

11007657

# BETTER LIVING

# WITH PARKINSON'S



Received SEC  
JUN 08 2011  
Washington, DC 20549

At ACADIA, we are dedicated to the discovery and development of innovative new therapies that can improve the lives of patients with central nervous system disorders.

## OUR PIPELINE

Compound/ Program	Indication	Preclinical	IND-Track	Phase I	Phase II	Phase III	Regulatory Approval	Commercialization Rights
<b>Pimavanserin</b>	Parkinson's Disease Psychosis	→	→	→	→	→		ACADIA
	Schizophrenia	→	→	→	→			ACADIA
	Alzheimer's Disease Psychosis	→	→	→	→			ACADIA
<b>AGN XX/YY</b>	Chronic Pain	→	→	→	→			ACADIA
<b>AC-262271</b>	Glaucoma	→	→	→				ACADIA
<b>AM-831</b>	Schizophrenia	→	→					Majlis Saka Aceh ACADIA - Rest of World
<b>ERβ</b>	Parkinson's Disease	→						ACADIA
	Alzheimer's Disease Chronic Pain	→					ACADIA	
<b>Nurr-1</b>	Parkinson's Disease	→					ACADIA	

- (1) Completed Phase II schizophrenia co-therapy trial.  
 (2) Protocol established for future ADP feasibility study.

## TO OUR STOCKHOLDERS

We closed 2010 and have begun the new year positioned to advance and build substantial value in our pipeline of product candidates, led by our Phase III program with pimavanserin for Parkinson's disease psychosis (PDP).

With no drug in the U.S. approved for PDP, we believe pimavanserin, a new chemical entity discovered by ACADIA, has the potential to be a first-in-class therapy for this debilitating disease. PDP afflicts up to four out of every ten patients with Parkinson's disease.

During 2010, we made important strides in advancing our Phase III PDP program. In July 2010, we initiated a new Phase III trial to evaluate the efficacy, tolerability and safety of pimavanserin in patients with PDP. This trial builds on the wealth of clinical experience we have generated in our PDP program and incorporates an enhanced study design. We also are continuing to conduct open-label safety extension studies with PDP patients. About 200 patients have now been treated with pimavanserin for over one year and we have accumulated over 400 patient years of exposures in PDP patients. We continue to be encouraged by the large number of patients who have remained on pimavanserin for long periods of time.

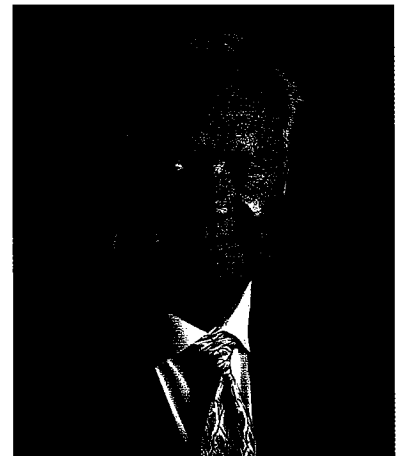
As a high-value specialty market, we believe PDP is an ideal lead indication for pimavanserin. Our PDP program also provides a strong foundation for broadened development into other areas of large unmet need, including schizophrenia and Alzheimer's disease psychosis. Antipsychotic medications generated over \$23 billion in worldwide sales in 2009, despite limitations with efficacy and severe side effects

commonly associated with such treatments. We believe pimavanserin has the potential to play an important role in the treatment of a range of neurological and psychiatric indications that are poorly served by existing antipsychotics.

Given the commercial potential of pimavanserin, we have worked diligently to establish a strong patent portfolio for this promising product candidate. Last year, we expanded our portfolio of issued patents that now provide intellectual property protection to mid-2028 in the U.S. and to 2024 in numerous countries outside the U.S.

During the fourth quarter of 2010, we concluded our collaboration with Biovail and regained worldwide rights to pimavanserin. This unique opportunity positioned ACADIA to realize all of the potential upside from pimavanserin and, at the same time, provided us with an \$8.75 million cash infusion.

While our Phase III PDP program remains our top priority, ACADIA also has other important programs in its pipeline. Through our long-standing alliance with Allergan, we have two clinical programs that provide the potential for new treatments in the areas of chronic pain and glaucoma. In partnership with Meiji Seika Pharma, we made important progress last year with AM-831, a compound in IND-track development that may offer a new approach to treating schizophrenia.



During 2010, we also made exciting advances in two research projects focused on Parkinson's disease through grants from the Michael J. Fox Foundation for our Nurr1 and ER-beta programs. These preclinical programs may provide new disease-modifying therapies for patients with Parkinson's disease.

In conjunction with our pipeline progress, we have significantly strengthened our financial position and extended our cash runway. In January 2011, we raised net proceeds of approximately \$13.8 million from a private equity financing.

We expect 2011 to be another busy and productive year for ACADIA. With our portfolio of product candidates, led by our Phase III PDP program with pimavanserin, and a solid cash runway, we believe ACADIA is well positioned with significant growth potential. We remain deeply committed to developing innovative new therapies that can improve the lives of patients with CNS disorders and the family members who care for them.

Uli Hacksell, Ph.D.  
Chief Executive Officer

## PARKINSON'S DISEASE PSYCHOSIS: AN UNDERSERVED MARKET

People are generally familiar with the motor disturbances associated with Parkinson's disease such as tremors, limb stiffness, balance problems, and slowness of movement. However, there is increasing recognition that "non-motor" symptoms, such as psychosis, are perhaps the most burdensome to Parkinson's patients and deeply affect their quality of life. Studies have suggested that up to 40% of

patients with Parkinson's disease will develop psychotic symptoms, commonly consisting of visual hallucinations and delusions. Today, there is no therapy in the U.S. approved to treat Parkinson's disease psychosis (PDP). There is a large unmet medical need for new therapies that can effectively treat PDP without compromising motor control.

▶ According to the National Parkinson Foundation, over one million people in the U.S. and from four to six million people worldwide suffer from Parkinson's disease.

▶ Psychotic symptoms are common in patients with Parkinson's disease. Patients may see, feel, or hear things that are not there. Others may believe they are in danger, being followed, or being mistreated.

▶ The development of PDP often disrupts the patients' ability to perform the activities of daily living that keep them independent and active. For family members, caring for a patient with PDP can be overwhelming.

▶ Psychosis is the leading cause of nursing home placements for Parkinson's patients and is associated with increased caregiver burden and increased mortality.

▶ With no drug in the U.S. approved to treat PDP, physicians have limited options available. Off-label use of current antipsychotic medications can worsen motor function and often is associated with numerous side effects that are problematic for elderly patients with Parkinson's disease.



ACADIA is dedicated to addressing the large unmet medical needs associated with Parkinson's disease and other CNS disorders. Our lead product candidate, pimavanserin, is in Phase III development as a potential first-in-class therapy that may effectively treat psychosis in patients with Parkinson's disease without compromising motor control, thereby significantly improving the quality of life for these patients. Pimavanserin also has the potential to treat other important neurological and psychiatric conditions, which are underserved by currently marketed antipsychotics.

**ACADIA PHARMACEUTICALS**  
FORM 10-K AND PERFORMANCE MEASUREMENT GRAPH

**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, 2010

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)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

06-1376651  
(I.R.S. Employer  
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

Common Stock, par value \$0.0001 per share

The NASDAQ Global Market

**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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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

As of June 30, 2010, 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 \$35.8 million, based on the closing price of the registrant's common stock on the NASDAQ Global Market on June 30, 2010 of \$1.09 per share.

As of March 1, 2011, 51,921,766 shares of the 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 May 2, 2011 are incorporated by reference into Part III of this report.

**ACADIA PHARMACEUTICALS INC.**

**TABLE OF CONTENTS**

**FORM 10-K**

**For the Year Ended December 31, 2010**

**INDEX**

	<u>Page</u>
<b>PART I</b>	
Item 1. Business.	1
Item 1A. Risk Factors.	18
Item 1B. Unresolved Staff Comments.	36
Item 2. Properties.	36
Item 3. Legal Proceedings.	36
Item 4. (Removed and Reserved).	36
<b>PART II</b>	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.	37
Item 6. Selected Financial Data.	38
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.	39
Item 7A. Quantitative and Qualitative Disclosures About Market Risk.	47
Item 8. Financial Statements and Supplementary Data.	48
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.	48
Item 9A. Controls and Procedures.	48
Item 9B. Other Information.	49
<b>PART III</b>	
Item 10. Directors, Executive Officers and Corporate Governance.	50
Item 11. Executive Compensation.	50
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.	50
Item 13. Certain Relationships and Related Transactions, and Director Independence.	50
Item 14. Principal Accounting Fees and Services.	50
<b>PART IV</b>	
Item 15. Exhibits, Financial Statement Schedules.	51

**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,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “aims,” “projects,” “predicts,” “pro forma,” “anticipates,” “potential” or other similar words (including their use in the negative), or by discussions of future matters such as the development of product 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 development and commercialization of small molecule drugs for the treatment of central nervous system disorders. Our pipeline consists of four product candidates including pimavanserin, which is in Phase III development as a treatment for Parkinson’s disease psychosis. We hold worldwide commercialization rights to pimavanserin. In addition, we have a product candidate in Phase II development for chronic pain and a product candidate in Phase I development for glaucoma, both in collaboration with Allergan, Inc., as well as a program in IND-track development in collaboration with Meiji Seika Kaisha, Ltd. All of the product candidates in our pipeline emanate from discoveries made using our proprietary drug discovery platform.

The product candidates in our pipeline address diseases that are not well served by currently available therapies and that represent large potential commercial opportunities. We believe our product candidates offer innovative therapeutic approaches and may provide significant advantages relative to current therapies. Our most advanced product candidates are as follows:

***Pimavanserin.*** Pimavanserin is a new chemical entity that we discovered and have advanced to Phase III development as a potential first-in-class treatment for 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. The U.S. Food and Drug Administration, or FDA, has not approved any drug to treat Parkinson’s disease psychosis. Pimavanserin provides an innovative approach to treating this disorder by selectively blocking a key serotonin



receptor that plays an important role in psychosis. We believe pimavanserin may effectively treat Parkinson's disease psychosis without compromising motor control, thereby significantly improving the quality of life for patients with Parkinson's disease.

