesses**

The Federal Food, Drug and Cosmetic Act, as amended, and FDA regulations provide certain mechanisms for the accelerated Fast Track approval of potential products intended to treat serious or life-threatening illnesses which have been studied for safety and effectiveness and which demonstrate the potential to address unmet medical needs. These procedures permit early consultation and commitment from the FDA regarding the preclinical and clinical studies necessary to gain marketing approval. Provisions of this regulatory framework also permit, in certain cases, NDAs to be approved on the basis of valid surrogate markers of product effectiveness, thus accelerating the normal approval process. Certain potential products employing our technology might qualify for this accelerated regulatory procedure. Even if the FDA agrees that these potential products qualify for accelerated approval procedures, the FDA may deny approval of our drugs or may require that additional studies be required before approval. The FDA may also require us to perform post-approval, or Phase IV, studies as a condition of such early approval. In addition, the FDA may impose restrictions on distribution and/or promotion in connection with any accelerated approval, and may withdraw approval if post-approval studies do not confirm the intended clinical benefit or safety of the potential product.

### **Other U.S. Regulatory Requirements**

In the United States, the research, manufacturing, distribution, sale, and promotion of drug products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health & Human Services, including, for example, the Office of Inspector General, and state and local governments. For example, if a drug product is reimbursed by Medicare, Medicaid or other federal or state health care programs, sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, and similar state laws. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug Improvement and Modernization Act of 2003. If drug products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

## **Table of Contents**

### **Marketing, Sales and Distribution**

We currently have limited marketing and no sales or distribution capabilities. In order to commercialize any of our drug candidates, we must develop these capabilities internally or through collaboration with third parties. In selected therapeutic areas where we feel that our drug candidates can be commercialized by a specialty sales force that calls on a limited and focused group of physicians, we plan to participate in the commercialization of our drug candidates. In therapeutic areas that require a large sales force selling to a large and diverse prescribing population, we plan to partner our drug candidates for commercialization.

### **Manufacturing**

We outsource and plan to continue to outsource manufacturing responsibilities for our existing and future drug candidates for development and commercial purposes. The production of pimavanserin and ACP-104 employs small molecule synthetic organic chemistry procedures that are standard in the pharmaceutical industry. Our collaboration agreements provide for our partners to arrange for the production of our drug candidates for use in clinical trials and potential commercialization.

### **Employees**

At December 31, 2007, we had 143 employees, of whom 51 hold Ph.D. or other advanced degrees. Of our total workforce, 114 are engaged in research and development activities and 29 are engaged in business development, finance and administration. 102 of our employees are located in the United States and 41 are located in Sweden. None of our employees is represented by a collective bargaining agreement, nor have we experienced work stoppages. We believe that our relations with our employees are good.

### **Research and Development Expenses**

Our research and development expenses were \$57.9 million in 2007, \$49.4 million in 2006, and \$30.3 million in 2005.

### **Long-Lived Assets**

Information regarding long-lived assets by geographic area is as follows:

	As of December 31,		
	2007	2006	2005
	(in thousands)		
United States	\$ 2,090	\$ 2,347	\$ 1,285
Europe	958	1,158	998
Total	\$ 3,048	\$ 3,505	\$ 2,283

### **Item 1A. Risk Factors.**

*You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report 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.*



---

## **Table of Contents**

### **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, 2007, we had an accumulated deficit of approximately \$229.9 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. Substantially all of our revenues for the year ended December 31, 2007 were from our collaborations with Allergan and Sepracor as well as our agreements with other parties. We anticipate that collaborations with pharmaceutical companies, which provide us with research funding and potential milestone payments and royalties, will continue to be our primary source of revenues for the next several years. We cannot be certain that the milestones required to trigger payments under our existing collaborations 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 drug candidates 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.

Our drug development programs are at various stages of development and the historical rate of failures for drug candidates is extremely high. Our four proprietary clinical programs are pimavanserin for the treatment of Parkinson's disease psychosis, pimavanserin as a co-therapy for schizophrenia, ACP-104 for the treatment of schizophrenia, and pimavanserin for the treatment of sleep maintenance insomnia. We also have neuropathic pain and glaucoma clinical programs in collaboration with Allergan.

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 U.S. Food and Drug Administration (the "FDA") or other regulatory agencies.

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 clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before a new drug application ("NDA") may be submitted to the FDA. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

## **Table of Contents**

*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 ( IND ) from the FDA;

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

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 trial 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, suspensions or terminations in a clinical trial, the commercial prospects for the related drug candidate 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, 2007 we used \$54.9 million in net cash to fund our operating activities. Our cash and investment securities totaled approximately \$126.9 million at December 31, 2007. Although we believe our existing cash resources and anticipated payments from our existing collaborators will be sufficient to fund our cash requirements

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

through 2009, 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;

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;

## **Table of Contents**

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

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

the costs associated with litigation.

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 substantially all 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, regulatory, and commercialization expertise for selected drug candidates. Substantially all of our revenues for the year ended December 31, 2007 were from our collaborations with Allergan and Sepracor as well as our agreements with other parties. The term of our collaboration agreement with Sepracor ended in January 2008 and the ongoing research term of our agreements with Allergan will end in late-March 2009. 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 can terminate our existing collaborations under specific circumstances, including in some cases the right to terminate upon notice. We may not be able to renew our existing 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;

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

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.

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.

## **Table of Contents**

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. Competing products, either developed by our collaborators or to which our collaborators have rights, may result in the allocation of resources by our competitors to competing products and their withdrawal of support for our drug candidates or may otherwise result in lower demand for our potential products.

***We rely on third parties to conduct 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 conduct 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 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 these 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 delay or 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 or our collaborators successfully complete the clinical trials of drug candidates, the drug candidates may fail for other reasons.***

Even if we or our collaborators successfully complete the clinical trials of drug candidates, the drug candidates 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;

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 competitors.

## **Table of Contents**

***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 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 blood monitoring for the first six months of treatment followed by twice monthly monitoring thereafter. 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 and our ability to generate revenues from it.

***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 related disorders. 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 numerous companies and academic and other research institutions.



## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

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.

## **Table of Contents**

All of our U.S. 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 therapeutic 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 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 development or commercialization 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, and reporting systems and procedures in at least two countries, and be required to attract and retain sufficient numbers of talented employees in at least two countries. In addition, we may have to develop internal sales, marketing, and distribution capabilities if we decide to market any drug that we may successfully develop. 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 an adverse impact on our operations.***

Our subsidiary in Malmö, Sweden, ACADIA Pharmaceuticals AB, employs approximately 29 percent of our total personnel and is engaged in research and development activities, with primary responsibility for combinatorial, 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 our

## **Table of Contents**

development and commercialization efforts. In addition, currency fluctuations involving our Swedish operations may cause foreign currency gains and losses. These exchange-rate fluctuations could have a negative effect on our operations. 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 pimavanserin and ACP-104 and the preclinical and clinical development of our other drug candidates, including compounds being developed under our collaborations;

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

whether we are required to make payments due to achieving specified milestones under any licensing or similar agreements or otherwise make 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 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;

the costs associated with litigation; 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 indications 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 clinical supplies of our compounds for us, including pimavanserin and ACP-104. 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

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

cannot estimate these delays or costs with certainty but do not expect them to be material.

The manufacturers of our drug candidates 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 in obtaining regulatory approval of drug candidates or the ultimate launch of products based on our drug candidates 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 pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

---

## **Table of Contents**

***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 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 have incurred, and expect to continue to incur, significant costs as a result of laws and regulations relating to corporate governance and other matters.***

Laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 ( SOX ) and rules adopted or proposed by the SEC and by The Nasdaq Global Market, have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. We issued an evaluation of our internal control over financial reporting under Section 404 of SOX with our Annual Report. In the future, 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. 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 coverage that is the same or similar to our current 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 and board committees, and as our executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

***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 related capabilities or make arrangements with third parties to perform these 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 or fire 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 addition, while our facilities were not adversely impacted by the October 2007 fires, there is the possibility of future fires in the area. In the event of an earthquake or fire, if our facilities

## **Table of Contents**

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. While we do have fire insurance for our property and equipment located in San Diego, any damage sustained in a fire could cause a delay in our research and development efforts and our results of operations could be materially and adversely affected.

### **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 numerous patent applications worldwide with respect to pimavanserin and ACP-104, we have been issued only a limited number of patents with respect to pimavanserin and only two foreign patents with respect to ACP-104.

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;

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;

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

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

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

---

## **Table of Contents**

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. 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, if the claims of our pending patent applications issue, 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 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 directed to the form of ACP-104 known prior to the filing of our patent applications. We have filed method of use patent applications for ACP-104, but a competitor could use ACP-104, and patent its method of use, for a treatment not covered by our patent applications. In addition, while we have filed patent applications directed to methods of synthesis of ACP-104 and various crystalline polymorphs thereof, those claims, if they issue, will not prevent a potential competitor from making ACP-104 using any method of synthesis or from using any polymorphic form of ACP-104, which is outside the scope of the claims that ultimately may issue.

***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.



## **Table of Contents**

*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.

*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 consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. The United States Patent and Trademark Office's standards are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings in the United States Patent and Trademark Office (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. The laws of some

## **Table of Contents**

countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our drug candidates. In addition, U.S. patent laws may change which could prevent or limit the Company from filing patent applications or patent claims to protect its products and/or technologies.

If we fail to obtain and maintain patent protection and trade secret protection of our drug candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

### **Risks Related to Our Industry**

***We will be subject to stringent regulation in connection with the marketing of any products derived from our drug candidates, which could delay the development and commercialization of our products.***

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product in the United States until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, it may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular drug candidate.

Outside the United States, the ability to market a product is contingent upon receiving approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing, and reimbursement vary widely from country to country. Only after the appropriate regulatory authority is satisfied that adequate evidence of safety, quality, and efficacy has been presented will it grant a marketing authorization. Approval by the FDA does not automatically lead to the approval by regulatory authorities outside the United States and, similarly, approval by regulatory authorities outside the United States will not automatically lead to FDA approval.

In addition, U.S. and foreign government regulations control access to and use of some human or other tissue samples in our research and development efforts. U.S. and foreign government agencies may also impose restrictions on the use of data derived from human or other tissue samples. Accordingly, if we fail to comply with these regulations and restrictions, the commercialization of our drug candidates may be delayed or suspended, which may delay or impede our ability to generate product revenues.

***If our competitors develop and market products that are more effective than our drug candidates, they may reduce or eliminate our commercial opportunity.***

Competition in the pharmaceutical and biotechnology industries is intense and expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our drug development programs.

For example, our potential product for Parkinson's disease psychosis would compete with off-label use of antipsychotic drugs, including Seroquel, marketed by Astra-Zeneca, and with the generic drug clozapine. Our potential products for the treatment of schizophrenia would compete with Zyprexa, marketed by Eli Lilly,

## Table of Contents

Risperdal, marketed by Johnson & Johnson, Abilify, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical, Seroquel, and clozapine. Our potential products for the treatment of sleep maintenance insomnia would compete with Ambien and Ambien CR, marketed by Sanofi-Aventis, Lunesta, marketed by Sepracor, Sonata, marketed by King Pharmaceuticals, Inc., Rozerem, marketed by Takeda Pharmaceuticals North America, Inc., and various benzodiazepines. In the area of neuropathic pain, potential products would compete with Neurontin and Lyrica, marketed by Pfizer, and Cymbalta, marketed by Eli Lilly, as well as a variety of generic or proprietary opioids. Our potential products for the treatment of glaucoma would compete with Xalatan, marketed by Pfizer, and Lumigan and Alphagan, marketed by Allergan.

Many of our competitors and their collaborators have significantly greater experience than we do in the following:

identifying and validating targets;

screening compounds against targets;

preclinical studies and clinical trials of potential pharmaceutical products; and

obtaining FDA and other regulatory approvals.

In addition, many of our competitors and their collaborators have substantially greater capital and research and development resources, manufacturing, sales and marketing capabilities, and production facilities. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. Our competitors, either alone or with their collaborators, may succeed in developing drugs that are more effective, safer, more affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse affect on our business.

***Any claims relating to improper handling, storage, or disposal of biological, hazardous, and radioactive materials used in our business could be costly and delay our research and development efforts.***

Our research and development activities involve the controlled use of potentially harmful hazardous materials, including volatile solvents, biological materials such as blood from patients that has the potential to transmit disease, chemicals that cause cancer, and various radioactive compounds. Our operations also produce hazardous waste products. We face the risk of contamination or injury from the use, storage, handling or disposal of these materials. We are subject to federal, state and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant, and current or future environmental regulations may impair our research, development, or production efforts. If one of our employees were accidentally injured from the use, storage, handling, or disposal of these materials, the medical costs related to his or her treatment would be covered by our workers compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our general liability insurance policy specifically excludes coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be subject to criminal sanctions or fines or be held liable for damages, our operating licenses could be revoked, or we could be required to suspend or modify our operations and our research and development efforts.

## **Table of Contents**

*Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.*

Researching, developing, and commercializing drug products entails significant product liability risks. Liability claims may arise from our and our collaborators' use of products in clinical trials and the commercial sale of those products. Consumers may make these claims directly and our collaborators or others selling these products may seek contribution from us if they receive claims from consumers. Although we currently have product liability insurance that covers our clinical trials, we will need to increase and expand this coverage as we commence larger scale trials and if our drug candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or our collaborators develop. Product liability claims could have a material adverse effect on our business and results of operations. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products.