We are currently conducting several studies in our Phase III program with pimavanserin for Parkinson's disease psychosis, including a Phase III efficacy, tolerability and safety trial, and open-label safety extension studies. We also believe that pimavanserin has the potential to address a range of additional neurological and psychiatric disorders, including Alzheimer's disease psychosis and schizophrenia, which are underserved by currently marketed antipsychotic drugs. We have completed a Phase II trial with pimavanserin as a co-therapy in schizophrenia and have established plans for a future Phase II feasibility study to explore the use of pimavanserin as a treatment for Alzheimer's disease psychosis.

**AGN-XX/YY.** In collaboration with Allergan, we have discovered and are developing a new class of small molecule product candidates for the treatment of chronic pain. Chronic pain is a common form of persistent pain that may be related to a number of medical conditions and is often resistant to treatment. Allergan has conducted several Phase II trials in this program and has reported preliminary results from its Phase II program, including positive proof-of-concept in a human visceral pain trial and efficacy signals in two chronic pain trials in the areas of fibromyalgia and irritable bowel syndrome. Allergan has announced that it is seeking a partner for the further development of this program and for commercialization in areas predominantly served by general practitioners.

**AC-262271.** We have discovered and, in collaboration with Allergan, are developing a small molecule product candidate for the treatment of glaucoma. Glaucoma is a chronic eye disease and is the second leading cause of blindness in the world. AC-262271 has demonstrated a promising preclinical profile, including robust efficacy and a long duration of action. Allergan is conducting Phase I clinical trials in glaucoma patients with AC-262271.

**AM-831.** We have discovered and, in collaboration with Meiji Seika, are in IND-track development with AM-831, a small molecule product candidate for the treatment of schizophrenia. Currently prescribed treatments do not effectively address or may exacerbate cognitive disturbances associated with schizophrenia. We believe that AM-831 provides the potential for a new class of pro-cognitive antipsychotic drugs. We and Meiji Seika are currently conducting required development studies in preparation for potential future clinical trials with AM-831.

In addition to our four most advanced product candidates in development, we have used our proprietary drug discovery platform to discover additional product candidates that we may elect to develop in the future in partnerships or independently. We have demonstrated that our platform can be used to rapidly discover new compounds that may serve as potential treatments for significant unmet medical needs. Currently, we have focused our resources on our most advanced product candidates, including pimavanserin.

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

"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.

We maintain a website at [www.acadia-pharm.com](http://www.acadia-pharm.com), to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission, or SEC, are available free of charge through our website as soon as reasonably practicable after being electronically filed

with or furnished to the SEC. Interested persons can subscribe on our website to email alerts that are sent automatically when we issue press releases, file our reports with the SEC or post certain other information to our website. Information contained in our website does not constitute a 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 product candidate, pimavanserin, for Parkinson's disease psychosis.*** We have selected Parkinson's disease psychosis as our lead indication for pimavanserin and we are currently focused on advancing our Phase III program for this indication. We plan to complete the development in this program in collaboration with partners or independently. If successful, we intend to participate in the commercialization of pimavanserin for Parkinson's disease psychosis in the United States by establishing a small specialty sales force that calls on a focused group of physicians. We plan to commercialize pimavanserin in markets outside of the United States by establishing one or more strategic alliances in the future.
- ***Maximize the commercial potential of pimavanserin by expanding to additional neurological and psychiatric disorders.*** We intend to use our Phase III Parkinson's disease psychosis program as a foundation to develop and commercialize pimavanserin for additional neurological and psychiatric indications that also are underserved by currently available antipsychotics and represent large unmet medical needs. This may include development of pimavanserin as a treatment for Alzheimer's disease psychosis and as a co-therapy for schizophrenia. In therapeutic areas that involve an extensive development program or address larger specialty or primary care markets, we intend to complete late-stage development and commercialization through, or in collaboration with, partners. We may elect to retain selected commercialization rights in areas where we feel pimavanserin can be sold by a specialty sales force that calls on a focused group of physicians.
- ***Continue to develop our other product candidates for the treatment of central nervous system and related disorders.*** We plan to continue developing our other product candidates, including our collaborative clinical programs with Allergan and our IND-track development program with Meiji Seika. While our resources are currently focused on our four most advanced product candidates, we may choose to pursue additional product candidates in the future. These may be directed at central nervous system disorders and may be developed in partnerships or independently. We believe that a diversified pipeline will mitigate the risks inherent in drug development and increase the likelihood of commercial success.
- ***Opportunistically in-license or acquire complementary product candidates.*** Although all of the product candidates currently in our pipeline emanate from discoveries made using our proprietary platform, in the future, we may elect to in-license or acquire clinical-stage product candidates or products to augment our pipeline and to leverage any sales force that we may establish in the future.

## **Disease and Market Overview**

Our product candidates address diseases that are not well served by currently available therapies and that represent large potential commercial market opportunities. Background information on the diseases and related commercial markets that may be addressed by our product candidates is set forth below.

### ***Parkinson's Disease Psychosis***

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, thereby rendering patients unable to initiate their movements in a normal manner. Parkinson's disease is characterized by well-known motor symptoms including tremors, limb stiffness, slowness of movements, and difficulties with posture and balance, as well as by non-motor symptoms, which may include psychosis. The severity of Parkinson's disease symptoms tends to worsen over time.

According to the National Parkinson Foundation, over one million people in the United States and from four to six million people worldwide 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.

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 and deeply affects their quality of life. As a result, Parkinson's disease psychosis is associated with increased caregiver burden, nursing home placement, and increased mortality.

The 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 manage the motor symptoms of Parkinson's disease. However, this approach is generally not effective in alleviating psychotic symptoms in most patients and is often associated with a significant worsening of motor function in these patients. Despite substantial limitations, currently marketed antipsychotic drugs, including Seroquel, are used off-label to treat patients with Parkinson's disease psychosis. Because antipsychotic drugs block dopamine receptors, and thereby may counteract the dopamine therapy used to manage motor symptoms, these drugs are generally not well tolerated by patients with Parkinson's disease at doses required to achieve antipsychotic effects. Current antipsychotic drugs also are associated with a number of side effects, which can be problematic for elderly patients with Parkinson's disease. In addition, antipsychotic drugs have a black box warning for use in elderly patients with dementia-related psychosis due to increased mortality and morbidity.

The only current antipsychotic drug 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. 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, but not in the United States, for the treatment of psychotic disorders in Parkinson's disease. However, patients being treated with clozapine require frequent blood monitoring because clozapine treatment is associated with the occurrence of a rare blood disorder. Currently, there is a large unmet medical need for new therapies that will effectively treat psychosis in patients with Parkinson's disease without unwanted side effects, including impairment of motor function.

### ***Schizophrenia***

Schizophrenia is a chronic and debilitating mental illness characterized by disturbances in thinking, emotional reaction, and behavior. These disturbances may include positive symptoms, such as hallucinations and delusions, a range of negative symptoms, including loss of interest and emotional withdrawal, and cognitive disturbances. Schizophrenia is associated with persistent impairment of a patient's social functioning and productivity. Cognitive disturbances often 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, approximately one percent of the U.S. population suffers from this disease. Worldwide sales of antipsychotic drugs used to treat schizophrenia and other psychiatric conditions exceeded \$23 billion in 2009. These drugs have been increasingly used by physicians to

address a range of disorders in addition to schizophrenia, including bipolar disorder and a variety of psychoses and related conditions in elderly patients. Despite their commercial success, current antipsychotic drugs 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 typical antipsychotics are effective against positive symptoms of schizophrenia in many patients, these drugs often induce disabling motor disturbances, and they fail to address or worsen most of the negative symptoms and cognitive disturbances associated with schizophrenia.

Most schizophrenia patients in the United States today are treated with second-generation, or atypical, antipsychotics, which induce fewer motor disturbances than typical antipsychotics, 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. 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. We believe that these side effects arise either from non-essential receptor interactions or from excessive dopamine blockade.

The limitations of currently available antipsychotics result in poor patient compliance. A study conducted by the National Institute of Mental Health, 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 an improved side effect and efficacy profile.

### ***Alzheimer's Disease Psychosis***

Alzheimer's disease is a progressive neurodegenerative disorder that slowly destroys memory and thinking skills, and eventually even the ability to carry out simple tasks. Its symptoms include cognitive dysfunction, memory abnormalities, progressive impairment in activities of daily living, and a host of behavioral and neuropsychiatric symptoms. Alzheimer's disease primarily affects older people and, in most cases, symptoms first appear after age 60. Alzheimer's disease gets worse over time and is fatal.

According to the Alzheimer's Association, 5.3 million people in the United States are living with Alzheimer's disease. While the diagnostic criteria for Alzheimer's disease mostly focus on the related cognitive deficits, it is often the behavioral and psychiatric symptoms that are most troublesome for caregivers and lead to poor quality of life for patients. These symptoms include agitation, aggressive behaviors, and psychosis. Studies have suggested that approximately 25 to 50 percent of Alzheimer's disease patients may develop psychosis, commonly consisting of hallucinations and delusions. The diagnosis of Alzheimer's disease psychosis is associated with more rapid cognitive and functional decline and institutionalization.

There is no proven safe and effective therapy for Alzheimer's disease psychosis. As symptoms progress and become more severe, physicians often resort to off-label use of antipsychotic medications in these patients. Current antipsychotic drugs are associated with a number of side effects, which can be problematic for elderly patients with Alzheimer's disease. In addition, antipsychotic drugs may exacerbate the cognitive disturbances associated with Alzheimer's disease. Current antipsychotic drugs also have a black box warning for use in elderly patients with dementia-related psychosis due to increased mortality and morbidity. There is a large unmet medical need for a safe and effective therapy to treat the psychosis in patients with Alzheimer's disease.

### ***Chronic Pain***

Chronic pain is a common form of pain that persists or progresses over a long period of time. In contrast to acute pain that usually arises suddenly in response to an identifiable injury and is transient, chronic pain persists

over time and is often resistant to medical treatments. Chronic pain may be related to a number of different medical conditions, including diabetes, arthritis, migraine, fibromyalgia, irritable bowel syndrome, cancer, shingles, and previous trauma or injury.