## **Risks Related to Our Common Stock**

*Our stock price may be particularly volatile because we are a drug discovery and development company.*

The market prices for securities of biotechnology companies in general, and drug discovery and development companies in particular, have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

the development status of our drug candidates, including results of our clinical trials for pimavanserin, ACP-104, or our neuropathic pain and glaucoma collaborations;

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

market conditions or trends related to biotechnology and pharmaceutical industries, or the market in general;

announcements of technological innovations, new commercial products, or other material events by our competitors or us;

disputes or other developments concerning our proprietary rights;

changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;

additions or departures of key personnel;

discussions of our business, products, financial performance, prospects, or stock price by the financial and scientific press and online investor communities such as chat rooms;

public concern as to, and legislative action with respect to, genetic testing or other research areas of biopharmaceutical companies, the pricing and availability of prescription drugs, or the safety of drugs and drug delivery techniques;

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

regulatory developments in the United States and in foreign countries;

the announcement of, or developments in, any litigation matters; or

economic and political factors, including but not limited to wars, terrorism, and political unrest.

In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. We may become subject to this type of litigation, which is often extremely expensive and diverts management's attention.

---

## **Table of Contents**

***If our officers, directors, and largest stockholders choose to act together, they may be able to significantly influence our management and operations, acting in their best interests and not necessarily those of our other stockholders.***

Our directors, executive officers and holders of five percent or more of our outstanding common stock and their affiliates beneficially own a substantial portion of our outstanding common stock. As a result, these stockholders, acting together, have the ability to significantly influence all matters requiring approval by our stockholders, including the election of all of our board members, amendments to our certificate of incorporation, going-private transactions, and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the company's interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of our other stockholders.

***If we or our stockholders sell substantial amounts of our common stock, the market price of our common stock may decline.***

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Holders of a significant number of shares of our common stock, from investments made when we were a private company, have rights to cause us to file a registration statement on their behalf or include their shares in registration statements that we may file on our behalf or on behalf of other stockholders. In addition, we included all of the 1.9 million shares of our common stock purchased by Sepracor in a registration statement that we filed in January 2006. Our stock price may decline as a result of the sale of the shares of our common stock included in these registration statements.

***Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and may make the removal and replacement of our directors and management more difficult.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;

authorize the issuance of blank check preferred stock that could be issued by our board of directors to increase the number of outstanding shares and prevent or delay a takeover attempt;

limit who may call a special meeting of stockholders;

establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;

prohibit our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with 66<sup>2</sup>/<sub>3</sub> percent stockholder approval; and

provide for a board of directors with staggered terms.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15 percent or more of our common stock for 5 years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.



**Table of Contents**

**Item 1B. *Unresolved Staff Comments.***

This item is not applicable.

**Item 2. *Properties.***

Our primary facilities consist of approximately 53,000 square feet of leased research and office space located in San Diego, California. The lease covering the primary building for our headquarters and laboratories in San Diego, comprising approximately 29,000 square feet, has been amended to include an additional 24,000 square feet of office and other space. These properties are leased through the end of 2012, with options to extend. We also have the right to early terminate the lease with respect to the primary building and/or the additional space. We also lease another facility in San Diego that covers approximately 8,000 square feet of laboratory, office, and other space. That lease is through December 2010, with an option to extend and also provides us with a right to terminate early. We have leased approximately 30,000 square feet of chemistry research and development space in a single facility in Malmö, Sweden. Our Swedish lease commenced in June 2005 and has a ten-year term with a five-year renewal provision. We believe that our existing facilities are adequate for our current needs.

**Item 3. *Legal Proceedings.***

This item is not applicable.

**Item 4. *Submission of Matters to a Vote of Security Holders.***

No matters were submitted to a vote of security holders during the quarter ended December 31, 2007.



**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

(a) Our common stock is traded on the NASDAQ Global Market under the symbol "ACAD". The following table sets forth the high and low sale prices for our common stock as reported on the NASDAQ Global Market for the periods indicated.

<b>2006</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 17.94	\$ 9.60
Second Quarter	\$ 16.23	\$ 7.60
Third Quarter	\$ 8.81	\$ 5.07
Fourth Quarter	\$ 10.55	\$ 8.10
<b>2007</b>		
First Quarter	\$ 16.84	\$ 6.63
Second Quarter	\$ 17.08	\$ 12.20
Third Quarter	\$ 17.33	\$ 13.14
Fourth Quarter	\$ 16.56	\$ 9.95

As of February 29, 2008, there were approximately 78 stockholders of record of our common stock. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future.

**Table of Contents****Item 6. Selected Financial Data.**

The following data has been derived from our audited financial statements, including the consolidated balance sheet at December 31, 2007 and 2006 and the related consolidated statements of operations for the three years ended December 31, 2007 and related notes appearing elsewhere in this report. The statement of operations data for the years ended December 31, 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004 and 2003 are derived from our audited consolidated financial statements that are not included in this report. You should read the selected financial data set forth below in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this report.

	2007	Years Ended December 31,				2003
		2006	2005	2004		
(In thousands, except per share data)						
Consolidated Statement of Operations Data:						
Revenues:						
Collaborative revenues	\$ 7,555	\$ 8,133	\$ 10,956	\$ 4,604	\$ 7,378	
Operating expenses(1):						
Research and development	57,942	49,398	30,336	23,885	17,402	
General and administrative	12,267	11,349	10,205	6,814	3,716	
Provision for loss from (settlement of) litigation		(3,560)	6,221			
Total operating expenses	70,209	57,187	46,762	30,699	21,118	
Loss from operations	(62,654)	(49,054)	(35,806)	(26,095)	(13,740)	
Interest income	6,532	4,153	1,851	607	360	
Interest expense	(268)	(198)	(180)	(429)	(712)	
Loss before change in accounting principle	(56,390)	(45,099)	(34,135)	(25,917)	(14,092)	
Cumulative effect of change in accounting principle		51				
Net loss	\$ (56,390)	\$ (45,048)	\$ (34,135)	\$ (25,917)	\$ (14,092)	
Net loss available to common stockholders	\$ (56,390)	\$ (45,048)	\$ (34,135)	\$ (17,330)	\$ (1,813)	
Net loss per common share, basic and diluted	\$ (1.60)	\$ (1.61)	\$ (1.55)	\$ (1.67)	\$ (1.24)	
Weighted average shares used in computing net loss per common share, basic and diluted(2)						
	35,211	27,923	22,014	10,353	1,459	
Net loss available to participating preferred stockholders	\$	\$	\$	\$ (8,587)	\$ (12,279)	
Net loss per participating preferred share, basic and diluted	\$	\$	\$	\$ (0.87)	\$ (1.46)	
Weighted average participating preferred shares outstanding, basic and diluted(2)				9,901	8,412	

- (1) As described in Note 2 of the notes to our consolidated financial statements appearing elsewhere in this report, we adopted the provisions of SFAS No. 123 (revised 2004), *Share-Based Payment*, effective January 1, 2006.
- (2) Please see Note 2 of the notes to our consolidated financial statements for an explanation of the determination of the number of shares used in computing per share data. All amounts reflect a 1-for-2 reverse stock split effected by us on May 25, 2004 in connection with our initial public offering.



**Table of Contents**

	2007	2006	At December 31, 2005 (in thousands)	2004	2003
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investment securities	\$ 126,858	\$ 83,255	\$ 55,521	\$ 35,927	\$ 27,214
Working capital	111,966	65,249	38,424	29,178	20,046
Total assets	134,584	89,544	62,506	40,365	31,693
Long-term debt, less current portion	1,156	1,379	892	1,044	1,624
Convertible preferred stock					74,514
Total stockholders' equity (deficit)	113,934	67,159	39,371	30,680	(52,671)

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report. Past operating results are not necessarily indicative of results that may occur in future periods. This discussion contains forward-looking statements, which involve a number of risks and uncertainties. Such forward-looking statements include statements about our strategies, objectives, expectations, discoveries, collaborations, clinical trials, proprietary and external programs, and other statements that are not historical facts, including statements which may be preceded by the words believes, expects, hopes, may, will, plans, intends, estimates, could, should, would, continue, seeks, aims, projects, anticipates, potential or similar words. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to update or revise publicly any forward-looking statements. Forward-looking statements are not guarantees of performance. Actual results or events may differ materially from those anticipated in our forward-looking statements as a result of various factors, including those set forth under the section captioned Risk Factors elsewhere in this report. Information in the following discussion for a yearly period means for the year ended December 31 of the indicated year.

**Overview****Background**

We are a biopharmaceutical company focused on the discovery, development, and commercialization of small molecule drugs for the treatment of central nervous system disorders. We currently have six clinical programs and several additional programs in discovery and development. In our most advanced program, we are conducting Phase III studies with pimavanserin for the treatment of Parkinson's disease psychosis. We have reported positive results from a Phase II trial in our program with pimavanserin as a co-therapy in schizophrenia. We also have completed enrollment of a Phase IIb trial in our program with ACP-104 as a stand-alone treatment for schizophrenia. In addition, we have completed a proof-of-concept clinical study with pimavanserin for the treatment of sleep maintenance insomnia in healthy older adults. We have retained worldwide commercialization rights for our programs with pimavanserin and ACP-104. Additionally, we have a neuropathic pain program in Phase II development and a glaucoma program in Phase I studies in collaboration with Allergan, Inc. All of the drug candidates in our product pipeline emanate from discoveries made using our proprietary drug discovery platform.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. At December 31, 2007, we had an accumulated deficit of \$229.9 million. We expect our operating losses to increase for at least the next several years as we pursue the clinical development of our lead drug candidates and expand our discovery and development pipeline.

## **Table of Contents**

### ***Revenues***

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for at least the next several years, if at all. Our revenues to date have been generated substantially from research and milestone payments under our collaboration agreements. We have entered into three separate collaboration agreements with Allergan and one with Sepracor. We have also entered into a development agreement with The Stanley Medical Research Institute ( SMRI ) and smaller scale collaboration and license agreements with other parties. As of December 31, 2007, we had received an aggregate of \$57.9 million in payments under these agreements, including research funding and related fees and upfront and milestone payments. We expect our revenues for the next several years to consist primarily of payments under our current agreements and any additional collaborations, including any upfront payments upon execution of new agreements, research funding throughout the research term of our agreements with these parties, and milestone payments contingent upon achievement of agreed-upon objectives.

Pursuant to the terms of our March 2003 collaboration agreement with Allergan, we had received an aggregate of \$14.5 million in payments as of December 31, 2007, consisting of upfront fees, and research funding and related fees. This collaboration originally provided for a three-year research term, which has been extended by the parties through March 2009. We are also a party to two other collaboration agreements with Allergan, pursuant to which we are currently pursuing the clinical development of drug candidates in the areas of neuropathic pain and glaucoma. We are eligible to receive milestone payments and royalties on product sales, if any, under each of our three collaboration agreements with Allergan.

Pursuant to the terms of a three-year collaboration agreement with Sepracor entered into in January 2005, we had received \$6.7 million in research funding as of December 31, 2007. The term of this collaboration ended in January 2008. In connection with this collaboration, Sepracor purchased an aggregate of \$20 million of our common stock in two \$10 million tranches. In January 2005, Sepracor purchased the first \$10 million of our common stock at a 40 percent premium to the 30-day trailing average closing price, resulting in a premium of \$3.1 million. In January 2006, Sepracor completed the second \$10 million purchase of our common stock at a 25 percent premium to the 30-day trailing average closing price at that time, resulting in a premium of \$1.1 million. We have recognized the premium from these stock purchases as revenue as the related research activities were performed over the research term. Pursuant to the terms of a development agreement with SMRI, which expired in May 2007, we received an aggregate of \$5 million in funding to support the development of ACP-104.

Each of our collaboration agreements is subject to early termination by the collaborator upon specified events, including if we breach the agreement or, in the case of one of our agreements with Allergan, if we have a change in control. Upon the conclusion of the research term under each agreement, our collaborator may terminate the agreement by notice.

### ***Research and Development Expenses***

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, laboratory supplies and costs for facilities and equipment. We charge all research and development expenses to operations as incurred. Our research and development activities are primarily focused on our most advanced clinical and preclinical programs. We are responsible for all costs incurred in the development of both pimavanserin and ACP-104, as well as the costs associated with our other proprietary programs. We are not responsible for, nor have we incurred, development expenses, including costs related to clinical trials, in our clinical programs for neuropathic pain and glaucoma, which we are pursuing in collaboration with Allergan.