Hypersensitivity is a common feature of many chronic pain disorders, including fibromyalgia and irritable bowel syndrome. Fibromyalgia is characterized by chronic widespread muscle pain, stiffness and tenderness of muscles, tendons and joints without detectable inflammation. It also is often associated with fatigue, restless sleep, awakening tired, anxiety, depression and disturbances in bowel function. Fibromyalgia affects an estimated three to six million people in the United States, predominately women between the ages of 35 and 55. Irritable bowel syndrome is one of the most common ailments of the intestines and affects an estimated 15 percent of the U.S. population.

There are a variety of drugs used to treat patients with chronic pain, including anticonvulsants, selective serotonin and norepinephrine reuptake inhibitors, or SNRIs, tricyclic antidepressants, opioid painkillers, and non-steroidal anti-inflammatory agents. Currently, the leading drugs include Lyrica, an anticonvulsant approved for postherpetic neuralgia, diabetic neuropathic pain and fibromyalgia, and Cymbalta, an SNRI indicated for treatment of diabetic peripheral neuropathic pain, fibromyalgia, and major depressive disorder. Lyrica and Cymbalta had worldwide sales of \$3.1 billion and \$3.5 billion, respectively, in 2010. Lyrica is the successor to Neurontin, which was the first product to be approved by the FDA for the treatment of neuropathic pain and is now generic.

Only a portion of patients with neuropathic pain and fibromyalgia get meaningful relief from anticonvulsants and antidepressants. There are no drugs currently indicated for treatment of irritable bowel syndrome and other conditions accompanied by an enhanced internal sensation of pain in the United States. Side effects of anticonvulsants may include dizziness, somnolence, dry mouth, blurred vision, weight gain, and concentration or attention difficulties. Side effects of SNRIs may include nausea, vomiting, dizziness, sleep disturbances, constipation, dry mouth, anxiety, abnormal vision, headache and sexual dysfunction. Tricyclic antidepressants have long been used to treat depression and these agents may have pain-relieving effects in some patients. Common side effects of these agents include dry mouth, blurred vision, constipation, difficulty with urination, impaired thinking and tiredness.

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 chronic pain. Opioid painkillers also have significant adverse side effects that limit their usefulness, and prolonged use of these drugs can lead to the need for increasing dosage and potentially to addiction.

Due to these shortcomings of current therapies, we believe that there is a large unmet medical need for new chronic pain therapies with improved efficacy and side effect profiles.

### ***Glaucoma***

Glaucoma is a chronic eye disease that, if left untreated, can lead to blindness. According to the World Health Organization, glaucoma is the second leading cause of blindness in the world. Loss of vision is caused by degeneration of the optic nerve, which is responsible for carrying images from the eye to the brain. A frequent symptom of glaucoma is increased fluid pressure within the eye, referred to as intraocular pressure. In the early stages of the disease, there may be no symptoms. It is estimated that over four million people in the United States have glaucoma but only half of those know they have it. Older people are at a higher risk for glaucoma and the disease is more prevalent in people over 60 years of age. The incidence of glaucoma is expected to increase as the average age of the population increases.

Currently there are a variety of options available to treat glaucoma, including eye medications, laser procedures and surgery. These treatment options are intended to decrease intraocular pressure and, thereby, protect the optic nerve. Physicians often treat glaucoma with multiple classes of drugs to optimize therapy and

minimize side effects. Drugs used to treat glaucoma include prostaglandin analogs such as Xalatan and Lumigan, beta blockers such as timolol, and alpha agonists such as Alphagan, as well as combined medications. Xalatan is the market leader for glaucoma treatment with worldwide sales of \$1.7 billion in 2010. While Xalatan is an effective anti-glaucoma agent, it frequently causes increased pigmentation of the iris that may lead to a change in iris color, and may cause other side effects, including blurred vision and burning and stinging sensations in the eye. We believe there is a need for new and more effective drugs that can treat glaucoma with fewer side effects and help patients reduce the risk of losing their vision.

### Our Product Candidates

We are focused on a portfolio of our four most advanced product candidates, consisting of three product candidates in clinical development and one product candidate in IND-track development for which we are conducting required development studies in preparation for potential future clinical trials. We believe that our product candidates offer innovative therapeutic approaches and may provide significant advantages relative to current therapies. The following table summarizes our most advanced product candidates:

<u>Product Candidate</u>	<u>Indication</u>	<u>Stage of Development</u>	<u>Commercialization Rights</u>
Pimavanserin	Parkinson's disease psychosis	Phase III	ACADIA
	Schizophrenia	Phase II	ACADIA
	Alzheimer's disease psychosis	Phase II (1)	ACADIA
AGN-XX/YY	Chronic Pain	Phase II	Allergan
AC-262271	Glaucoma	Phase I	Allergan
AM-831	Schizophrenia	IND-track	Meiji Seika—Asia ACADIA—Rest of World

(1) ACADIA has established a protocol for a future Phase II feasibility study in Alzheimer's disease psychosis.

### *Pimavanserin*

#### *Overview*

Pimavanserin is a new chemical entity that we discovered and have advanced to Phase III development as a potential first-in-class treatment for Parkinson's disease psychosis. Pimavanserin is a small molecule product candidate that can be taken orally as a tablet once-a-day. Pimavanserin selectively blocks the activity of the 5-HT<sub>2A</sub> receptor, a drug target that plays an important role in psychosis. We hold worldwide rights to pimavanserin and have established a patent portfolio, which includes numerous issued patents generically covering pimavanserin as well as issued patents specifically covering pimavanserin in the United States, Europe and several additional countries.

We have selected Parkinson's disease psychosis as our lead indication for pimavanserin and we are currently focused on advancing our Phase III program for this indication. We also believe that pimavanserin has the potential to address a range of additional neurological and psychiatric indications that are undeserved by currently marketed antipsychotics. We have completed a Phase II trial with pimavanserin as a co-therapy in schizophrenia and have established a protocol for a future Phase II feasibility study to explore the potential of pimavanserin as a treatment for Alzheimer's disease psychosis. In the future, we intend to use our Phase III Parkinson's disease psychosis program as a foundation to develop and commercialize pimavanserin for these and other potential central nervous system indications through or in collaboration with strategic partners.

### *Pimavanserin as a Treatment for Parkinson's Disease Psychosis*

We are in Phase III development with pimavanserin as a treatment for Parkinson's disease psychosis. Currently, there are no therapies approved to treat Parkinson's disease psychosis in the United States. We believe that pimavanserin may effectively treat the psychosis in patients with Parkinson's disease without compromising motor control, thereby significantly improving the quality of life for these patients. As a result, we believe that, if approved, pimavanserin will offer significant advantages relative to current antipsychotics used off-label for the treatment of Parkinson's disease psychosis.

We are currently conducting several studies in our Phase III program with pimavanserin for Parkinson's disease psychosis, including a Phase III trial, referred to as the -020 Study, designed to evaluate the efficacy, tolerability and safety of pimavanserin as a treatment for patients with Parkinson's disease psychosis. The -020 Study is multi-center, double-blind, placebo-controlled trial expected to enroll about 200 patients at clinical centers located in the United States. Patients are randomized to two study arms and receive oral doses of either 40 mg of pimavanserin or placebo once-daily for six weeks. Patients also continue to receive stable doses of their existing dopamine replacement therapy used to manage the motor symptoms of Parkinson's disease. The primary endpoint of the -020 Study is antipsychotic efficacy as measured using 9 items from the hallucinations and delusions domains of the Scale for the Assessment of Positive Symptoms, or SAPS. We employ independent centralized ratings to assess the primary endpoint in the -020 Study. Motoric tolerability is a key secondary endpoint in the study and is measured using Parts II and III of the Unified Parkinson's Disease Rating Scale, or UPDRS. The -020 Study builds on the signals of efficacy observed in our earlier studies and incorporates several study design enhancements based on the previous data and experience we have gained in our Parkinson's disease program.

In addition to the -020 Study, we are continuing to conduct an open-label safety extension study, referred to as the -015 Study, involving patients with Parkinson's disease psychosis who have completed our earlier Phase III studies as well as patients who complete the -020 Study. Patients are eligible to participate in the -015 Study if, in the opinion of the treating physician, the patient may benefit from continued treatment with pimavanserin. The -015 Study, together with a similar extension study that is still ongoing from our earlier Phase II Parkinson's disease psychosis trial, has generated a considerable amount of long-term safety data on pimavanserin. A total of over 200 patients have now been treated with pimavanserin for over one year and our longest single-patient exposure is greater than six years. We believe that our experience to date suggests that long-term administration of pimavanserin is safe and well tolerated in this fragile, elderly patient population.

In September 2009, we announced top-line results from an initial Phase III trial with pimavanserin in patients with Parkinson's disease psychosis, referred to as the -012 Study. While the -012 Study was impacted by a larger than expected placebo response and did not meet its primary endpoint, signals of antipsychotic efficacy were consistently observed in the pimavanserin 40 mg study arm. These signals were most prominent in the United States portion of the study, which comprised nearly one-half of the patients in the study. The -012 Study met the key secondary endpoint of motoric tolerability and pimavanserin was safe and well tolerated in the study. On the basis of data from the -012 Study, during 2010 we concluded a second Phase III trial, referred to as the -014 Study, early and analyzed this study in order to use the findings to support our design of the -020 Study. In the -014 Study, the 20 mg pimavanserin arm showed a signal of efficacy on the primary assessment scale and a statistically significant difference from placebo on a secondary outcome measure. The -014 Study met the key secondary endpoint of motoric tolerability and pimavanserin was safe and well tolerated in the study.

In 2006, we announced top-line results from a multi-center, double-blind, placebo-controlled Phase II clinical trial with pimavanserin in 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.

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

By combining pimavanserin with a low dose of an antipsychotic drug such as risperidone, a commonly prescribed atypical antipsychotic drug, we believe that the optimal relationship between 5-HT<sub>2A</sub> receptor blockade and partial dopamine receptor blockade can be achieved. Therefore, we believe 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, potentially, related psychiatric disorders.

We reported positive results in 2007 from a multi-center, double-blind, placebo-controlled Phase II clinical trial designed to evaluate pimavanserin as a co-therapy in patients with schizophrenia. The trial results showed several advantages of co-therapy with pimavanserin and a 2 mg, or low, dose of risperidone in patients with schizophrenia. These advantages included enhanced efficacy comparable to that of a 6 mg, or standard, dose of risperidone, a faster onset of antipsychotic action, and an improved side effect profile, including significantly less weight gain, compared to the standard dose of risperidone. If we elect to pursue further development for this indication in the future, we expect that it will be through, or in collaboration with, a partner.

### *Pimavanserin as a Treatment for Alzheimer's Disease Psychosis*

Patients with Alzheimer's disease psychosis and Parkinson's disease psychosis share many common characteristics. They are typically elderly and frail, and often exhibit similar psychiatric symptoms associated with their underlying neurodegenerative disease. In preclinical models of Alzheimer's disease psychosis, we have shown that pimavanserin attenuates psychosis-related behaviors in those models. In addition, pimavanserin has been shown to positively interact with muscarinic agonists and cholinesterase inhibitors to enhance their pro-cognitive and antipsychotic actions in preclinical models. Because of its mechanism of action and the favorable safety profile observed to date in studies conducted in elderly patients with Parkinson's disease psychosis, we believe that pimavanserin also may be ideally suited to address the need for a new treatment for Alzheimer's disease psychosis that is safe, effective and well tolerated.

We have established a protocol for a Phase II feasibility study to evaluate the potential of pimavanserin as a treatment for Alzheimer's disease psychosis. While our resources are currently focused on our Phase III program in Parkinson's disease psychosis, we intend to pursue our planned feasibility study in Alzheimer's disease psychosis in the future independently or in collaboration with a partner.

### **AGN-XX/YY**

In collaboration with Allergan, we have discovered and are developing a new class of small molecule product candidates for the treatment of chronic pain. Our novel alpha adrenergic agonists provide pain relief in a range of preclinical models, without the side effects of current pain therapies, including sedation and cardiovascular and respiratory effects.

Allergan has conducted several Phase II trials in this program and has reported preliminary results from its Phase II program, including positive proof-of-concept in a visceral pain trial in patients that had hypersensitivity of the esophagus, and efficacy signals in two chronic pain trials in the areas of fibromyalgia and irritable bowel syndrome. Allergan has announced that it is seeking a partner for the further development of this program and for commercialization in areas predominantly served by general practitioners.

### **AC-262271**

We have discovered and, in collaboration with Allergan, are developing AC-262271, a small molecule product 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 preclinical models, AC-262271 has demonstrated a promising preclinical profile, including robust efficacy and a long duration of action. Allergan is conducting Phase I clinical trials in glaucoma patients with AC-262271.



## **AM-831**

We have discovered and, in collaboration with Meiji Seika, are in IND-track development with AM-831, a small molecule product candidate for the treatment of schizophrenia and related psychiatric disorders. AM-831 was selected from a series of lead compounds that provide the potential for a new class of pro-cognitive antipsychotic drugs. These compounds combine muscarinic m1 agonism with actions on both dopamine and serotonin receptors. AM-831 has demonstrated robust effects in animal models of psychosis and pro-cognitive effects in animal models of cognition.

In collaboration with Meiji Seika, we are conducting required development studies in preparation for potential future clinical trials. We intend to co-develop AM-831 in collaboration with Meiji Seika through completion of proof-of-concept clinical studies, at which point Meiji Seika will be solely responsible for continued development and commercialization in Asia and we plan to seek a strategic partner to pursue development and commercialization in the rest of the world.

## ***Other Product Candidates***

In addition to our four most advanced product candidates in development, we have used our proprietary drug discovery platform to discover additional product candidates. These include two preclinical programs in the area of Parkinson's disease. The first is our ER-beta program where we have discovered compounds that may possess neuroprotective and anti-inflammatory properties and may have the ability to slow down the progression of Parkinson's disease. Our initial research studies of these ER-beta compounds have been supported by grants from The Michael J. Fox Foundation. In the second preclinical program, we discovered compounds that selectively activate Nurr1-RXR complexes and promote viability of dopamine-containing neurons. We are conducting studies to examine the effects of these compounds on neuroprotection and neuroregeneration in preclinical models of Parkinson's disease pursuant to another grant from The Michael J. Fox Foundation.

Currently, our resources are focused on our most advanced product candidates, including pimavanserin, and we are not devoting significant resources to earlier-stage programs that are not directly funded. However, we may elect to pursue the development of additional product candidates in the future in partnerships or independently.

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

### ***Overview***

All of our product 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 our expertise combined with our proprietary platform has allowed us to discover product candidates more efficiently than traditional approaches.

### ***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. A key to our discovery approach has been our set of proprietary functional test systems, or assays, that we developed for a large number of targets predominantly in the G-protein coupled receptor and nuclear receptor gene families. We believe that these gene families represent the most relevant and feasible targets for small molecule drug discovery focused on central nervous system indications. We have used our proprietary assays in conjunction with our proprietary receptor selection and amplification technology, a cell-based assay system which we refer to as R-SAT, to validate drug targets, and to discover novel small molecules that are specific for these targets.

## **Collaboration Agreements**

We have established three separate collaboration agreements with Allergan, a collaboration agreement with Meiji Seika and a technology license agreement with Aventis to leverage our drug discovery platform and related assets, and to advance development of and commercialize selected product candidates. Our collaborations have typically included upfront payments at initiation of the collaboration, research support during the research term, if applicable, 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 2011. As of December 31, 2010, we had received an aggregate of \$17.4 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, as well as royalties on future product sales worldwide, if any.

In July 1999, we entered into a collaboration agreement with Allergan to discover, develop and commercialize selective muscarinic drugs for the treatment of glaucoma. 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 development. As of December 31, 2010, we had received an aggregate of \$9.4 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 pain, which program is in Phase II development, and ophthalmic indications. This agreement was amended in conjunction with the execution and subsequent amendments of the March 2003 collaboration agreement, and provides for the continued development of product 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, 2010 under this agreement. 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 product licensed under the collaboration and at least 10 years from the date of first commercial sale of a product. 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.

### ***Meiji Seika Kaisha***

In March 2009, we entered into a collaboration agreement with Meiji Seika to develop and commercialize a novel class of pro-cognitive drugs to treat patients with schizophrenia and related disorders in Japan and several other Asian countries. Under the agreement, we are eligible to receive up to \$25 million in aggregate payments,

including \$3 million in license fees and up to \$22 million in potential development and regulatory milestone payments, as well as royalties on product sales, if any, in the Asian territory. Meiji Seika also is responsible for the first \$15 million of development expenses and we and Meiji Seika will share remaining expenses through clinical proof-of-concept, subject to possible adjustment in the event we further license the program outside of the Asian territory. Meiji Seika is responsible for all costs associated with the development, manufacturing and commercialization of the product candidate in the Asian territory, and is eligible to share a portion of any product-related revenues received by us in the rest of the world. As of December 31, 2010, we had received an aggregate of \$4.1 million in payments under the agreement, including \$3 million in license fees and reimbursement of initial development expenses. Our agreement with Meiji Seika is subject to early termination upon specified events.

#### ***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 46 issued U.S. patents and 199 issued foreign patents. All of these patents originated from us. In addition, we have 24 provisional and utility U.S. patent applications and 142 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***

Seven U.S. patents have been issued to us that provide coverage for pimavanserin, comprising two that cover the compound generically and five that specifically cover pimavanserin, polymorphs thereof, or use thereof for treating Parkinson's disease psychosis, schizophrenia, and sleep disorders. The generic coverage expires in 2021. The pimavanserin specific patent and the Parkinson's disease psychosis treatment patent provide protection until June 2027 and 2026, respectively. The patent that covers polymorphs of pimavanserin provides protection until June 2028. We have 35 issued foreign patents that specifically cover pimavanserin, including patents in 25 European countries, Australia, Hong Kong, India, Mexico, New Zealand, Russia, Singapore and South Africa, which provide patent protection through 2024. 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.

#### ***AGN-XX/YY***

We have not been issued, and are not pursuing, patents covering the compounds being pursued by Allergan under this collaboration as the compounds are covered by Allergan patents.

### ***AC-262271***

We have two U.S. patents that have been issued to us providing coverage for the compounds covered by our collaboration with Allergan for the treatment of glaucoma. These U.S. patents will expire in 2023. We have 41 issued foreign patents and 19 pending foreign applications that cover these compounds. The issued foreign patents for this program will expire in 2022 and 2025.

### ***AM-831***

Two U.S. patents have been issued to us that provide coverage for the compounds covered by our collaboration with Meiji Seika. These patents expire in 2024 and 2026. We have 34 issued foreign patents that cover these compounds. These patents provide protection through 2024.

### ***Other Product Candidates***

We have 17 issued U.S. patents and 33 issued foreign patents with claims for other product candidates that are at earlier stages of development.

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

Our core R-SAT technology is protected by eight issued U.S. patents and 17 foreign patents. Our U.S. patents for R-SAT will expire over the range of 2013 to 2025. The foreign patents covering R-SAT will expire over the range of 2014 to 2024.

### **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 product candidates as compared to the current standard of care.

Even if we and our collaborators are successful in developing our product candidates, the resulting products would compete with a variety of established drugs in the areas of Parkinson's disease psychosis, schizophrenia, Alzheimer's disease psychosis, chronic 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. Our potential product for Alzheimer's disease psychosis would compete with off-label use of antipsychotic drugs.

Our potential products for the treatment of chronic 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. Currently, the leading drugs approved for chronic pain indications include Lyrica, the successor to Neurontin, and Cymbalta. Lyrica had worldwide sales of \$3.1 billion in 2010. Cymbalta, indicated for treatment of diabetic peripheral neuropathic pain as well as treatment of major depressive disorder, had worldwide sales of \$3.5 billion in 2010.

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 of \$1.7 billion in 2010.