We use our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs are not attributable to a specific project but are directed to broadly applicable research activities. Accordingly, we do not report our internal research and

**Table of Contents**

development costs on a project basis. We use external service providers to manufacture our drug candidates to be used in clinical trials and for the majority of the services performed in connection with the preclinical and clinical development of our drug candidates. To the extent that costs associated with external service providers are not attributable to a specific project, they are included in other external costs. The following table summarizes our research and development expenses for the years ended December 31, 2007, 2006 and 2005 (in thousands):

	Years Ended December 31,		
	2007	2006	2005
Costs of external service providers:			
Pimavanserin	\$ 10,932	\$ 18,930	\$ 7,301
ACP-104	16,480	3,722	1,380
Other	1,604	1,529	1,050
Subtotal	29,016	24,181	9,731
Internal costs	26,205	23,351	19,865
Stock-based compensation	2,721	1,866	740
Total research and development	\$ 57,942	\$ 49,398	\$ 30,336

At this time, due to the risks inherent in the clinical trial process and given the stage of development of our programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our drug candidates for potential commercialization. Due to these same factors, we are unable to determine the anticipated completion dates for our current research and development programs. Clinical development timelines, probability of success, and development costs vary widely. While we are currently focused on advancing the clinical development of pimavanserin and ACP-104, we anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each drug candidate, as well as an ongoing assessment as to each drug candidate's commercial potential. We cannot forecast with any degree of certainty which drug candidates will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. As a result, we cannot be certain when and to what extent we will receive cash inflows from the commercialization of our drug candidates.

We expect our research and development expenses to be substantial and to increase as we continue the development of our clinical programs and expand our discovery and development pipeline. The lengthy process of completing clinical trials and seeking regulatory approval for our drug candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals could cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

**General and Administrative Expenses**

Our general and administrative expenses consist primarily of salaries and other costs for employees serving in executive, finance, business development, and business operations functions, as well as professional fees associated with legal and accounting services, and costs associated with patents and patent applications for our intellectual property. We anticipate that our general and administrative expenses may increase in future periods as we support the future growth of our business and incur additional professional fees, including costs associated with our intellectual property.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements. We have identified the accounting policies that we believe require application of management's most subjective judgments, often requiring the need to make estimates about the effect of matters

## **Table of Contents**

that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to consolidated financial statements included in this report, we believe that the following accounting policies require the application of significant judgments and estimates.

### ***Revenue Recognition***

We recognize revenues in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, *Revenue Recognition*. Arrangements with multiple elements are accounted for in accordance with Emerging Issues Task Force Issue No. 00-21, or EITF 00-21, *Revenue Arrangements With Multiple Deliverables*. We analyze our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting in accordance with EITF 00-21. Our revenues are primarily related to our collaboration agreements, and such agreements may provide for various types of payments to us, including upfront payments, research funding and related fees during the term of the agreement, milestone payments based on the achievement of established development objectives, licensing fees, and royalties on future product sales.

Upfront, non-refundable payments under collaboration agreements are recorded as deferred revenue once received and recognized ratably over the term of the agreement. Non-refundable payments for research funding are generally recognized as revenues over the period as the related research activities are performed. Revenues from non-refundable milestones are recognized when the earnings process is complete and the payment is reasonably assured. Non-refundable milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the milestone, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the triggering event. Revenues from non-refundable license fees are recognized upon receipt of the payment if the license has stand-alone value, we do not have ongoing involvement or obligations, and the fair value of any undelivered items can be determined.

### ***Accrued Expenses***

We are required to estimate accrued expenses as part of our process of preparing financial statements. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for preclinical development, manufacturing of clinical materials, and clinical trials. We accrue for costs incurred as the services are being provided by monitoring the status of the trials or services provided, and the invoices received from our external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in our trials and we recognize this cost over the estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed significantly from the actual costs incurred. However, we expect to expand the level of our clinical trials and related services in the future. As a result, we anticipate that our estimated accruals for clinical services will be more material to our operations in future periods. Subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

### ***Stock-Based Compensation***

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards ( SFAS ) No. 123 (revised 2004), *Share-Based Payment* ( SFAS No. 123(R) ), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS No. 123 ), using the modified prospective transition method. Under that transition method, compensation cost recognized for the years ended December 31, 2007 and 2006 included (a) compensation cost for all share-based payments granted prior to, but

## **Table of Contents**

not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, excluding stock options granted prior to December 31, 2003, which were valued using the minimum value method, and for which the related compensation cost will continue to be determined by using the intrinsic value method under Accounting Principles Board ( APB ) Opinion No. 25, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). The adoption of SFAS No. 123(R) resulted in a cumulative benefit from accounting change of \$51,000 which reflects the net cumulative impact of estimating future forfeitures for options granted subsequent to December 31, 2003 and outstanding at January 1, 2006, rather than recording forfeitures when they occur as previously permitted. Results for prior periods have not been restated.

Prior to January 1, 2006, as permitted by SFAS No. 123, we measured compensation expense for our employee stock-based compensation plans using the intrinsic value method under APB Opinion No. 25 and provided pro forma disclosures of net income (loss) as if a fair value method had been applied in measuring compensation expense. Accordingly, compensation cost for stock awards was measured as the excess, if any, of the fair value of our common stock at the date of grant over the amount an employee must pay to acquire the stock.

Unearned stock-based compensation related to stock options granted prior to December 31, 2003 is reflected as a separate component of stockholders' equity in our balance sheet. Unearned stock-based compensation represents the difference between the exercise price of grants made to employees and the fair value of our common stock on the date of grant. The balance of unearned stock-based compensation, totaling \$368,000 and which related to stock options granted during the period from January 1, 2004 to the closing of our initial public offering on June 2, 2004, was reclassified to additional paid-in capital upon the adoption of SFAS No. 123(R) on January 1, 2006.

The value of each employee stock option and each employee stock purchase right granted is estimated on the grant date under the fair value method using the Black-Scholes option pricing model. For options granted prior to January 1, 2006, we amortize the fair value on an accelerated basis. For options granted after January 1, 2006, we amortize the fair value on a straight-line basis. All option expense is amortized over the requisite service period of the awards, which is generally the vesting period. As of December 31, 2007, total unrecognized compensation cost related to stock options and purchase rights was approximately \$5.3 million, and the weighted average period over which this cost is expected to be recognized is 2.2 years.

Stock-based awards issued to non-employees other than directors are accounted for using a fair value method and are re-measured to fair value at each period end until the earlier of the date that performance by the non-employee is complete or a performance commitment has been obtained. The fair value of each award is estimated using the Black-Scholes option pricing model.

## **Results of Operations**

### ***Fluctuations in Operating Results***

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the timing and amount of payments received pursuant to our current and future collaborations, and the progress and timing of expenditures related to our discovery and development efforts. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.



## **Table of Contents**

### ***Comparison of the Years Ended December 31, 2007 and 2006***

#### ***Revenues***

Revenues totaled \$7.6 million in 2007 compared to \$8.1 million in 2006, and were comprised of revenues from our collaborations with Sepracor and Allergan as well as our agreements with SMRI and other parties. The decrease in revenues was primarily due to lower research funding from our collaborations with Allergan and Sepracor, and completion of our agreement with SMRI, partially offset by increased revenues from smaller scale research and license agreements with other parties. Revenues from our collaborations with Allergan totaled \$1.6 million in 2007 compared to \$2.2 million in 2006. Revenues from our collaboration with Sepracor totaled \$3.4 million in 2007 compared to \$3.8 million in 2006. Revenues from our agreement with SMRI, which ended in May 2007, totaled \$1.0 million in 2007 compared to \$2.0 million in 2006. The term of our collaboration with Sepracor ended in January 2008 and, therefore, we anticipate lower revenues from our existing collaborations in 2008 relative to 2007.

#### ***Research and Development Expenses***

Research and development expenses totaled \$57.9 million in 2007, including \$2.7 million in stock-based compensation, compared to \$49.4 million in 2006, including \$1.9 million in stock-based compensation, primarily due to increased clinical development activity associated with our proprietary clinical programs. The increase in research and development expenses was primarily due to \$4.8 million in increased fees paid to external service providers, \$3.3 million in increased salaries and related personnel costs, and \$855,000 in increased stock-based compensation, partially offset by a net reduction in other expenses. External service costs totaled \$29.0 million, or 50 percent of our research and development expenses in 2007, compared to \$24.2 million, or 49 percent of our research and development expenses in 2006. We expect that our research and development costs will continue to increase in future periods as we continue to pursue the clinical development of our lead drug candidates and expand our discovery and development pipeline.

#### ***General and Administrative Expenses***

General and administrative expenses totaled \$12.3 million in 2007, including \$1.6 million in stock-based compensation, compared to \$11.3 million in 2006, including \$1.5 million in stock-based compensation. The increase in general and administrative expenses was primarily due to \$552,000 in increased salaries and related personnel costs and increases in other administrative costs, offset in part by decreases in professional fees associated with accounting and legal services. We anticipate that our general and administrative expenses may increase in future periods as we support the future growth of our business and incur additional professional fees.

#### ***Provision for Loss From (Settlement of) Litigation***

In 2006, we recorded a gain of \$3.6 million associated with an agreement we entered into to fully settle a civil action inclusive of all fees and costs.

#### ***Interest Income***

Interest income increased to \$6.5 million in 2007 from \$4.2 million in 2006. The increase in interest income was primarily due to higher average levels of cash and investment securities resulting from sales of our common stock.

## **Table of Contents**

### ***Comparison of the Years Ended December 31, 2006 and 2005***

#### ***Revenues***

Revenues decreased to \$8.1 million in 2006 from \$11.0 million in 2005 primarily due to lower revenues recognized from our collaborations with Allergan. Revenues from our collaboration agreements with Allergan decreased to \$2.2 million in 2006 from \$5.2 million in 2005 primarily due to lower research funding during the extended term of our March 2003 collaboration. The remaining revenues during 2006 and 2005 were primarily attributable to revenues earned under our agreements with Sepracor and SMRI. Revenues from our collaboration with Sepracor totaled \$3.8 million and \$3.6 million in 2006 and 2005, respectively. Revenues from our agreement with SMRI totaled \$2.0 million in each of 2006 and 2005.

#### ***Research and Development Expenses***

Research and development expenses totaled \$49.4 million in 2006, including \$1.9 million in stock-based compensation, compared to \$30.3 million in 2005, including \$740,000 in stock-based compensation, primarily due to increased clinical development activity associated with our proprietary clinical programs. Excluding stock-based compensation, the increase in research and development expenses was primarily due to \$14.5 million in increased fees paid to external service providers, and increased costs associated with our research and development organization, including \$1.8 million in increased salaries and related personnel costs, and \$1.6 million in increased facility, equipment and supply costs. External service costs totaled \$24.2 million, or 49 percent of our research and development expenses in 2006, compared to \$9.7 million, or 32 percent of our research and development expenses in 2005. The increase in stock-based compensation in 2006 in relation to 2005 was primarily attributable to adoption of SFAS 123(R) effective as of January 1, 2006.

#### ***General and Administrative Expenses***

General and administrative expenses totaled \$11.3 million in 2006, including \$1.5 million in stock-based compensation, compared to \$10.2 million in 2005, including \$568,000 in stock-based compensation. Excluding stock-based compensation, general and administrative expenses increased by \$199,000 in 2006. This increase was primarily due to \$524,000 in increased salaries and related personnel costs, and increased costs associated with patents and patent applications for our intellectual property, partially offset by a decrease in professional fees associated with our Sarbanes-Oxley compliance efforts. The increase in stock-based compensation in 2006 in relation to 2005 was primarily attributable to adoption of SFAS 123(R) effective as of January 1, 2006.

#### ***Provision for Loss From (Settlement of) Litigation***

In 2006, we recorded a gain of \$3.6 million associated with an agreement we entered into to fully settle a civil action inclusive of all fees and costs. In 2005, we had recorded a provision for loss from litigation of \$6.2 million related to this matter.

#### ***Interest Income***

Interest income increased to \$4.2 million in 2006 from \$1.9 million in 2005. The increase in interest income was primarily due to higher average levels of cash and investment securities resulting from sales of our common stock and, to a lesser degree, increased yields on our investment portfolio.

### **Liquidity and Capital Resources**

Since inception, we have funded our operations primarily through sales of our equity securities, payments received under our collaboration agreements, debt financings, and interest income. As of December 31, 2007, we had received \$324.3 million in net proceeds from sales of our equity securities, including \$6.9 million in debt we had retired through the issuance of our common stock, \$57.9 million in payments from collaboration agreements, \$22.4 million in debt financing, and \$18.7 million in interest income.

## **Table of Contents**

At December 31, 2007, we had approximately \$126.9 million in cash, cash equivalents and investment securities compared to \$83.3 million at December 31, 2006. We have invested a substantial portion of our available cash in investment securities consisting of high quality, marketable debt instruments of corporations, financial institutions, and government agencies. We have adopted an investment policy and established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least AA or A1+/P1 as determined by Moody's Investors Service and/or Standard & Poor's. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt.

Net cash used in operating activities totaled \$54.9 million in 2007 compared to \$41.4 million in 2006 and \$20.3 million in 2005. The increase in net cash used in operating activities in 2007 relative to 2006 was primarily due to an increase in our net loss and changes in operating assets and liabilities, including an increase in prepaid expenses, receivables and other current assets, decreases in deferred revenue and accounts payable and a smaller increase in accrued expenses in 2007 compared to 2006. Prepaid expenses, receivables and other current assets increased \$1.8 million in 2007 compared to a decrease of \$2.1 million in 2006. This increase was primarily attributable to advance payments made in connection with external service costs for our clinical trials. The decrease in deferred revenue of \$2.0 million in 2007 and \$780,000 in 2006 was primarily attributable to amortization of payments from our collaboration with Sepracor, including the premium amount resulting from Sepracor's purchases of our common stock. The increase in accrued expenses in 2007 was primarily due to increased external service costs related to our clinical trials. We anticipate that payments related to these accrued expenses will result in an increase in our cash used in operating activities during the first quarter of 2008.