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 product 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 product 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 product candidate, is lengthy, expensive and uncertain.

In the United States, product candidates are tested in animals until adequate proof of safety is established. Clinical trials for new product candidates are typically conducted in three sequential phases that may overlap. Phase I trials involve the initial introduction of the product 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 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 clinical trial registration, institutional review board oversight, informed consent, health information privacy, and good clinical practices.

To establish a new product 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 product candidate under development would delay or prevent regulatory approval of the product 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. 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 product 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 a "response 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 risk management, including 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, warning letters, 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 product 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 product 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.

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, anti-fraud and abuse laws, 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. Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and

Education Affordability Reconciliation Act, or collectively the PPACA, enacted in March 2010, substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the PPACA establishes: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices that can be charged for drug products, or the amounts of reimbursement available for drug products. 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.

### Marketing, Sales and Distribution

We currently have no marketing, sales or distribution capabilities. In order to commercialize any of our product candidates, we must develop these capabilities internally or through collaboration with third parties. In selected therapeutic areas where we feel that our product 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 product candidates. In therapeutic areas that require a large sales force selling to a large and diverse prescribing population, we plan to partner our product candidates for commercialization.

### Manufacturing

We outsource and plan to continue to outsource manufacturing responsibilities for our existing and future product candidates for development and commercial purposes. The production of pimavanserin 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 product candidates for use in clinical trials and potential commercialization.

### Employees

At December 31, 2010, we had 27 employees, of whom 13 hold Ph.D. or other advanced degrees. Of our total workforce, 17 are engaged in research and development activities and 10 are engaged in executive, finance, and administration activities. 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 \$20.6 million in 2010, \$41.6 million in 2009, and \$56.8 million in 2008.

### Long-Lived Assets

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

	As of December 31,		
	2010	2009	2008
	(in thousands)		
United States .....	\$282	\$ 738	\$1,537
Europe .....	144	324	566
Total .....	<u>\$426</u>	<u>\$1,062</u>	<u>\$2,103</u>



## **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.*

### **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, 2010, we had an accumulated deficit of approximately \$324.1 million. While we did report net income in 2010 due to recognition of revenue following the conclusion of our collaboration with Biovail Laboratories International SRL, a subsidiary of Biovail Corporation, we expect to incur net losses over the next several years as we advance our programs and incur significant clinical development costs.

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. Substantially all of our revenues for the year ended December 31, 2010 were from our collaborations with Biovail, Allergan, and Meiji Seika as well as our agreements with other parties. We anticipate that collaborations, 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. In connection with our October 2010 agreement with Biovail to end our collaboration and regain all rights to pimavanserin, during the fourth quarter of 2010, we recorded as revenue all of the remaining \$25.9 million of deferred revenue from the Biovail collaboration and the \$8.75 million one-time payment received upon the termination of this collaboration. There will be no additional revenue from this collaboration and, as a result, we expect our revenues to decrease significantly beginning in the first quarter of 2011.

We cannot be certain that the milestones required to trigger payments under our other existing collaborations will be reached or that we will secure additional collaboration agreements. To obtain revenues from our product 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.

***We depend on collaborations with third parties to develop and commercialize selected product candidates and to provide substantially all of our revenues.***

A key aspect of our strategy is to selectively enter into collaboration agreements 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 product candidates. The ongoing research term of our agreements with Allergan will end in March 2011, unless extended, and additional payments from our agreements with Allergan and Meiji Seika are dependent on successful advancement of our applicable product candidates. There is no guarantee that revenues from our ongoing collaborations will continue at current or past levels. Given the current economic environment, it is possible that our existing collaborators may elect to reduce their external spending.

Our collaborators may fail to develop or effectively commercialize products using our product 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 or a change in strategic focus;

- decide to pursue a competitive product developed outside of the collaboration; or
- cannot obtain the necessary regulatory approvals.

For example, Allergan has announced that it is seeking a partner for further development and commercialization of drug candidates in our chronic pain program. If Allergan is unable to successfully partner this program, it may elect to not pursue further development. In addition, any partner that Allergan does identify may devote substantially less resources than Allergan has devoted to our chronic pain program to date.

Each of Meiji Seika and Allergan can terminate our existing collaborations under specific circumstances, including in some cases the right to terminate without cause upon prior 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 we seek a new partner for our pimavanserin program. Given the current economic environment, it is possible that competition for new collaborators may increase. If we are unable to renew any existing collaboration or find new collaborations, we may not be able to continue advancing our programs alone.

***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. Our cash and investment securities totaled approximately \$37.1 million at December 31, 2010. In January 2011, we raised net proceeds of approximately \$13.8 million from a private equity financing. While we believe that our existing cash resources and anticipated payments from our collaborations will be sufficient to fund our cash requirements at least into the first half of 2013, 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 extent to which we are obligated to reimburse our collaborators or our collaborators are obligated to reimburse us for clinical trial costs under our collaboration agreements;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market our product candidates; and
- the costs associated with litigation.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, private or public sales of our securities, debt financings, or by licensing all or a portion of our product candidates or technology. Turmoil in the financial markets has adversely affected the market capitalizations of many biotechnology companies, including us, and generally made equity and debt financing more difficult to obtain. This, coupled with other factors, may limit our access to additional financing over the near-term future. This could have a material adverse effect on our ability to access sufficient funding, including pursuant to our Committed Equity Financing Facility, or CEFF, or from other sources. In addition, according to its terms, our CEFF will expire in August 2011. 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, if obtained, may significantly dilute existing stockholders, including any funds that may be raised under the CEFF.

***We do not have a partner for the development of our lead product candidate, pimavanserin, and are solely responsible for the advancement of this program.***

Following a September 2010 merger of Biovail Corporation, the parent of our then-collaborator Biovail, in October 2010, we entered into an agreement with Biovail to end our collaboration regarding North American rights to pimavanserin. This agreement allowed us to regain the rights that we had licensed to Biovail and receive a one-time payment of \$8.75 million. Pursuant to the collaboration, Biovail had been responsible for funding development of pimavanserin, and seeking regulatory approval for and any future marketing of pimavanserin in North America. Following the end of the collaboration, we now have full responsibility for the pimavanserin program. We expect our research and development costs to continue to be substantial for the continued development of pimavanserin. While we are continuing to run the ongoing trials for pimavanserin, we would need to add resources in the future in order to take this product candidate to market, if we do not secure another partner.

***Our most advanced product 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 product candidates is extremely high. In fact, we previously had an unsuccessful Phase III trial with our product candidate, pimavanserin. In July 2010, we announced the initiation of the -020 Study, a new Phase III trial with pimavanserin for the treatment of Parkinson's disease psychosis. An unfavorable outcome in our Phase III trial with pimavanserin would be a major set-back for the program and for our company, generally. In particular, an unfavorable outcome in this or other studies in our pimavanserin program may require us to delay, reduce the scope of, or eliminate this program and could have a material adverse effect on our company and the value of our common stock. In addition to our pimavanserin program, we also have clinical programs in collaboration with Allergan for the treatment of chronic pain and glaucoma, which are in Phase II and Phase I development, respectively.

In connection with clinical trials, we face risks that:

- a product 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 product 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, or 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 product 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, or 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.

***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 product candidate;
- obtaining approval of an Investigational New Drug Application, or IND, from the FDA;
- obtaining institutional review board approval to conduct a clinical trial at a prospective 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 screening or retention rates of patients in clinical trials;
- serious adverse events or side effects experienced by participants; and
- insufficient supply or deficient quality of product 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 product candidate. If we experience delays, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

***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 or breaches with respect to payments that we believe are due under the applicable agreements, particularly in the current economic environment when companies, including large established ones, may be seeking to reduce external payments;
- disputes on strategy as to what development or commercialization activities should be pursued under the applicable agreements;
- disputes as to the responsibility for conducting development and commercialization activities pursuant to the applicable collaboration, including the payment of costs related thereto;

- disagreements with respect to ownership of intellectual property rights;
- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities;
- delay of a collaborator's development or commercialization efforts with respect to our product candidates; or
- termination or non-renewal of the collaboration.

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

In addition, in 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 the applicable program. 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. 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 product candidates or may otherwise result in lower demand for our potential products.

We have collaborations with Allergan for the development of product candidates related to chronic pain and ophthalmic diseases, including glaucoma. Allergan currently markets therapeutic products to treat glaucoma and is engaged in other research programs related to glaucoma and other ophthalmic products that are independent from our development program in this therapeutic area. Allergan is also pursuing other research programs related to pain management that are independent from our collaboration in this therapeutic area.

Our collaboration with Meiji Seika is initially focused on the advancement of pro-cognitive drugs, or PCAPs, as a treatment for schizophrenia and related disorders. While Meiji Seika has rights to the PCAPs in the Asian territory, we have the right to pursue them, alone or with a partner, in the rest of the world.

***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 product 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 product candidates on our own. 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 product 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 product 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 product candidates, the product candidates may fail for other reasons.***

Even if we or our collaborators successfully complete the clinical trials of product candidates, the product candidates may fail for other reasons, including the possibility that the product 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 product candidates or other treatments commercialized by competitors.

***Our Committed Equity Financing Facility may not be available to us if we elect to make a draw down, may require us to make additional "blackout" or other payments to Kingsbridge Capital Limited and may result in dilution to our stockholders.***

Pursuant to the CEFF, Kingsbridge committed to purchase up to the lesser of \$60 million or up to approximately 7 million shares of our common stock over a three-year period ending in August 2011. Through February 2011, we have raised an aggregate of \$1.9 million through the issuance of 1.7 million shares of our common stock. Kingsbridge will not be obligated to purchase shares under the CEFF unless specified conditions are met, which include a minimum price of \$0.90 for our common stock, the effectiveness of a registration statement registering for resale the shares of common stock to be issued in connection with the CEFF, and customary other conditions, such as accuracy of representations and warranties and compliance with applicable laws. Kingsbridge is permitted to terminate the CEFF under certain circumstances. If we are unable to access funds through the CEFF or Kingsbridge terminates the CEFF, we may be unable to access capital on favorable terms or at all.