The increase in net cash used in operating activities in 2006 relative to 2005 was primarily due to an increase in our net loss and changes in the operating assets and liabilities, including decreases in accrued loss from litigation and in deferred revenue, which were offset by increases in accrued expenses and accounts payable, and a decrease in prepaid expenses, receivables and other current assets in 2006, relative to 2005. The reduction in the \$8.7 million accrued loss from litigation, which had been recorded in 2005, was due to the settlement of a civil action in 2006. Current deferred revenue decreased \$780,000 in 2006 compared to an increase of \$2.1 million in 2005. The increase in deferred revenue during 2005 was primarily attributable to payments from our collaboration with Sepracor, including the premium amount resulting from Sepracor's first purchase of our common stock. The increase in accrued expenses and accounts payable in 2006 was primarily due to increased external service costs related to our clinical trials. The decrease in prepaid expenses, receivables and other current assets in 2006 was primarily due to receipt of \$2.4 million in proceeds from our insurance policy in connection with the settlement of a civil action.

Net cash used in investing activities totaled \$41.9 million in 2007 compared to \$22.9 million in 2006 and \$19.2 million in 2005, and has fluctuated significantly from period to period primarily due to the timing of purchases and maturities of investment securities. The increase in net cash used in investing activities in 2007 relative to 2006 was primarily due to increased purchases of investment securities, net of maturities, resulting from higher levels of cash following our public offering in 2007, partially offset by a decrease in restricted cash in 2006. The increase in net cash used in investing activities in 2006 relative to 2005 was primarily due to increased purchases of investment securities, net of maturities, and an increase in restricted cash in 2005.

Net cash provided by financing activities increased to \$98.2 million in 2007 from \$70.0 million in 2006 and \$40.9 million in 2005. This increase was primarily attributable to increased proceeds from the sale of our equity securities. The net cash provided by financing activities in 2007 was primarily due to \$98.6 million in net proceeds received from the sales of our common stock, including \$96.1 million received from a follow-on public offering, offset by net repayments of our long-term debt. The net cash provided by financing activities in 2006 was primarily due to \$69.4 million in net proceeds received from the sales of our common stock, including \$59.4 million received from a follow-on public offering and \$8.9 million received from the second purchase of our common stock by Sepracor, which amount did not include the \$1.1 million premium received in connection with this stock purchase that was included in deferred revenue in operating activities. The net cash provided by

## Table of Contents

financing activities in 2005 was primarily due to \$41.7 million in net proceeds received from sales of our equity securities, including \$34.0 million received from a private placement and \$6.9 million from the first purchase of our common stock by Sepracor, which did not include the \$3.1 million premium received in connection with this stock purchase that was included in deferred revenue in operating activities, offset by net repayments of our long-term debt.

We have entered into equipment financing agreements from time to time, which we have utilized to fund the majority of our property and equipment purchases. The agreements contain fixed interest rates ranging from 8.46 to 10.41 percent per annum. At December 31, 2007, we had \$2.1 million in outstanding borrowings under these agreements, which are secured by the related equipment. We were in compliance with required financial covenants and conditions at December 31, 2007.

The following table summarizes our contractual obligations, including interest, at December 31, 2007 (in thousands):

	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>After 5 Years</b>
Operating leases	\$ 16,077	\$ 2,469	\$ 7,315	\$ 3,499	\$ 2,794
Long-term debt	2,411	1,144	1,234	33	
<b>Total</b>	<b>\$ 18,488</b>	<b>\$ 3,613</b>	<b>\$ 8,549</b>	<b>\$ 3,532</b>	<b>\$ 2,794</b>

We have also entered into agreements with contract research organizations and other external service providers for services in connection with the development of our drug candidates. We were contractually obligated for up to approximately \$24.3 million of future services under these agreements as of December 31, 2007. The nature of the work being conducted under our agreements with contract research organizations is such that, in most cases, the services may be stopped with short notice. In such event, we would not be liable for the full amount of the contract. Our actual contractual obligations may vary depending upon several factors, including the results of the underlying studies.

We have also entered into certain other agreements that may require us to make payments in the future and currently cannot forecast with any degree of certainty when or if we will be required to make payments under these agreements. Under our agreement with SMRI, assuming the successful development and commercialization of our drug candidate ACP-104, we are required to pay to SMRI royalties on product sales up to a specified level. Under another agreement, we have provided initial seed funding to help establish Abbey Pharmaceuticals, Inc. and have agreed to increase our investment to an aggregate of \$1 million upon Abbey's satisfaction of certain conditions. Under the terms of another agreement in which we licensed certain intellectual property rights that complement our patent portfolio, if certain conditions are met, we are required to make future payments, including milestones, royalties and sublicensing fees for compounds covered by the agreement.

We have consumed substantial amounts of capital since our inception. Although we believe our existing cash resources and the anticipated payments from our existing collaborations will be sufficient to fund our anticipated cash requirements through at least 2009, we will require significant additional financing in the future 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 clinical trials, preclinical studies and other research and development programs;

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

the ability of our collaborators and us to reach the milestones, and other events or developments, under our collaboration agreements;

## **Table of Contents**

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 of drug candidates; 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 funding will be available to us on acceptable terms, or 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.

### *Off-Balance Sheet Arrangements*

To date, we have not had any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

### *Recent Accounting Pronouncements*

In December 2007, the Financial Accounting Standards Board, or FASB, ratified EITF No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and would be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. We are currently evaluating the potential impact of EITF 07-1 on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, or SFAS 141(R). SFAS 141(R) will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize in-process research and development and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008.

In December 2007, the FASB issued SFAS No. 160, *Interests in Consolidated Financial Statements - an amendment of ARB No. 51*, or SFAS 160. SFAS 160 impacts the accounting for minority interest in the consolidated financial statements of filers. The statement requires the reclassification of minority interest to the equity section of the balance sheet and the results from operations attributed to minority interest to be included in net income. The related minority interest impact on earnings would then be disclosed in the summary of other comprehensive income. SFAS 160 is effective for fiscal years beginning after December 15, 2008.

In June 2007, the FASB ratified EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used or rendered for future research and development activities be deferred and capitalized. These amounts will be recognized as expense in

## **Table of Contents**

the period that the related goods are delivered or the related services are performed, subject to an assessment of recoverability. EITF 07-3 is effective prospectively for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We are currently evaluating the potential impact of the provisions of EITF 07-3 on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities- Including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS 159 is to reduce both the complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Most of the provisions in SFAS 159 are elective; however, the amendment to FASB Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the potential impact of SFAS 159 on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair-Value Measurements*, or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair-value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 for all financial assets and liabilities and any other assets and liabilities that are recognized or disclosed at fair value on a recurring basis. For nonfinancial assets and liabilities, SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2008. We are currently evaluating the potential impact of SFAS 157 on our consolidated financial statements.

### **Item 7A. *Quantitative and Qualitative Disclosures About Market Risk.***

#### ***Interest Rate Risk***

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in highly liquid and high quality marketable debt instruments of corporations, financial institutions, and government agencies with contractual maturity dates of generally less than two years. All investment securities have a credit rating of at least AA or A1+/P1 as determined by Moody's Investors Service and/or Standard & Poor's. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. If a 10 percent change in interest rates were to have occurred on December 31, 2007, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

#### ***Foreign Currency Risk***

We have wholly owned subsidiaries in Sweden and Denmark, which expose us to foreign exchange risk. The functional currency of our subsidiary in Sweden is the Swedish kroner and the functional currency of our subsidiary in Denmark is the Danish kroner. Accordingly, all assets and liabilities of our subsidiaries are translated to U.S. dollars based on the applicable exchange rate on the balance sheet date. Expense components are translated to U.S. dollars at weighted average exchange rates in effect during the period. Gains and losses resulting from foreign currency translation are included as a component of our stockholders' equity. Other foreign currency transaction gains and losses are included in our results of operations and, to date, have not been significant. We have not hedged exposures denominated in foreign currencies or any other derivative financial instrument.

### **Item 8. *Financial Statements and Supplementary Data.***

The consolidated financial statements required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

## **Table of Contents**

### **Item 9. *Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.***

None.

### **Item 9A. *Controls and Procedures.***

#### *Disclosure Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of December 31, 2007, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2007.

#### *Management's Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2007, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2007, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2007 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in its Report, which appears under Item 15 in this report.

#### *Changes in Internal Control Over Financial Reporting*

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably

**Table of Contents**

likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. *Other Information.***

None.



**Table of Contents**

**PART III**

**Item 10. *Directors, Executive Officers and Corporate Governance.***

The information required by this Item will be set forth in the section headed "Proposal 1 Election of Directors" in our definitive Proxy Statement for our 2008 Annual Meeting of Stockholders to be filed with the SEC by April 29, 2008 (the "Proxy Statement") and is incorporated in this report by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at <http://www.acadia-pharm.com> under the Corporate Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Stockholders may request a free copy of the Code of Business Conduct and Ethics from our corporate compliance officer, Glenn F. Baity c/o ACADIA Pharmaceuticals Inc., 3911 Sorrento Valley Boulevard, San Diego, CA 92121.

**Item 11. *Executive Compensation.***

The information required by this Item will be set forth in our Proxy Statement and is incorporated in this report by reference.

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

The information required by this Item will be set forth in our Proxy Statement and is incorporated in this report by reference.

Information regarding our equity compensation plans will be set forth in our Proxy Statement and is incorporated in this report by reference.

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

The information required by this Item will be set forth in our Proxy Statement and is incorporated in this report by reference.

**Item 14. *Principal Accounting Fees and Services.***

The information required by this Item will be set forth in our Proxy Statement and is incorporated in this report by reference.

**Table of Contents**

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

*(a) Documents filed as part of this report.*

1. The following financial statements of ACADIA Pharmaceuticals Inc. and Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm, are included in this report:

	<b>Page Number</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets at December 31, 2007 and 2006</u>	F-2
<u>Consolidated Statements of Operations for Each of the Three Years Ended December 31, 2007, 2006, and 2005</u>	F-3
<u>Consolidated Statements of Cash Flows for Each of the Three Years Ended December 31, 2007, 2006, and 2005</u>	F-4
<u>Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for Each of the Three Years Ended December 31, 2007, 2006, and 2005</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6
2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.	

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

*(b) Exhibits.* See the Exhibit Index and Exhibits filed as part of this report.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ACADIA PHARMACEUTICALS INC.

/s/ ULI HACKSELL  
**Uli Hacksell, Ph.D.**

**Chief Executive Officer**

Date: March 5, 2008

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Uli Hacksell and Thomas H. Aasen, and each of them, his true and lawful attorneys-in-fact and agents with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ ULI HACKSELL  <b>Uli Hacksell</b>	Chief Executive Officer and Director (Principal Executive Officer)	March 5, 2008
/s/ THOMAS H. AASEN  <b>Thomas H. Aasen</b>	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 5, 2008
/s/ LESLIE IVERSEN  <b>Leslie Iversen</b>	Chairman of the Board	March 5, 2008
/s/ GORDON BINDER  <b>Gordon Binder</b>	Director	March 5, 2008
/s/ MICHAEL BORER  <b>Michael Borer</b>	Director	March 5, 2008
/s/ MARY ANN GRAY  <b>Mary Ann Gray</b>	Director	March 5, 2008
/s/ LESTER KAPLAN  <b>Lester Kaplan</b>	Director	March 5, 2008

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

**Lester Kaplan**

/s/ TORSTEN RASMUSSEN

Director

March 5, 2008

**Torsten Rasmussen**

/s/ ALAN WALTON

Director

March 5, 2008

**Alan Walton**

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

ACADIA Pharmaceuticals Inc.

In our opinion, the consolidated financial statements listed in the index appearing under item 15(a)(1) present fairly, in all material respects, the financial position of ACADIA Pharmaceuticals Inc. and its subsidiaries at December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits which were integrated audits in 2007 and 2006. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP

San Diego, California

March 4, 2008

**Table of Contents****ACADIA PHARMACEUTICALS INC.****CONSOLIDATED BALANCE SHEETS**

(in thousands, except for par value and share data)

	December 31,	
	2007	2006
<b>Assets</b>		
Cash and cash equivalents	\$ 16,987	\$ 15,480
Investment securities, available-for-sale	109,871	67,775
Prepaid expenses, receivables and other current assets	4,395	2,528
Total current assets	131,253	85,783
Property and equipment, net	3,048	3,505
Other assets	283	256
Total assets	\$ 134,584	\$ 89,544
<b>Liabilities and stockholders' equity</b>		
Accounts payable	\$ 2,590	\$ 3,387
Accrued expenses	15,012	13,485
Current portion of deferred revenue	707	2,666
Current portion of long-term debt	978	996
Total current liabilities	19,287	20,534
Other long-term liabilities	207	472
Long-term debt, less current portion	1,156	1,379
Total liabilities	20,650	22,385
Commitments and contingencies (Note 10)		
<b>Stockholders' equity</b>		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at December 31, 2007 and 2006; no shares issued and outstanding at December 31, 2007 and 2006		
Common stock, \$0.0001 par value; 75,000,000 shares authorized at December 31, 2007 and 2006; 37,035,389 shares and 29,940,477 shares issued and outstanding at December 31, 2007 and 2006, respectively	4	3
Additional paid-in capital	343,293	240,446
Accumulated deficit	(229,856)	(173,466)
Unearned stock-based compensation		(64)
Accumulated other comprehensive income	493	240
Total stockholders' equity	113,934	67,159
	\$ 134,584	\$ 89,544

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

**Table of Contents****ACADIA PHARMACEUTICALS INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(in thousands, except per share data)**

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>Revenues</b>			
Collaborative revenues	\$ 7,555	\$ 8,133	\$ 10,956
<b>Operating expenses</b>			
Research and development (includes stock-based compensation of \$2,721, \$1,866 and \$740, respectively)	57,942	49,398	30,336
General and administrative (includes stock-based compensation of \$1,574, \$1,512 and \$568, respectively)	12,267	11,349	10,205
Provision for loss from (settlement of) litigation		(3,560)	6,221
<b>Total operating expenses</b>	<b>70,209</b>	<b>57,187</b>	<b>46,762</b>
Loss from operations	(62,654)	(49,054)	(35,806)
Interest income	6,532	4,153	1,851
Interest expense	(268)	(198)	(180)
Loss before change in accounting principle	(56,390)	(45,099)	(34,135)
Cumulative effect of change in accounting principle		51	
<b>Net loss</b>	<b>\$ (56,390)</b>	<b>\$ (45,048)</b>	<b>\$ (34,135)</b>
Net loss per common share, basic and diluted			
Before change in accounting principle	\$ (1.60)	\$ (1.61)	\$ (1.55)
Cumulative effect of change in accounting principle			
<b>Net loss per common share, basic and diluted</b>	<b>\$ (1.60)</b>	<b>\$ (1.61)</b>	<b>\$ (1.55)</b>
Weighted average common shares outstanding, basic and diluted	35,211	27,923	22,014

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

**Table of Contents****ACADIA PHARMACEUTICALS INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	Years Ended December 31,		
	2007	2006	2005
<b>Cash flows from operating activities</b>			
Net loss	\$ (56,390)	\$ (45,048)	\$ (34,135)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,065	852	1,026
Stock-based compensation	4,295	3,378	1,308
Amortization of investment premium/discount	(297)	(998)	
Other	(155)	(176)	152
Changes in operating assets and liabilities:			
Prepaid expenses, receivables and other current assets	(1,788)	2,075	(2,713)
Other assets	(27)	(158)	(98)
Accounts payable	(845)	1,314	(80)
Accrued expenses	1,443	6,902	2,901
Accrued loss from litigation		(8,710)	8,710
Deferred revenue	(1,959)	(780)	2,125
Other long-term liabilities	(268)	(69)	542
Net cash used in operating activities	(54,926)	(41,418)	(20,262)
<b>Cash flows from investing activities</b>			
Purchases of investment securities	(222,231)	(116,596)	(54,523)
Maturities of investment securities	180,745	83,166	48,893
Decrease (increase) in restricted cash		12,520	(12,520)
Purchases of property and equipment	(416)	(2,026)	(1,022)
Net cash used in investing activities	(41,902)	(22,936)	(19,172)
<b>Cash flows from financing activities</b>			
Proceeds from issuance of common stock and warrants, net of issuance costs	98,599	69,403	41,670
Proceeds from issuance of long-term debt	754	1,626	782
Repayments of long-term debt	(1,133)	(1,033)	(1,562)
Net cash provided by financing activities	98,220	69,996	40,890
Effect of exchange rate changes on cash	115	42	38
Net increase in cash and cash equivalents	1,507	5,684	1,494
<b>Cash and cash equivalents</b>			
Beginning of year	15,480	9,796	8,302
End of year	\$ 16,987	\$ 15,480	\$ 9,796
<b>Supplemental schedule of cash flow information</b>			
Interest paid	\$ 265	\$ 169	\$ 181
<b>Supplemental schedule of noncash investing and financing activities</b>			
Unrealized gain (loss) on investment securities, net of tax	188	131	(50)



Net property acquired under capital leases	139	31
The accompanying notes are an integral part of these consolidated financial statements.		

**Table of Contents****ACADIA PHARMACEUTICALS INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME (LOSS)**

(in thousands, except share data)

	Common Stock		Additional	Accumulated	Unearned	Accumulated	Total	Comprehensive
	Shares	Amount	Paid-in	Deficit	Stock-Based	Other	Stockholders	Income
			Capital		Compensation	(Loss)/Income	Equity	(Loss)
<b>Balances at December 31, 2004</b>	16,922,850	\$ 1	\$ 126,755	\$ (94,283)	\$ (2,108)	\$ 314	\$ 30,679	
Issuance of common stock to collaborator, net of issuance costs	1,077,029		6,864				6,864	
Issuance of common stock and warrants, net of issuance costs	5,277,621	1	34,053				34,054	
Issuance of common stock from exercise of stock options	216,985		490				490	
Issuance of common stock pursuant to Employee Stock Purchase Plan	44,642		262				262	
Repurchase of restricted common stock	(21,251)							
Net loss				(34,135)			(34,135)	\$ (34,135)
Noncash compensation related to stock options granted			2		1,335		1,337	
Unrealized gain (loss) on investment securities						(50)	(50)	(50)
Cumulative translation adjustment						(130)	(130)	(130)
<b>Balances at December 31, 2005</b>	23,517,876	\$ 2	\$ 168,426	\$ (128,418)	\$ (773)	\$ 134	\$ 39,371	\$ (34,315)
Issuance of common stock to collaborator, net of issuance costs	813,393		8,930				8,930	
Issuance of common stock, net of issuance costs	5,285,806	1	59,385				59,386	
Issuance of common stock from exercise of stock options	258,860		675				675	
Issuance of common stock pursuant to Employee Stock Purchase Plan	64,542		412				412	
Net loss				(45,048)			(45,048)	\$ (45,048)
Noncash compensation related to stock options granted			2,986		341		3,327	
Reclassification of unearned stock-based compensation to additional paid-in capital upon adoption of SFAS No. 123(R)			(368)		368			
Unrealized gain (loss) on investment securities						131	131	131
Cumulative translation adjustment						(25)	(25)	(25)
<b>Balances at December 31, 2006</b>	29,940,477	\$ 3	\$ 240,446	\$ (173,466)	\$ (64)	\$ 240	\$ 67,159	\$ (44,942)
Issuance of common stock, net of issuance costs	6,612,500	1	96,110				96,111	
Issuance of common stock from exercise of stock options	416,736		1,984				1,984	
	65,676		522				522	

# Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

Issuance of common stock pursuant to  
Employee Stock Purchase Plan

Net loss			(56,390)			(56,390)	\$	(56,390)					
Noncash compensation related to stock options granted	4,231		64			4,295							
Unrealized gain (loss) on investment securities					188	188		188					
Cumulative translation adjustment					65	65		65					
<b>Balances at December 31, 2007</b>	37,035,389	\$	4	\$	343,293	\$	(229,856)	\$	493	\$	113,934	\$	(56,137)

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

F-5

---

**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Nature of Operations**

ACADIA Pharmaceuticals Inc. (the Company) was originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. The Company reincorporated in Delaware in 1997. ACADIA is focused on the discovery and development of small molecule drugs for the treatment of central nervous system disorders. The Company maintains two wholly owned subsidiaries: ACADIA Pharmaceuticals AB based in Malmö, Sweden and ACADIA Pharmaceuticals A/S based in Denmark.

The Company has not been profitable and has generated substantial operating losses since its inception. The Company's operations are subject to certain risks and uncertainties, including those associated with its history of operating losses and risk of continued losses, early stage of development, dependence on the outcome of clinical trials, and dependence on regulatory approvals to sell products. At December 31, 2007, the Company's accumulated losses were approximately \$229.9 million. The Company expects to increase its operating expenses over the next several years as it expands its research and development activities. The Company will require additional financing in the future to fund its operations. The Company does not know whether additional financing will be available when needed or, if available, whether it will be available on favorable terms. If adequate funds are not available or are not available on acceptable terms, the Company's ability to fund its operations, take advantage of opportunities, develop drug candidates and technologies or otherwise respond to competitive pressures could be significantly limited.

**2. Summary of Significant Accounting Policies**

Significant accounting policies followed in the preparation of these financial statements are as follows:

***Principles of Consolidation***

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an initial maturity date at the date of purchase of three months or less to be cash equivalents.

***Investment Securities***

Investment securities are considered to be available-for-sale and are carried at fair value. Unrealized gains and losses, if any, are reported as a separate component of stockholders' equity. The cost of investment securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses, if any, are also included in interest income. The cost of securities sold is based on the specific identification method.

***Fair Value of Financial Instruments***

For financial instruments consisting of cash and cash equivalents, accounts payable and accrued expenses included in the Company's financial statements, the carrying amounts are reasonable estimates of fair value due to their short maturities. Estimated fair values for investment securities, which are separately disclosed elsewhere, are based on quoted market prices for the instruments or discounted cash flows using market rates of interest for certain corporate commercial paper. Based on borrowing rates currently available to the Company, the carrying value of the long-term debt approximates fair value.

**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Property and Equipment***

Property and equipment are recorded at cost and depreciated over their estimated useful lives (generally three to ten years) using the straight line method. Leasehold improvements are amortized over the shorter of their estimated useful lives or the term of the respective leases by use of the straight line method. Maintenance and repair costs are expensed as incurred. When assets are retired or sold, the assets and accumulated depreciation are removed from the respective accounts and any gain or loss is recognized. During the years ended December 31, 2007, 2006 and 2005, losses of \$13,000, \$34,000 and \$152,000, respectively, were recorded on the disposal of property and equipment.

***Revenues***

The Company recognizes revenues in accordance with Securities and Exchange Commission Staff Accounting Bulletin, *Revenue Recognition*, or SAB No. 104. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectibility is reasonably assured. Arrangements with multiple elements are accounted for in accordance with Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. The Company analyzes its multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting in accordance with EITF 00-21. The Company's revenues are primarily related to its collaboration agreements, and such agreements may provide for various types of payments to the Company, including upfront payments, research funding and related fees during the term of the agreement, milestone payments based on the achievement of established development objectives, licensing fees, and royalties on future product sales.

Upfront, non-refundable payments under collaboration agreements are recorded as deferred revenue once received and recognized ratably over the term of the agreement. Non-refundable payments for research funding are generally recognized as revenues over the period as the related research activities are performed. Revenues from non-refundable milestones are recognized when the earnings process is complete and the payment is reasonably assured. Non-refundable milestone payments related to arrangements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the milestone, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the triggering event. Any amount received under an agreement in advance of performance is recorded as deferred revenue and recognized over the term of the agreement as the Company completes its performance obligations. Revenues from non-refundable license fees are recognized upon receipt of the payment if the license has stand-alone value, the Company does not have ongoing involvement or obligations, and the fair value of any undelivered items can be determined. If the license is considered to have stand-alone value but the fair value of the undelivered items cannot be determined, the license payments are recognized as revenues over the period of performance for such undelivered items or services. No revenues recognized to date pursuant to our agreements are refundable even if the related research activities are not successful.

***Research and Development Expenses***

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, costs associated with services provided by contract organizations for preclinical development, manufacturing of clinical materials and clinical trials. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or services provided and the invoices received from its external service providers. In the case of clinical trials, a portion of the estimated cost

**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

normally relates to the projected cost to treat a patient in the trials, and this cost is recognized over the estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known, the Company adjusts its accruals. Certain research and development projects are funded under agreements with collaboration partners, and the costs related to these activities are included in research and development expenses.

***Concentrations of Risk***

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, and investment securities. The Company invests its excess cash primarily in marketable debt securities of corporations, financial institutions, and government agencies with strong credit ratings. The Company has adopted an investment policy that includes guidelines relative to diversification and maturities to maintain safety and liquidity. The Company does not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt.

During the years ended December 31, 2007, 2006, and 2005, revenue from two customers comprised 66 percent, 74 percent, and 81 percent of total revenues, respectively, of which 22 percent, 27 percent, and 48 percent of total revenues, respectively, were from Allergan, Inc. Revenue from Sepracor Inc. comprised 44 percent, 47 percent and 33 percent of total revenues for the years ended December 31, 2007, 2006 and 2005, respectively.

***Foreign Currency Translation***

The functional currencies of ACADIA Pharmaceuticals AB and ACADIA Pharmaceuticals A/S are the local currencies. Accordingly, assets and liabilities of these entities are translated at the current exchange rate at the balance sheet date and historical rates for equity. Revenue and expense components are translated at weighted average exchange rates in effect during the period. Gains and losses resulting from foreign currency translation are included as a component of stockholders' equity. At December 31, 2007 and 2006, the balance within accumulated other comprehensive (loss) income from foreign currency translation was \$290,000 and \$225,000, respectively. Foreign currency transaction gains and losses are included in the results of operations and, to date, have not been significant.

***Stock-Based Compensation***

Effective January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards ( SFAS ) No. 123 (revised 2004), *Share-Based Payment* ( SFAS No. 123(R) ), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS No. 123 ), using the modified prospective transition method. Under that transition method, compensation cost recognized for the years ended December 31, 2007 and 2006 included (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, excluding stock options granted prior to December 31, 2003, which were valued using the minimum value method, and for which the related compensation cost will continue to be determined by using the intrinsic value method under Accounting Principles Board ( APB ) Opinion No. 25, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). The adoption of SFAS No. 123(R) resulted in a cumulative benefit from accounting change of \$51,000 during the year ended December 31, 2006, which reflects the net cumulative impact of estimating future forfeitures for options granted subsequent to December 31, 2003 and outstanding at January 1, 2006, rather than recording forfeitures when they occur as previously permitted. Results for prior periods have not been restated.