In connection with the CEFF, we filed a registration statement with the SEC to register the resale of shares of our common stock that may be issued pursuant to the CEFF or upon exercise of the warrant we issued to Kingsbridge in connection with establishing the CEFF. This registration statement was declared effective by the SEC on September 23, 2008. We are entitled, in certain circumstances, to deliver a "blackout" notice to Kingsbridge to suspend the use of the prospectus, which is a part of such registration statement, and prohibit Kingsbridge from selling shares under that prospectus for a certain period of time. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement covering the resale of the shares of common stock to be issued in connection with the CEFF is not effective in circumstances not permitted by our registration rights agreement with Kingsbridge, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of a specified number of shares held by Kingsbridge immediately prior to the blackout period and the change in the market price of our common stock during the period in which the use of the resale registration statement is suspended. If the trading price of our common stock declines during a suspension of the resale registration statement, the blackout or other payment could be significant.

If we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a

discount of up to 12% from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing and may further decrease our share price.

***If we do not realize the expected benefits from the reductions of our Swedish activities following our restructurings, our operating results and financial conditions could be negatively impacted.***

In 2008 and 2009, we implemented restructurings designed to streamline our operations, reduce our internal operating expenses, and extend our cash runway. As part of the restructurings, we focused our resources on our most advanced product candidates and substantially reduced our early-stage programs. In connection with these efforts, our Swedish subsidiary substantially reduced its headcount and its research activities. This subsidiary is a party to a lease agreement that extends to June 2015. In connection with its reductions, the Swedish subsidiary has been seeking to reduce the obligations under this lease due to its minimal operations and assets. However, the subsidiary may not be able to reach an agreement with the leaseholder to reduce the remaining lease amounts on acceptable terms or at all. While the lease was signed by our Swedish subsidiary and the parent company is not a party to the lease, and we do not believe that the parent company is responsible for any lease amounts, there can be no assurance that the leaseholder will not seek to recover against the parent company or force our Swedish subsidiary into bankruptcy. If we are forced to pay any amounts to the Swedish leaseholder or incur other charges related to operations in Sweden, our operating results and financial condition would be adversely affected.

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

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

- the 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 product candidate that we discover and/or 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.

***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 product candidates.***

Our success depends on our ability to attract, retain, and motivate highly qualified management and scientific personnel. In particular, our development programs depend on our ability to attract and retain highly skilled development personnel, especially in the fields of central nervous system disorders, including neuropsychiatric and related disorders. In the future, we may need to hire additional personnel if we expand our research and development efforts from our current levels. We face competition for experienced scientists, clinical operations personnel, and other technical personnel from numerous companies and academic and other research

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

All of our employees are “at will” employees, which means that any employee may quit at any time and we may terminate any employee at any time. We do not carry “key person” insurance covering members of senior management.

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

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

Our research and development 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 product candidates to treat diseases or conditions in other therapeutic areas. If we are not able to use our technologies to discover and develop product 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 product candidates to augment the results of our internal discovery activities. If we are unable to identify new product 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 product candidates.

***We will need to continue to manage our organization and we may encounter difficulties with our reduced staffing and any future transitions, which could adversely affect our results of operations.***

We will need to effectively manage our operations and facilities in order to advance our drug development programs, including those covered by our collaborations with Allergan and Meiji Seika, achieve milestones under our collaboration agreements, facilitate additional collaborations, and pursue other development activities. It is possible that our infrastructure may be inadequate to support our future efforts and growth. In particular, 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 our operations and, accordingly, may not achieve our research, development, and commercialization goals.

***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 our other product candidates, including compounds being developed under our collaborations;



- whether we generate revenues or reimbursements by achieving specified research, development 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, including reimbursement obligations pursuant to our collaboration agreements;
- 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 and benefits associated with our restructuring;
- 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 product candidates for clinical trials. If any of our product 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. While we believe that there are alternative sources available to manufacture our product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts.

The manufacturers of our product 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 product candidates or the ultimate launch of products based on our product 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.

***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 provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act that was enacted in July 2010, the provisions of the Sarbanes-Oxley Act of 2002, or 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.

***Healthcare legislation may make it more difficult to receive revenues, if we have products that are approved.***

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. Among the provisions of PPACA of importance to our potential product candidates are the following:

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in 2011;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers, effective March 30, 2013, and reporting any investment interests held by physicians and their immediate family members during the preceding calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;
- a licensure framework for follow-on biologic products; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

***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 have not been adversely impacted by local wildfires, there is the possibility of future fires in the area. In the event of an earthquake or fire, if our facilities or the equipment in our facilities is significantly damaged or destroyed for any reason, we may not be able to rebuild or relocate our facilities or replace any damaged equipment in a timely manner and our business, financial condition, and results of operations could be materially and adversely affected. We do not have insurance for damages resulting from earthquakes. 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 product 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 product 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, we have been issued only a limited number of patents with respect to these filings.

Our ability to obtain patent protection for our product candidates 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 product 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;
- others may identify prior art which could invalidate our patents; or
- changes to patent laws that limit the exclusivity rights of patent holders.

Even if we have or obtain patents covering our product candidates or technologies, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, genes, gene products or therapeutic products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to genes, nucleic acids, polypeptides, chemical compounds or therapeutic products, and some of these may encompass reagents utilized in the identification of candidate drug compounds or compounds that we desire to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of central nervous system disorders and the other fields in which we are developing products. These could materially affect our ability to develop our product 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 product 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. Additionally, employees whose positions were eliminated in connection with restructurings may seek future employment with our competitors. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of such future employment. 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.

***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.

***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 product 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 product 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 us 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. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some 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 product candidates. In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders.

If we fail to obtain and maintain patent protection and trade secret protection of our product 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 product 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 product 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 product 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 product 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, Fanapt marketed by Novartis Pharmaceuticals, Risperdal, marketed by Johnson & Johnson, Abilify, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical, Seroquel, and clozapine. Our potential product for Alzheimer's disease psychosis would compete with off-label use of antipsychotic drugs. In the area of chronic 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.

***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 product 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 product candidates, including results of our clinical trials for our pimavanserin program or our chronic pain or glaucoma collaborations;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes or developments regarding our 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;
- our failure to meet applicable Nasdaq listing standards and the possible delisting of our common stock from the Nasdaq Global Market;
- 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 blogs and 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;
- 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 economic and financial crises, wars, terrorism, and political unrest.

In particular, our development program with pimavanserin encompass a number of studies, including Phase III trials, open-label safety extension trials and a range of supporting studies, including carcinogenicity studies, and drug-drug interaction studies. Another unfavorable outcome in one or more of the studies in the development of pimavanserin could be a major set-back for our company, generally. Such an unfavorable outcome could have a material adverse effect on our company and the value of our common stock.

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.

***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. In connection with the CEFF, we filed a registration statement with the SEC to register the resale of up to a total of approximately 7.4 million shares of our common stock that may be issued pursuant to the CEFF or upon exercise of the warrant we issued in connection with establishing the CEFF. We also filed a registration statement in connection with a private financing that we concluded in January 2011, which registration covers approximately 17.0 million shares of our common stock. We also have an effective registration statement to sell shares of our common stock on our own behalf, and may elect to sell shares pursuant to such registration from time to time. Our stock price may decline as a result of the sale of the shares of our common stock included in any of these registration statements.

***If the price of our common stock trades below \$1.00 per share for a sustained period or we do not meet other continued listing requirements, our common stock may be delisted from the Nasdaq Global Market.***

The Nasdaq Global Market imposes, among other requirements, listing maintenance standards as well as minimum bid and public float requirements. In particular, Nasdaq rules require us to maintain a minimum bid

price of \$1.00 per share of our common stock and to have a specified level of stockholder equity. If the closing bid price of our common stock is below \$1.00 per share for 30 consecutive trading days, which was the case in 2010, or we do not meet other requirements, which was the case in 2010 when we failed to meet the minimum market value listing requirement, we would fail to be in compliance with Nasdaq's continued listing standards and, if we are unable to cure the non-compliance within 180 days, our common stock may be delisted from the Nasdaq Global Market and we may not be able to maintain the continued listing of our common stock on the Nasdaq Global Market. Delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Such delisting could also adversely affect our ability to obtain financing for the continuation of our operations.

***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.

***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 $\frac{2}{3}$  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 3 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.

***Adverse securities and credit market conditions have reduced our market capitalization and may significantly affect our ability to raise capital.***

Turmoil in the financial markets has adversely affected the market capitalizations of many biotechnology companies, including us, and generally made equity and debt financing more difficult to obtain. This, coupled with other factors, may limit access to financing over the near-term future. This could have a material adverse effect on our ability to access funding pursuant to our CEFF or from other sources on acceptable terms, or at all, and our stock price may suffer further as a result.

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

This item is not applicable.

***Item 2. Properties.***

Our primary facility consists of approximately 29,000 square feet of leased research and office space located in San Diego, California, which is leased through the end of 2012 with options to extend and a right to early terminate the lease. We also lease another facility in San Diego that covers approximately 8,000 square feet of laboratory, office, and other space. That lease runs through November 2011, with an option to extend. Our Swedish subsidiary has leased approximately 30,000 square feet of chemistry research and development space in a single facility in Malmö, Sweden. This Swedish lease commenced in June 2005 and has a ten-year term. We believe that our existing facilities are adequate for our current needs.

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

This item is not applicable.

***Item 4. (Removed and Reserved).***

**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.

<u>2009</u>	<u>High</u>	<u>Low</u>
First Quarter .....	\$1.26	\$0.75
Second Quarter .....	\$2.97	\$0.88
Third Quarter .....	\$6.60	\$1.66
Fourth Quarter .....	\$2.08	\$1.16
<u>2010</u>		
First Quarter .....	\$1.75	\$1.21
Second Quarter .....	\$2.00	\$1.00
Third Quarter .....	\$1.42	\$0.91
Fourth Quarter .....	\$1.50	\$0.65

As of March 1, 2011, there were approximately 51 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.

**Item 6. Selected Financial Data.**

The following data has been derived from our audited financial statements, including the consolidated balance sheet at December 31, 2010 and 2009 and the related consolidated statements of operations for the three years ended December 31, 2010 and related notes appearing elsewhere in this report. The statement of operations data for the years ended December 31, 2007 and 2006 and the balance sheet data as of December 31, 2008, 2007 and 2006 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.

	Years Ended December 31,				
	2010	2009	2008	2007	2006
	(In thousands, except per share data)				
<b>Consolidated Statement of Operations Data:</b>					
Revenues:					
Collaborative revenues (1) .....	\$42,135	\$ 6,399	\$ 1,590	\$ 7,555	\$ 8,133
Operating expenses:					
Research and development .....	20,579	41,585	56,750	57,942	49,398
General and administrative .....	6,462	10,282	11,818	12,267	11,349
Gain from settlement of litigation .....	—	—	—	—	(3,560)
Total operating expenses .....	27,041	51,867	68,568	70,209	57,187
Income (loss) from operations .....	15,094	(45,468)	(66,978)	(62,654)	(49,054)
Interest income .....	82	409	2,915	6,532	4,153
Interest expense .....	(37)	(86)	(181)	(268)	(198)
Income (loss) before change in accounting principle ....	15,139	(45,145)	(64,244)	(56,390)	(45,099)
Cumulative effect of change in accounting principle ....	—	—	—	—	51
Net income (loss) .....	\$15,139	\$(45,145)	\$(64,244)	\$(56,390)	\$(45,048)
Net income (loss) per common share, basic .....	\$ 0.39	\$ (1.20)	\$ (1.73)	\$ (1.60)	\$ (1.61)
Net income (loss) per common share, diluted .....	\$ 0.39	\$ (1.20)	\$ (1.73)	\$ (1.60)	\$ (1.61)
Weighted average shares used in computing net income					
(loss) per common share, basic .....	38,593	37,476	37,113	35,211	27,923
Weighted average shares used in computing net income					
(loss) per common share, diluted .....	38,720	37,476	37,113	35,211	27,923

- (1) As described in Note 7 of the notes to our consolidated financial statements appearing elsewhere in this report, during the fourth quarter of 2010 we recognized an aggregate of \$34.7 million in revenues in connection with our agreement with Biovail to conclude our collaboration.

	At December 31,				
	2010	2009	2008	2007	2006
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investment securities .....	\$37,087	\$47,060	\$60,083	\$126,858	\$83,255
Working capital .....	31,890	33,766	51,331	111,966	65,249
Total assets .....	38,394	49,680	64,677	134,584	89,544
Long-term debt, less current portion .....	32	98	430	1,156	1,379
Total stockholders' equity .....	29,688	12,114	52,992	113,934	67,159

## **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," "predicts," "pro forma," "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 development and commercialization of small molecule drugs for the treatment of central nervous system disorders. Our pipeline consists of four product candidates including pimavanserin, which is in Phase III development as a potential first-in-class treatment for Parkinson's disease psychosis. We hold worldwide commercialization rights to pimavanserin. In addition, we have a product candidate in Phase II development for chronic pain and a product candidate in Phase I development for glaucoma, both in collaboration with Allergan, Inc., as well as a program in IND-track development in collaboration with Meiji Seika Kaisha, Ltd. All of the product candidates in our 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. In October 2010, we entered into an agreement with Biovail Laboratories International SRL, a subsidiary of Biovail Corporation, pursuant to which we regained all rights to pimavanserin and concluded our earlier collaboration agreement. In connection with concluding this collaboration, we recorded \$34.7 million in revenues during the fourth quarter of 2010, which resulted in us reporting net income for the fourth quarter and year ended December 31, 2010. However, we will no longer recognize revenues from the Biovail collaboration and we expect to continue to incur operating losses for at least the next several years as we pursue the clinical development of our product candidates. As of December 31, 2010, we had an accumulated deficit of \$324.1 million.

#### **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 payments under our current and past collaboration agreements. As of December 31, 2010, we had received an aggregate of \$110.8 million in payments under these agreements, including upfront payments, research funding, and milestone payments. We expect our revenues for the next several years to consist primarily of revenues derived from payments under our current agreements with Allergan and Meiji Seika and potential additional collaborations.

We currently are a party to three separate collaboration agreements with Allergan. Pursuant to our March 2003 collaboration agreement with Allergan, we had received an aggregate of \$17.4 million in payments as of

December 31, 2010, consisting of an upfront payment, research funding and related fees. This collaboration originally provided for a three-year research term, which has been extended by the parties through March 2011. We have had a reduced level of research activities and related research funding under this collaboration during the extension. Our two other collaboration agreements with Allergan involve the development of product candidates in the areas of chronic pain and glaucoma. We are eligible to receive payments upon achievement of development and regulatory milestones, as well as royalties on product sales, if any, under each of our three collaboration agreements with Allergan. Each of our agreements with Allergan is subject to early termination upon specified events, including, in the case of one of our agreements, if we have a change in control. Upon the conclusion of the research term under each agreement, Allergan may terminate the agreement by notice.

In March 2009, we entered into a collaboration agreement with Meiji Seika. Under the agreement, we are eligible to receive up to \$25 million in aggregate payments, including \$3 million in license fees and up to \$22 million in potential development and regulatory milestones, as well as royalties on product sales, if any, in the licensed Asian territory. Meiji Seika also is responsible for the first \$15 million of development expenses and we will share the remaining expenses through clinical proof-of-concept, subject to possible adjustment in the event we further license the program outside of the Asian territory. Our agreement with Meiji Seika is subject to early termination upon specified events.

In May 2009, we entered into a collaboration agreement with Biovail, pursuant to which we received a non-refundable \$30 million upfront payment. Under this collaboration, we also were eligible to receive potential development, regulatory and sales milestones as well as royalties on future net sales of pimavanserin. In October 2010, in connection with our agreement with Biovail to regain all rights to pimavanserin and conclude our collaboration, we recorded an aggregate of \$34.7 million in revenue consisting of an \$8.75 million cash payment we received from Biovail and recognition of \$25.9 million of deferred revenue remaining from this collaboration. We have no ongoing involvement with or future obligations to Biovail, and we will no longer recognize revenue from this collaboration. As a result, we expect our revenues to decrease significantly beginning in the first quarter of 2011.

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

Our research and development expenses consist primarily of fees paid to external service providers, salaries and related personnel expenses, facilities and equipment expenses, and other costs. We charge all research and development expenses to operations as incurred. Our research and development activities are primarily focused on our most advanced product candidates, including pimavanserin. Following our agreement with Biovail in October 2010 to conclude our collaboration to develop and commercialize pimavanserin, we are responsible for all future costs incurred in the development of pimavanserin and remain responsible for the costs associated with our other internal programs.

Pursuant to our collaboration with Meiji Seika, which we established in March 2009, Meiji Seika is responsible for the first \$15 million of development expenses for the product candidate, AM-831, and we and Meiji Seika will share remaining expenses through clinical proof-of-concept, subject to possible adjustment. We expect to coordinate a significant portion of the planned external development services and, accordingly, we will incur the related development costs for these external services and receive reimbursement of Meiji Seika's portion of these costs pursuant to the agreement. Meiji Seika is responsible for all costs associated with the development of AM-831 in the Asian territory. We are not responsible for, nor have we incurred, development expenses in our clinical programs for chronic pain and glaucoma, which we are pursuing in collaboration with Allergan.

We use external service providers to manufacture our product 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 product candidates. We have used our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs have not been attributable to a specific project but were directed to broadly applicable research activities. Accordingly, we have not reported our internal

research and development costs on a project basis. Our internal research and development expenses decreased significantly during 2010 and 2009, relative to the previous year, primarily due to restructurings and related workforce reductions. To the extent that external expenses 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, 2010, 2009, and 2008 (in thousands):

	Years Ended December 31,		
	2010	2009	2008
Costs of external service providers:			
Pimavanserin .....	\$12,506	\$27,079	\$27,189
AM-831 and other .....	1,087	807	2,251
ACP-104 (1) .....	—	15	2,658
Subtotal .....	13,593	27,901	32,098
Internal costs .....	6,387	12,810	23,327
Stock-based compensation .....	599	874	1,325
Total research and development .....	<u>\$20,579</u>	<u>\$41,585</u>	<u>\$56,750</u>

(1) ACP-104 was a product candidate that we were previously developing.

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 for the continued development of our product 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 our current focus is primarily on advancing the clinical development of pimavanserin, 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 product candidate, as well as an ongoing assessment of each product candidate's commercial potential and our financial position. We cannot forecast with any degree of certainty which product 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.

We expect our external research and development expenses to continue to be substantial as we pursue the development of pimavanserin and our other product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product 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 have consisted 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.

#### **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 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 authoritative guidance established by U.S. Generally Accepted Accounting Principles, or GAAP. Our revenues are primarily related to our collaboration agreements, which may provide for various types of payments to us, including upfront payments, funding of research and development, milestone payments, and licensing fees. Our collaboration agreements also include potential payments for product royalties; however, we have not received any product royalties to date.

We consider a variety of factors in determining the appropriate method of accounting under our collaboration agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting. Where there are multiple deliverables identified within a collaboration agreement that are combined into a single unit of accounting, revenues are deferred and recognized over the expected period of performance. The specific methodology for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances applicable to each agreement.

Upfront, non-refundable payments that do not have stand-alone value are recorded as deferred revenue once received and recognized as revenues over the expected period of performance. 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. When non-refundable license fees do not meet all of these criteria, the license revenues are recognized over the expected period of performance. Non-refundable payments for research funding are generally recognized as revenues over the period as the related research activities are performed. Payments for reimbursement of external development costs are generally recognized as revenues using a contingency-adjusted performance model over the expected period of performance based on the nature of the related agreement.

We evaluate milestone payments on an individual basis and recognize revenues from non-refundable milestone payments 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 associated 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 milestone event. Where separate milestone payments do not meet these criteria, we recognize revenue using a contingency-adjusted performance model over the period of performance.