**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Prior to January 1, 2006, as permitted by SFAS No. 123, the Company measured compensation expense for its employee stock-based compensation plans using the intrinsic value method under APB Opinion No. 25 and provided pro forma disclosures of net income (loss) as if a fair value method had been applied in measuring compensation expense. Accordingly, compensation cost for stock awards was measured as the excess, if any, of the fair value of the Company's common stock at the date of grant over the amount an employee must pay to acquire the stock.

Unearned stock-based compensation related to stock options granted prior to December 31, 2003 is reflected as a separate component of stockholders' equity in the Company's balance sheet. Unearned stock-based compensation represents the difference between the exercise price of grants made to employees and the fair value of the Company's common stock on the date of grant. The remaining balance of unearned stock-based compensation, totaling \$368,000 and which related to stock options granted during the period from January 1, 2004 to the closing of the Company's initial public offering on June 2, 2004, was reclassified to additional paid-in capital upon the adoption of SFAS No. 123(R) on January 1, 2006.

In November 2005, the FASB issued Staff Position No. FAS 123(R)-3, Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards (FSP No. 123(R)-3). The Company has elected to adopt the alternative transition method provided in FSP No. 123(R)-3 for calculating the tax effects of stock-based compensation pursuant to SFAS No. 123(R). The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital, or APIC, pool related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and consolidated statements of cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS No. 123(R).

The value of each employee stock option and employee stock purchase right granted is estimated on the grant date under the fair value method using the Black-Scholes option pricing model. For options granted prior to January 1, 2006, the Company amortizes the fair value on an accelerated basis. For options granted after January 1, 2006, the Company amortizes the fair value on a straight-line basis. All option expense is amortized over the requisite service period of the awards, which are generally the vesting periods. The following assumptions were used to estimate the fair value of employee stock options:

	Years Ended December 31,		
	2007	2006	2005
Expected volatility	64-68%	64-65%	65-70%
Risk-free interest rate	4-5%	5%	4%
Expected forfeiture rate	6%	6-7%	0%
Expected dividend yield	0%	0%	0%
Expected life of options in years	5.4-5.5	5.3-5.4	5.0-5.3

*Expected Volatility.* The Company completed its initial public offering on June 2, 2004, so there is limited trading history for its shares in the public markets. Therefore, the Company considers the expected and historic volatility of peer companies as well as its own historical volatility and implied volatility when determining the volatility factor. In considering peer companies, the Company considers characteristics such as industry, stage of development, size and financial leverage.

*Risk-Free Interest Rate.* The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term approximating the expected term of the option.

*Expected Forfeiture Rate.* The Company considers its pre-vesting forfeiture history to determine its expected forfeiture rate.

**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Expected Dividend Yield.* The Company has never paid any dividends and currently has no plans to do so.

*Expected Life of Options.* The Company considers, among other factors, its historical exercise experience to date as well as the mean time remaining to full vesting of all outstanding options and the mean time remaining to end of the contractual term of all outstanding options.

The following assumptions were used to estimate fair value for the offerings that commenced during 2007 under the employee stock purchase plan: expected volatility of 45 to 111 percent; risk-free interest rate of 3-5 percent; dividend yield of 0 percent; and expected life in years of 0.5 to 2.0. The following assumptions were used to estimate fair value for the offerings that commenced during 2006 under the employee stock purchase plan: expected volatility of 51 to 64 percent; risk-free interest rate of 5 percent; dividend yield of 0 percent; and expected life in years of 0.5 to 2.0.

The following table illustrates the effect on net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to options granted under the Company's stock plans for the year ended December 31, 2005. For purposes of this pro forma disclosure, the value of options is estimated using the Black-Scholes option pricing model and amortized to expense over the options' vesting periods on an accelerated basis. The following assumptions were used for the employee stock purchase plan: volatility of 50.0 percent; risk-free interest rate of 3.0 to 4.2 percent; dividend yield of 0 percent; and expected life in years of 0.5.

	<b>Year Ended December 31, 2005 (in thousands, except per share data)</b>
Net loss, as reported	\$ (34,135)
Add: Total stock-based employee compensation costs included in the determination of net loss	1,041
Deduct: Total stock-based employee compensation costs that would have been included in net loss if the fair value method had been applied	(2,873)
Pro forma net loss	\$ (35,967)
Actual net loss per common share, basic and diluted	\$ (1.55)
Pro forma net loss per common share, basic and diluted	\$ (1.63)

***Income Taxes***

Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is computed for the expected future impact of differences between the financial reporting and income tax bases of assets and liabilities and for the expected future tax benefit to be derived from tax credits and loss carryforwards. Deferred income tax expense or benefit represents the net change during the year in the deferred income tax asset or liability. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.



F-10

**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Long-Lived Assets***

The Company assesses potential impairments to its long-lived assets when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when the estimated undiscounted cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. The amount of the impairment loss, if any, will generally be measured as the difference between the net book value of the assets and their estimated fair values. No such impairment losses have been recorded by the Company.

***Comprehensive Income (Loss)***

All components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity (net assets) of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Accordingly, in addition to reporting net income (loss) under the current rules, the Company is required to display the impact of any fluctuations in its foreign currency translation adjustments and any unrealized gains or losses on its investment securities as components of comprehensive income (loss) and to display an amount representing total comprehensive income (loss) for each period.

Accumulated other comprehensive income consists of the following:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(in thousands)</b>	
Unrealized gain on investment securities, net of tax of \$135 and \$10, respectively	\$ 203	\$ 15
Foreign currency translation adjustments, net of tax of \$192 and \$149, respectively	290	225
	<b>\$ 493</b>	<b>\$ 240</b>

***Net Income (Loss) Per Common Share***

Basic earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period increased to include potential dilutive common shares that were outstanding during the period. The effect of outstanding stock options and warrants is reflected, when dilutive, in diluted earnings per common share by application of the treasury stock method. The Company has excluded all outstanding stock options and warrants from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented. Shares used in calculating basic and diluted net loss per common share above exclude these potential common shares (in thousands):

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Antidilutive options to purchase common stock	2,834	2,713	2,107
Antidilutive warrants to purchase common stock	1,393	1,393	1,064
Restricted vesting common stock	6	34	95
	<b>4,233</b>	<b>4,140</b>	<b>3,266</b>

F-11

**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Segment Reporting***

Management has determined that the Company operates in one business segment. All revenues for the years ended December 31, 2007 and 2006 were generated in the United States. Information regarding long-lived assets by geographic area is as follows:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(in thousands)</b>	
United States	\$ 2,090	\$ 2,347
Europe	958	1,158
	<b>\$ 3,048</b>	<b>\$ 3,505</b>

***Recently Issued Accounting Standards***

In December 2007, the Financial Accounting Standards Board, or FASB, ratified EITF No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and would be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. The Company is currently evaluating the potential impact of EITF 07-1 on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, or SFAS 141(R). SFAS 141(R) will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize in-process research and development and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008.

In December 2007, the FASB issued SFAS No. 160, *Interests in Consolidated Financial Statements - an amendment of ARB No. 51*, or SFAS 160. SFAS 160 impacts the accounting for minority interest in the consolidated financial statements of filers. The statement requires the reclassification of minority interest to the equity section of the balance sheet and the results from operations attributed to minority interest to be included in net income. The related minority interest impact on earnings would then be disclosed in the summary of other comprehensive income. SFAS 160 is effective for fiscal years beginning after December 15, 2008.

In June 2007, the FASB ratified EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used or rendered for future research and development activities be deferred and capitalized. These amounts will be recognized as expense in the period that the related goods are delivered or the related services are performed, subject to an assessment of recoverability. EITF 07-3 is effective prospectively for new contracts entered into beginning after December 15, 2007, including interim periods within those fiscal years. The Company is currently evaluating the potential impact of the provisions of EITF 07-3 on its consolidated financial statements.

**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities- Including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS 159 is to reduce both the complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Most of the provisions in SFAS 159 are elective; however, the amendment to FASB Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the potential impact of SFAS 159 on its consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair-Value Measurements*, or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair-value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 for all financial assets and liabilities and any other assets and liabilities that are recognized or disclosed at fair value on a recurring basis. For nonfinancial assets and liabilities, SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2008. The Company is currently evaluating the potential impact of SFAS 157 on our consolidated financial statements.

**3. Investment Securities**

Investment securities available-for-sale consist of the following (in thousands):

December 31, 2007				Estimated
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Fair Value
Corporate debt securities, including commercial paper	\$ 88,343	\$ 323	\$ (2)	\$ 88,664
Asset-backed securities	21,190	18	(1)	21,207
	\$ 109,533	\$ 341	\$ (3)	\$ 109,871

December 31, 2006				Estimated
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Fair Value
Corporate debt securities, including commercial paper	\$ 52,821	\$ 24	\$	\$ 52,845
Asset-backed securities	14,929	1		14,930
	\$ 67,750	\$ 25	\$	\$ 67,775

As of December 31, 2007, all investments are high quality securities in compliance with the Company's investment policy guidelines. The Company did not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. The Company's investment portfolio has not been adversely impacted by the recent disruption in the credit markets. However, if there is continued and expanded disruption in the credit markets, the Company's investment portfolio could be adversely affected in the future. No gains or losses were realized during the years ended December 31, 2007 and 2006. As of December 31, 2007, all corporate debt securities had contractual maturity dates of less than one year. Asset-backed securities with estimated fair values at December 31, 2007 of \$16.2 million and \$5.0 million had contractual maturity dates of two and three years, respectively. Actual maturities for asset-backed securities may differ from the contractual maturities because they may be settled at an earlier date. The Company expects that all securities will be settled within one

year.

F-13

**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Balance Sheet Components**

Property and equipment, net, consist of:

	Estimated Useful Lives (Years)	December 31, (in thousands)	
		2007	2006
Machinery and equipment	5 7	\$ 5,860	\$ 5,579
Computers and software	3	1,826	1,648
Furniture and fixtures	3 10	274	261
Leasehold improvements	6 10	1,102	1,062
		9,062	8,550
Accumulated depreciation and amortization		(6,014)	(5,045)
		\$ 3,048	\$ 3,505

Depreciation and amortization of property and equipment was \$1.1 million, \$852,000, and \$1.0 million for the years ended December 31, 2007, 2006, and 2005, respectively.

Accrued expenses consist of:

	December 31, (in thousands)	
	2007	2006
Accrued clinical and research services	\$ 10,650	\$ 9,768
Accrued compensation and benefits	3,410	2,649
Other	952	1,068
	\$ 15,012	\$ 13,485

**5. Long-Term Debt**

The Company has entered into equipment financing agreements that were used to finance capital expenditures. These agreements provide for equal monthly installments to be paid over a three to four year period, with interest at rates ranging from 8.46 percent to 10.41 percent per annum. At December 31, 2007 and 2006, the Company had \$2.1 million and \$2.4 million, respectively, in outstanding borrowings under these agreements. Outstanding borrowings under these agreements are collateralized by the related equipment. The Company was in compliance with financial covenants and conditions required at each of December 31, 2007 and 2006.

At December 31, 2007, future payments under the Company's long-term debt were as follows (in thousands):

Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-K

Year Ending	
2008	\$ 978
2009	726
2010	331
2011	67
2012	32
	2,134
Less: Current portion	(978)
Long-term portion	\$ 1,156

F-14



**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. Collaborative Research and Licensing Agreements**

In March 2003, the Company entered into a collaboration agreement with Allergan to discover, develop and commercialize new therapeutics for ophthalmic and other indications. The agreement originally provided for a three-year research term which has been extended by the parties through March 2009. During the extended research term, Allergan could exclusively license specified chemistry and related assets. As of December 31, 2007, the Company had received an aggregate of \$14.5 million under the agreement, consisting of an upfront payment, research funding and related fees. The Company may also receive license fees and milestone payments as well as royalties on future product sales worldwide, if any. Revenue recognized under this agreement during the years ended December 31, 2007, 2006, and 2005 totaled \$1.3 million, \$2.0 million, and \$4.2 million, respectively.

In July 1999, the Company entered into a collaboration agreement with Allergan to discover, develop and commercialize drugs for glaucoma based on the Company's compounds. Under the agreement, the Company provided its drug discovery expertise to enable the selection by Allergan of a drug candidate for development and commercialization. Allergan was granted worldwide rights to products based on this compound for the treatment of ocular disease. As of December 31, 2007, the Company had received an aggregate of \$9.3 million in payments under the agreement, consisting of upfront fees, research funding, and milestone payments. In addition, the Company is eligible to receive additional milestone payments as well as royalties on future product sales worldwide, if any. Revenue recognized under this agreement during the years ended December 31, 2007 and 2006 totaled \$336,000 and \$179,000, respectively. The Company recognized no revenue under this agreement during the year ended December 31, 2005.

In September 1997, the Company entered into a collaboration agreement with Allergan focused primarily on the discovery and development of new therapeutics for neuropathic pain and ophthalmic indications. This agreement was subsequently amended in conjunction with the execution of the March 2003 collaboration agreement and provides for the continued development of drug candidates for one target area. Pursuant to the 1997 agreement, the Company granted Allergan exclusive worldwide rights to commercialize products resulting from the collaboration. The Company had received an aggregate of \$10.5 million in research funding and milestone payments through December 31, 2007. The Company is also eligible to receive additional milestone payments as well as royalties on future product sales worldwide, if any. Revenue recognized under this agreement totaled \$1.0 million during the year ended December 31, 2005. The Company recognized no revenue under this agreement during the years ended December 31, 2007 and 2006. In connection with the execution of the collaboration agreement in 1997, Allergan made a \$6.0 million equity investment in the Company.

On January 10, 2005, the Company entered into a three-year collaboration agreement with Sepracor for the development of new drug candidates. The term of this agreement ended in January 2008. In connection with the collaboration, Sepracor purchased 1,890,422 shares of the Company's common stock for an aggregate of \$20 million in two \$10 million tranches. In January 2005, Sepracor purchased 1,077,029 shares at a price per share of approximately \$9.28, which represented a 40 percent premium to the 30-day trailing average closing price of the Company's common stock on the date of the agreement. The Company recorded the aggregate premium of \$3.1 million, which was computed based on the excess of the purchase price over the closing price of the Company's common stock on January 10, 2005, as deferred revenue and the remaining balance of \$6.9 million as stockholders' equity. In January 2006, Sepracor purchased an additional 813,393 shares at a price per share of approximately \$12.29, which represented a 25 percent premium to the 30-day trailing average closing price at the one-year anniversary of the agreement. The Company recorded the aggregate premium amount of \$1.1 million, which was computed based on the excess of the purchase price over the closing price of the Company's common stock on January 10, 2006, as deferred revenue and the remaining purchase amount of \$8.9 million as stockholders' equity. The deferred revenue has been recognized as revenue as the related research activities were

**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

performed over the research term. Pursuant to the terms of the collaboration agreement, the Company had received \$6.7 million in research funding as of December 31, 2007. During the years ended December 31, 2007, 2006 and 2005, revenue of \$3.4 million, \$3.8 million, and \$3.6 million was recognized under the collaboration, respectively.

In May 2004, the Company entered into a three-year development agreement with The Stanley Medical Research Institute, or SMRI, which term ended in May 2007. Under this agreement, the Company received an aggregate of \$5.0 million in funding to support the further development of one of the Company's drug candidates for the treatment of schizophrenia. Assuming the successful development and commercialization of this drug candidate, the Company is required to pay to SMRI royalties on product sales up to a specified level. Upon signing this agreement, the Company also received \$1.0 million from SMRI in exchange for a convertible promissory note issued to SMRI bearing interest at 9 percent per annum (the SMRI Note). Upon the closing of the Company's initial public offering on June 2, 2004, the SMRI Note and accrued interest automatically converted into 143,914 shares of the Company's common stock at the initial public offering price. Revenue recognized under this agreement totaled \$1.0 million, \$2.0 million, and \$2.0 million during the years ended December 31, 2007, 2006, and 2005, respectively.

**7. Stockholders' Equity**

***Public Offerings***

In April 2007, the Company raised net proceeds of \$96.1 million from the sale of 6,612,500 shares of its common stock in a public offering, including 862,500 shares sold pursuant to an exercise of the underwriters' over-allotment option.

In May 2006, the Company raised net proceeds of \$59.4 million from the sale of 5,285,806 shares of its common stock in a public offering, including 338,577 shares sold pursuant to an exercise of the underwriters' over-allotment option.

***Private Placement***

In April 2005, the Company completed a private placement in which it raised net proceeds of \$34.1 million through the sale, at a price of \$6.82125 per share, of 5,277,621 shares of its common stock and warrants to purchase 1,319,402 shares of its common stock. In accordance with EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, the allocated fair value of the warrants at the issuance date of \$4.5 million has been included as permanent equity. The fair value was determined at the date of issuance using the Black-Scholes model.

***Warrants***

In connection with the private placement completed in April 2005, the Company issued warrants to purchase an aggregate of 1,319,402 shares of its common stock. These warrants have an exercise price of \$8.148 per share and will expire in April 2010. The Company also had warrants outstanding at December 31, 2007 to purchase an additional 74,073 shares of its common stock that were issued in connection with a secured promissory note in 2002. Each of the warrants issued in connection with the promissory note has an exercise price of \$8.10 per share and expire in May 2012.

**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Stock Option Plans***

The Company's 2004 Equity Incentive Plan (the "2004 Plan") became effective upon the closing of the initial public offering on June 2, 2004. The 2004 Plan permits the grant of options to directors, officers, other employees, and consultants. In addition, the 2004 Plan permits the grant of stock bonuses, rights to purchase restricted stock, and other stock awards. The exercise price of options granted under the 2004 Plan cannot be less than 100 percent of the fair market value of the common stock on the date of grant and the maximum term of any option is ten years. Options granted under the 2004 Plan generally vest over a four-year period. At December 31, 2007, 2,968,699 shares of common stock were authorized for issuance under the 2004 Plan. Upon the closing of the Company's initial public offering on June 2, 2004, all shares that remained eligible for grant under the Company's 1997 stock option plan (the "1997 Plan") were transferred to the 2004 Plan. The 2004 Plan share reserve also has been, and may be, increased by the number of shares that otherwise would have reverted to the 1997 Plan reserve after June 2, 2004. The 2004 Plan also includes an "evergreen" provision, which provides for automatic increases to the number of shares included in the share reserve in connection with each annual meeting of stockholders for a period of five years, which period began with the meeting in 2005. At December 31, 2007, there were 889,883 shares of common stock available for new grants under the 2004 Plan.

The 1997 Plan provided for the grant of incentive stock options and nonqualified stock options to employees, officers, directors, consultants and advisors of the Company. The exercise price of each option grant was set at the fair market value for the Company's common stock as determined by the Company's Board of Directors and each option's maximum term was ten years. Options granted under the 1997 Plan generally vest over a four-year period. The 1997 Plan permitted grants to certain employees allowing those employees to early exercise their options for restricted shares of the Company's common stock that were subject to the original vesting terms of the option. Restricted shares are generally subject to a repurchase option in favor of the Company that is exercisable upon termination of the continuous service of the optionee at an amount per share equal to the purchase price of the restricted shares. During the year ended December 31, 2007, 16,124 restricted common shares with an aggregate intrinsic value of \$161,000 vested. There were no unvested restricted shares outstanding at December 31, 2007.

Table of Contents

## ACADIA PHARMACEUTICALS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock option transactions under the 1997 Plan and 2004 Plan during the years ended December 31, 2007, 2006, and 2005 are presented below:

	Number of Shares	Weighted- Average Exercise Prices	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
<b>Outstanding at December 31, 2004</b>	1,773,875	\$ 2.52		
Granted	716,196	\$ 8.17		
Exercised	(216,985)	\$ 1.94		
Canceled/forfeited	(34,439)	\$ 5.58		
<b>Outstanding at December 31, 2005</b>	2,238,647	\$ 4.34		
Granted	913,564	\$ 11.19		
Exercised	(258,861)	\$ 2.42		
Canceled/forfeited	(72,961)	\$ 8.51		
<b>Outstanding at December 31, 2006</b>	2,820,389	\$ 6.62		
Granted	511,724	\$ 10.19		
Exercised	(416,736)	\$ 4.72		
Canceled/forfeited	(104,034)	\$ 9.30		
<b>Outstanding at December 31, 2007</b>	2,811,343	\$ 7.46	7.0	\$ 12,089
Vested and expected to vest at December 31, 2007	2,670,237	\$ 7.32	7.0	\$ 11,784
Exercisable at December 31, 2007	1,741,816	\$ 5.93	6.1	\$ 9,617

At December 31, 2007, 2006, and 2005, there were 1,741,816, 1,581,353, and 1,411,019 options exercisable, respectively. Were these options to have been exercised, 7,085, 145,631, and 350,999 shares would have been restricted shares and subject to repurchase by the Company at December 31, 2007, 2006, and 2005, respectively.

The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2007 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the shares that had exercise prices that were lower than the \$11.07 closing price of the Company's common stock on December 31, 2007. The aggregate intrinsic value of options exercised during the years ended December 31, 2007, 2006, and 2005 was approximately \$3.8 million, \$2.0 million, and \$1.4 million, respectively, determined as of the date of exercise. The Company received approximately \$2.0 million in cash from options exercised during the year ended December 31, 2007. SFAS No. 123(R) requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows provided by financing activities and cash outflows used in operating activities. Due to the Company's net loss position, no tax benefits have been recognized in the cash flow statement.

The weighted average fair value of options granted during the years ended December 31, 2007, 2006, and 2005 was approximately \$6.25, \$6.84, and \$4.95, respectively. As of December 31, 2007, total unrecognized compensation cost related to stock options and purchase rights was approximately \$5.3 million, and the weighted average period over which this cost is expected to be recognized is 2.2 years.



**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes information about stock options outstanding at December 31, 2007:

Range of Exercise Prices		Options Outstanding		Options Exercisable		
		Number of Shares	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number of Shares	Weighted- Average Exercise Price
\$ 1.08	\$ 1.20	402,767	5.5	\$ 1.08	391,391	\$ 1.08
\$ 1.50	\$ 4.00	398,773	3.6	\$ 2.26	398,085	\$ 2.26
\$ 5.49	\$ 6.95	677,456	7.9	\$ 6.71	272,790	\$ 6.60
\$ 7.01	\$ 9.10	486,178	7.4	\$ 8.40	340,558	\$ 8.49
\$ 9.15	\$12.02	353,347	8.1	\$ 10.24	172,136	\$ 10.49
\$13.02	\$15.98	492,824	8.8	\$ 14.97	166,856	\$ 15.05
		2,811,345		\$ 7.46	1,741,816	

Stock-based awards issued to non-employees are accounted for using a fair value method and are remeasured to fair value at each period end until the earlier of the date that performance by the non-employee is complete or a performance commitment has been obtained. The fair value of each award is estimated using the Black-Scholes option pricing model with the following assumptions for the year ended December 31, 2007: dividend yield of 0 percent; volatility of 72 to 74 percent; risk free interest rate of 4 to 5 percent and remaining contractual life of 7 to 10 years. For the year ended December 31, 2006, the following assumptions were used: dividend yield of 0 percent; volatility of 72 to 74 percent; risk free interest rate of 5 percent and remaining contractual life of 7 to 10 years. For the year ended December 31, 2005 the following assumptions were used: dividend yield of 0 percent; volatility of 65 percent; risk free interest rate of 4 percent; and remaining contractual life of 7 to 10 years. During the years ended December 31, 2007, 2006, and 2005, in connection with the grant of stock options to non-employees, the Company recorded expense of \$1.3 million, \$740,000, and \$267,000, respectively.

**Employee Stock Purchase Plan**

The Company's 2004 Employee Stock Purchase Plan (the "Purchase Plan") became effective upon the closing of the Company's initial public offering. The Purchase Plan includes an "evergreen" provision providing that an additional number of shares will automatically be added to the shares authorized for issuance at each annual meeting of stockholders for a period of ten years, which began with the meeting in 2005. A total of 575,000 shares of common stock have been reserved for issuance under the Purchase Plan. Eligible employees who elect to participate in an offering under the Purchase Plan may have up to 15 percent of their earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the Purchase Plan. The price of common stock purchased under the Purchase Plan is equal to 85 percent of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant purchase date. During the years ended December 31, 2007, 2006 and 2005, 65,676, 64,542, and 44,642 shares of common stock were issued at average prices of \$7.94, \$6.38 and \$5.88 under the Purchase Plan, respectively. The weighted average fair value of purchase rights granted during the years ended December 31, 2007, 2006 and 2005 was \$5.48, \$3.78 and \$2.04, respectively. During the years ended December 31, 2007, 2006 and 2005, the Company recorded cash received from the exercise of purchase rights of \$522,000, \$412,000 and \$262,000, respectively.

**Common Stock Reserved For Future Issuance**

At December 31, 2007, 2,811,345 and 1,393,475 shares of common stock were reserved for issuance upon the exercise of stock options and warrants, respectively.



**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. 401(k) Plan**

Effective January 1997, the Company established a deferred compensation plan (the "401(k) Plan") pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended (the "Code"), whereby substantially all employees are eligible to contribute up to 60 percent of their pretax earnings, not to exceed amounts allowed under the Code. The Company makes contributions to the 401(k) Plan equal to 100 percent of each employee's pretax contributions up to 5 percent of his or her eligible compensation. The Company's total contributions to the 401(k) Plan were \$435,000, \$372,000 and \$290,000, for the years ended December 31, 2007, 2006 and 2005, respectively.

**9. Income Taxes**

At December 31, 2007, the Company had both federal and state net operating loss ("NOL") carryforwards of approximately \$204.1 and \$130.8 million, respectively. The federal and state net operating losses begin to expire in 2012. The Company has \$4.4 million of federal research and development ("R&D") credit carryforwards that will begin to expire in 2012. In addition, the Company has \$3.0 million of state R&D credit carryforwards that have no expiration date. The Company also has foreign NOL carryforwards of approximately \$4.3 million that have no expiration date.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions (both before and after its initial public offering) which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future upon subsequent disposition.

The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation due to the complexity and cost associated with such a study, and the fact that there may be additional such ownership changes in the future. If the Company has experienced an ownership change at any time since its formation, utilization of the NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit under Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes ("FIN 48"), an interpretation of FASB Statement No. 109. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance.

Approximately \$1.0 million of the NOL carryforwards relates to excess tax deductions for stock compensation, the income tax benefit of which will be recorded as additional paid-in capital if and when realized.



**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The components of the deferred tax assets and deferred tax liabilities are as follows (in thousands):

	2007	2006
NOL carryforwards	\$ 77,717	\$ 57,361
R&D credit carryforwards	6,341	4,747
Capitalized R&D	3,337	2,596
Deferred revenue	281	551
Purchased intellectual property	791	878
Property and equipment	140	189
Stock-based compensation	1,976	1,376
Other	858	544
	91,441	68,242
Valuation allowance	(90,839)	(67,904)
Deferred tax liabilities	(634)	(338)
	\$ (32)	\$

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately \$22.9 million in 2007 primarily due to NOL carryforwards. The valuation allowance was \$48.9 million and \$35.8 million as of December 31, 2005 and 2004, respectively.

A reconciliation of income taxes to the amount computed by applying the statutory federal income tax rate to the net loss is summarized as follows (in thousands):

	2007	2006	2005
Amounts computed at statutory federal rate	\$ (19,167)	\$ (15,294)	\$ (11,606)
Permanent differences	499	716	414
Federal R&D credits	(1,593)	(1,403)	(377)
Change in valuation allowance	22,900	19,025	13,075
State taxes	(3,218)	(2,476)	(2,116)
Foreign taxes	105	(16)	386
Other	489	(646)	224
	\$ 15	\$ (94)	\$

The net income tax expense (benefits) for the years ended December 31, 2007 and 2006 are recorded in the Company's statement of operations in general and administrative expenses.

The Company has adopted FIN 48 as of January 1, 2007. Upon adoption, the Company recognized no adjustment in the amount of unrecognized tax benefits. As of the date of adoption, the Company had no unrecognized tax benefits. The Company's policy is to recognize interest and penalties, if any, as a component of income tax expense.

The tax years 1997-2007 remain open to examination by the major taxing jurisdictions to which the Company is subject.

F-21

**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Commitments and Contingencies**

The Company and its Swedish subsidiary lease office and laboratory facilities and certain equipment under noncancelable operating leases that expire at various dates through May 2015. Under the terms of the facilities leases, the Company is required to pay its proportionate share of property taxes, insurance and normal maintenance costs. The Company's facilities leases provide for the extension of their lease terms and the U.S. leases each provide for early termination.

Future noncancelable minimum payment obligations under operating lease arrangements are as follows at December 31, 2007 (in thousands):

<b>Years Ending</b>	
2008	\$ 2,469
2009	2,498
2010	2,509
2011	2,308
2012	2,342
Thereafter	3,951
	<b>\$ 16,077</b>

Rent expense was \$2.5 million, \$2.2 million and \$1.9 million for the years ended December 31, 2007, 2006, and 2005, respectively. Facility operating leases contain escalation clauses. The Company recognizes rent expense on a straight-line basis over the lease term. The difference between rent expense recorded and amounts paid under lease agreements is recorded as deferred rent and included in other long-term liabilities in the accompanying consolidated balance sheet.

The Company has also entered into agreements with contract research organizations and other external service providers for services in connection with the development of its drug candidates. The Company was contractually obligated for up to approximately \$24.3 million of future services under these agreements as of December 31, 2007. The nature of the work being conducted under the Company's agreements with contract research organizations is such that, in most cases, the services may be stopped with short notice. In such event, the Company would not be liable for the full amount of the contract. The Company's actual contractual obligations may vary depending upon several factors, including the results of the underlying studies.

In October 2006, the Company entered into an agreement to provide initial seed funding to help establish Abbey Pharmaceuticals, Inc. ( Abbey ), a startup biotechnology company led by the Company's former President and Chief Scientific Officer. The Company has agreed to increase its investment in Abbey to an aggregate of \$1 million upon Abbey's satisfaction of certain conditions, including completion of an external equity financing. The Company has concluded that Abbey initially represents a variable interest entity and thus, under the guidance of FASB Interpretation No. 46(R), *Consolidation of Variable Interest Entities - an Interpretation of ARB No.51*, it has included the accounts of Abbey in the accompanying consolidated financial statements.

In November 2006, the Company entered into an agreement to license certain intellectual property rights that complement its patent portfolio. If certain conditions specified in the agreement are met, the Company is required to make payments, including milestones, royalties and sublicensing fees for compounds covered by this agreement.

**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

During the year ended December 31, 2006, the Company recorded a gain of \$3.6 million associated with an agreement it entered into to fully settle a civil action inclusive of all fees and costs. During the year ended December 31, 2005, the Company had recorded a provision for loss from litigation of \$6.2 million related to this matter.

**11. Selected Quarterly Financial Data (Unaudited)**

<b>2007</b>	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
	<b>(in thousands, except per share data)</b>			
Revenues	\$ 1,960	\$ 2,055	\$ 1,957	\$ 1,583
Net loss	\$ (12,554)	\$ (10,753)	\$ (16,045)	\$ (17,038)
Net loss per common share, basic and diluted	\$ (0.42)	\$ (0.29)	\$ (0.43)	\$ (0.46)

  

<b>2006</b>	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
Revenues	\$ 2,537	\$ 1,881	\$ 1,943	\$ 1,773
Loss before change in accounting principle	\$ (9,518)	\$ (11,867)	\$ (11,263)	\$ (12,451)
Net loss	\$ (9,467)	\$ (11,867)	\$ (11,263)	\$ (12,451)
Net loss per common share, basic and diluted	\$ (0.39)	\$ (0.43)	\$ (0.38)	\$ (0.42)

Revenues, loss before change in accounting principle, and net loss are rounded to thousands each quarter. Therefore, the sum of the quarterly amounts may not equal the annual amounts reported. Net loss per common share, basic and diluted, are computed independently for each quarter and the full year based upon respective average shares outstanding. Therefore, the sum of the quarterly net loss per common share amounts may not equal the annual amounts reported. As disclosed in Note 2, the Company adopted the provisions of SFAS No. 123(R), effective January 1, 2006.

**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit</b>	
<b>Number</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to Registration Statement File No. 333-113137).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.5 to Registration Statement File No. 333-113137).
4.1	Form of common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to Registration Statement No. 333-52492).
4.2	Form of Warrant to Purchase Preferred Stock issued to GATX Ventures on May 31, 2002 (incorporated by reference to Exhibit 4.3 to Registration Statement No. 333-113137).
4.3	Form of Warrant to Purchase Common Stock issued to purchasers in a private placement on April 20, 2005 (incorporated by reference to Exhibit 4.3 to Registration Statement No 333-124753).
10.1	Amended and Restated Stockholders Agreement, dated March 27, 2003, by and among the Registrant and the stockholders named therein (incorporated by reference to Exhibit 4.2 to Registration Statement No. 333-113137).
10.2 <sup>a</sup>	Form of Indemnity Agreement for directors and officers (incorporated by reference to Exhibit 10.1 to Registration Statement No. 333-113137).
10.3 <sup>a</sup>	1997 Stock Option Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.2 to Registration Statement No. 333-113137).
10.4 <sup>a</sup>	2004 Equity Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.3 to Registration Statement No. 333-113137).
10.5 <sup>a</sup>	2004 Employee Stock Purchase Plan and initial offering thereunder (incorporated by reference to Exhibit 10.4 to Registration Statement No. 333-113137).
10.6 <sup>a</sup>	401(k) Plan (incorporated by reference to Exhibit 10.5 to Registration Statement No. 333-113137).
10.7 <sup>a</sup>	Employment Letter Agreement, dated December 21, 1998, between the Registrant and Uli Hacksell, Ph.D. (incorporated by reference to Exhibit 10.7 to Registration Statement No. 333-52492).
10.9 <sup>a</sup>	Employment Letter Agreement, dated March 4, 1998, between the Registrant and Thomas H. Aasen (incorporated by reference to Exhibit 10.9 to Registration Statement No. 333-52492).
10.10 <sup>a</sup>	Employment Contract, dated November 21, 2000, between the Registrant and Bo-Ragnar Tolf, Ph.D. (incorporated by reference to Exhibit 10.11 to Registration Statement No. 333-113137).
10.11 <sup>a</sup>	Employment Offer Letter, dated November 4, 2004, between the Registrant and Brian Lundstrom (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed April 28, 2006).
10.12 <sup>a</sup>	Employment Offer Letter, dated May 26, 2006, between the Registrant and Roger Mills (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed April 2, 2007).
10.13 <sup>a</sup>	Description of Outside Director Compensation Program (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed November 5, 2007).
10.14 <sup>b</sup>	Collaborative Research, Development and License Agreement, dated September 24, 1997, by and among the Registrant, Allergan, Inc. and Vision Pharmaceuticals L.P. (now Allergan Sales, Inc.) (incorporated by reference to Exhibit 10.12 to Registration Statement No. 333-113137).

## **Table of Contents**

### **Exhibit**

<b>Number</b>	<b>Description</b>
10.15 <sup>b</sup>	Amendment to Collaborative Research, Development and License Agreement, dated March 27, 2003, by and among the Registrant, Allergan Sales LLC (as successor in interest of Vision Pharmaceuticals L.P.) and Allergan, Inc. (incorporated by reference to Exhibit 10.13 to Registration Statement No. 333-113137).
10.16 <sup>b</sup>	Collaborative Research, Development and License Agreement, dated July 26, 1999, by and among the Registrant and Allergan, Inc., Allergan Pharmaceuticals (Ireland) Limited, Inc. and Allergan Sales, Inc. (incorporated by reference to Exhibit 10.14 to Registration Statement No. 333-113137).
10.17 <sup>b</sup>	Collaborative Research, Development and License Agreement, dated March 27, 2003, by and among the Registrant, Allergan, Inc. and Allergan Sales, Inc. (incorporated by reference to Exhibit 10.15 to Registration Statement No. 333-113137).
10.18 <sup>b</sup>	Second Amendment to Collaborative Research, Development and License Agreement, dated February 28, 2006, by and among the Registrant, Allergan Sales LLC (as successor in interest of Vision Pharmaceuticals L.P.) and Allergan, Inc. (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K, filed March 15, 2006).
10.19	Standard Industrial/Commercial Single-Tenant Lease-Net, dated August 15, 1997, between the Registrant and R.G. Harris Co. (incorporated by reference to Exhibit 10.18 to Registration Statement No. 333-52492).
10.20	Lease Amendment, dated November 1, 2005, between the Registrant and E.G. Sirrah, LLC (successor in interest to R.G. Harris Co.), to Standard Industrial/Commercial Single-Tenant Lease-Net, dated August 15, 1997, between the Registrant and R.G. Harris Co. (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed November 14, 2005).
10.21	Lease Amendment, dated November 30, 2007, between the Registrant and E.G. Sirrah, LLC (successor in interest to R.G. Harris Co.), to Standard Industrial/Commercial Single-Tenant Lease-Net, dated August 15, 1997, between the Registrant and R.G. Harris Co.
10.22	Lease Agreement, executed November 2, 2005, between ACADIA Pharmaceuticals AB and Medeon Fastigheter AB (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed November 14, 2005).
10.23	Assignment of Brann Intellectual Property Rights, dated January 29, 1997, by Mark R. Brann in favor of the Registrant (incorporated by reference to Exhibit 10.17 to Registration Statement No. 333-52492).
10.24 <sup>b</sup>	Development Agreement, dated May 3, 2004, between the Registrant and The Stanley Medical Research Institute (incorporated by reference to Exhibit 10.18 to Registration Statement No. 333-113137).
10.25 <sup>b</sup>	License, Option and Collaboration Agreement, dated January 10, 2005, by and between the Registrant and Sepracor Inc. (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed January 14, 2005).
10.26 <sup>b</sup>	Common Stock Purchase Agreement, dated January 10, 2005, by and between the Registrant and Sepracor Inc. (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed January 14, 2005).
10.27 <sup>b</sup>	Registration Rights Agreement, dated January 10, 2005, by and between the Registrant and Sepracor Inc. (incorporated by reference to Exhibit 99.3 to the Registrant's Current Report on Form 8-K, filed January 14, 2005).

## **Table of Contents**

### **Exhibit**

<b>Number</b>	<b>Description</b>
10.28 <sup>a</sup>	Description of Executive Officer Annual Incentive Cash Compensation Program (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K, filed March 9, 2007).
10.29 <sup>b</sup>	License Agreement, dated November 30, 2006, by and between the Registrant and Société de Conseils, de Recherches et d'Applications Scientifiques SAS, a French corporation member of the Ipsen Group (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed December 4, 2006).
21.1	List of subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see page 53).
31.1	Certification of Uli Hacksell, Ph.D., Chief Executive Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Thomas H. Aasen, Chief Financial Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Uli Hacksell, Ph.D., Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Thomas H. Aasen, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

<sup>a</sup> Indicates management contract or compensatory plan or arrangement.

<sup>b</sup> We have received confidential treatment of certain portions of this agreement, which have been omitted and filed separately with the SEC pursuant to Rule 406 under the Securities Act of 1933.