### ***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 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, 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***

The fair value of each employee stock option and each employee stock purchase plan right granted is estimated on the grant date under the fair value method using the Black-Scholes model, which requires us to make a number of assumptions including the estimated expected life of the award and related volatility. The estimated fair values of stock options or purchase plan rights, including the effect of estimated forfeitures, are then expensed over the vesting period. As of December 31, 2010, total unrecognized compensation cost related to stock options and purchase plan rights was approximately \$1.9 million, and the weighted average period over which this cost is expected to be recognized is 2.3 years.

### **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 potential future collaborations, including as a result of the conclusion of our collaboration with Biovail in October 2010, and the progress and timing of expenditures related to our 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.

#### ***Comparison of the Years Ended December 31, 2010 and 2009***

##### ***Revenues***

Revenues increased to \$42.1 million in 2010 from \$6.4 million in 2009. This increase was primarily due to \$39.5 million in revenues recognized under our collaboration with Biovail during 2010 compared to \$4.6 million in 2009. The Biovail collaboration commenced in May 2009 and concluded in October 2010. In connection with the conclusion of this collaboration, during the fourth quarter of 2010, we recorded an aggregate of \$34.7 million in revenue consisting of an \$8.75 million cash payment we received from Biovail and \$25.9 million of deferred revenue remaining from this collaboration. We will no longer recognize revenue from this collaboration and, as a result, we expect our revenues to decrease significantly beginning in the first quarter of 2011. Revenues from our collaborations with Allergan totaled \$1.1 million in each of 2010 and 2009. Revenues from our agreements with other parties, including our collaboration with Meiji Seika, which commenced in March 2009, totaled \$1.5 million in 2010 compared to \$714,000 in 2009.

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

Research and development expenses decreased to \$20.6 million in 2010, including \$599,000 in stock-based compensation, from \$41.6 million in 2009, including \$874,000 in stock-based compensation. The decrease in research and development expenses was primarily due to \$14.3 million in decreased external service costs and \$6.7 million in decreased costs associated with our internal research and development organization. External service costs totaled \$13.6 million, or 66 percent of our research and development expenses in 2010, compared to \$27.9 million, or 67 percent of our research and development expenses in 2009. The decrease in external service costs was largely attributable to decreased costs incurred for our Phase III clinical trials for pimavanserin. The decrease in internal research and development costs was primarily attributable to \$4.3 million in decreased salaries and related personnel costs, and decreases in laboratory supply, equipment, facility and other costs resulting from a restructuring and related workforce reductions implemented in October 2009. Salaries and related personnel costs for the year ended December 31, 2009 included a charge of \$905,000 in connection with these workforce reductions.

### *General and Administrative Expenses*

General and administrative expenses decreased to \$6.4 million in 2010, including \$984,000 in stock-based compensation, from \$10.3 million in 2009, including \$1.3 million in stock-based compensation. The decrease in general and administrative expenses was primarily due to \$2.3 million in decreased salaries, related personnel costs and other costs resulting from our October 2009 restructuring and \$1.6 million in decreased external service costs.

### *Comparison of the Years Ended December 31, 2009 and 2008*

#### *Revenues*

Revenues increased to \$6.4 million in 2009 from \$1.6 million in 2008. The increase was primarily due to \$4.6 million in revenues recognized under our collaboration with Biovail, which commenced in May 2009. Revenues from our collaborations with Allergan totaled \$1.1 million in 2009 compared to \$1.0 million in 2008. Revenues from our agreements with other parties, including our collaboration with Meiji Seika, which commenced in March 2009, totaled \$714,000 in 2009 compared to \$578,000 in 2008.

#### *Research and Development Expenses*

Research and development expenses decreased to \$41.6 million in 2009, including \$874,000 in stock-based compensation, from \$56.8 million in 2008, including \$1.3 million in stock-based compensation. The decrease in research and development expenses was primarily due to \$11.0 million in decreased costs associated with our internal research and development organization and \$4.2 million in lower external service costs. The decrease in internal research and development costs was primarily attributable to \$7.6 million in decreased salaries and related personnel costs, and decreases in laboratory supply, equipment and other costs largely resulting from the restructuring and related workforce reductions implemented in August 2008 and, to a lesser degree, from a second restructuring and related workforce reductions implemented in October 2009. Salaries and related personnel costs for the year ended December 31, 2009 included a charge of \$905,000 in connection with workforce reductions from our October 2009 restructuring. Salaries and related personnel costs for the year ended December 31, 2008 included a charge of \$1.7 million in connection with workforce reductions from our August 2008 restructuring. External service costs totaled \$27.9 million, or 67 percent of our research and development expenses in 2009, compared to \$32.1 million, or 57 percent of our research and development expenses in 2008. The decrease in external expenses was largely attributable to decreased development costs for ACP-104 and other programs.

#### *General and Administrative Expenses*

General and administrative expenses decreased to \$10.3 million in 2009, including \$1.3 million in stock-based compensation, from \$11.8 million in 2008, including \$1.7 million in stock-based compensation. The decrease in general and administrative expenses was primarily due to \$1.3 million in decreased salaries and related personnel costs resulting from our August 2008 restructuring and related workforce reductions. Salaries and related personnel costs for the year ended December 31, 2009 included a charge of \$382,000 in connection with workforce reductions from our October 2009 restructuring. Salaries and related personnel costs for the year ended December 31, 2008 included a charge of \$454,000 in connection with workforce reductions from our August 2008 restructuring.

#### *Interest Income*

Interest income decreased to \$409,000 in 2009 from \$2.9 million in 2008. The decrease in interest income was due to decreased yields on our investment security portfolio and lower average levels of cash and investment securities.

## 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, 2010, we had received \$327.5 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, \$110.8 million in payments from collaboration agreements, \$22.4 million in debt financing, and \$22.1 million in interest income.

At December 31, 2010, we had \$37.1 million in cash, cash equivalents, and investment securities compared to \$47.1 million at December 31, 2009. In January 2011, we raised net proceeds of approximately \$13.8 million from a private equity financing. We currently anticipate that our cash, cash equivalents, investment securities, and anticipated payments from our ongoing collaborations will be sufficient to fund our operations at least into the first half of 2013.

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, or other events or developments, under our collaboration agreements;
- the extent to which we are obligated to reimburse our collaborators or our collaborators are obligated to reimburse us for clinical trial costs under our collaboration agreements;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for clinical or commercial production of product candidates; and
- the costs of establishing, or contracting for, sales and marketing capabilities if we obtain regulatory clearances to market our product 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 product candidates or technology. In August 2008, we entered into a Committed Equity Financing Facility, or CEFF, which provides us with access, at our discretion, to capital for a three-year period through the sale of newly issued shares of our common stock. According to its terms, the CEFF will expire in August 2011. The funds that can be raised under the CEFF will depend on the then-current price of our common stock and the number of shares actually sold, which may not exceed an aggregate of approximately 7 million shares. The aggregate amount raised under the CEFF may not exceed \$60 million. Under the terms of the CEFF, we may access capital in tranches of up to a maximum of between 2.0 and 3.5 percent of our market capitalization at the time of the draw down of each tranche, subject to certain conditions, including a minimum share price threshold of \$0.90. To date, we have raised \$1.9 million through the issuance of 1.7 million shares of our common stock pursuant to the CEFF.

We cannot be certain that additional funding will be available to us on acceptable terms, or at all. Over the last few years, turmoil and volatility in the financial markets has adversely affected the market capitalizations of many biotechnology companies and generally made equity and debt financing more difficult to obtain. This, coupled with other factors, may limit access to additional financing over the near-term future. In particular, given the current market conditions and the disappointing results from an initial Phase III Parkinson's disease psychosis trial with pimavanserin that we announced in September 2009, any unfavorable outcome in our development of pimavanserin could have a material adverse effect on our ability to raise additional capital.

If we cannot raise adequate additional capital in the future, we will be required to delay, further reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. In addition, in connection with our restructurings, we have reduced the scope of our research and development activities, and we may be required to further reduce the scope of our research and development activities in the future. This may lead to an impairment of our equipment and additional charges, which could materially affect our balance sheet and results of operations. We also are seeking to reduce our obligations under our facilities leases and may incur certain charges as a result.

We have invested a substantial portion of our available cash in a money market fund, U.S. Treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises. We have adopted an investment policy and established guidelines relating to credit quality, 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. Our investment portfolio has not been adversely impacted by the disruption in the credit markets. However, if there is further and expanded disruption in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected in the future.

Net cash used in operating activities totaled \$10.7 million in 2010 compared to \$13.7 million in 2009 and \$64.9 million in 2008. The decrease in net cash used in operating activities in 2010 relative to 2009 was primarily due to net income in 2010 of \$15.1 million compared to a net loss of \$45.1 million in 2009, as well as changes in operating assets and liabilities, including changes in deferred revenue, and accounts payable and accrued expenses. Deferred revenue decreased by \$25.3 million in 2010 compared to an increase in deferred revenue of \$28.2 million in 2009. The decrease in deferred revenue in 2010 was primarily attributable to the recognition of \$25.9 million in deferred revenue in connection with the conclusion of our collaboration with Biovail in October 2010. The increase in deferred revenue in 2009 was primarily attributable to the \$30 million non-refundable upfront payment received pursuant to our collaboration with Biovail as well as initial licensing fees received from our collaboration with Meiji Seika, offset by initial revenues recognized pursuant to these agreements. Accounts payable and accrued expenses decreased by an aggregate of \$3.1 million in 2010 compared to an aggregate decrease in accounts payable and accrued expenses of \$1.6 million in 2009. The decrease in accounts payable and accrued expenses in 2010 was primarily due to payments made for external service costs related to our clinical trials, the timing and amount of which may fluctuate significantly from period to period.

The decrease in cash used in operating activities in 2009 relative to 2008 was primarily due to a decrease in our net loss and changes in operating assets and liabilities, including an increase in deferred revenue of \$28.2 million in 2009 compared to a decrease of \$268,000 in 2008, offset in part by a smaller aggregate decrease in accrued expenses and accounts payable. The increase in deferred revenue in 2009 was primarily attributable to the upfront payment received from our collaboration with Biovail and initial licensing fees received from our collaboration with Meiji Seika, offset by initial revenues recognized pursuant to these agreements. Accrued expenses and accounts payable decreased by an aggregate of \$1.6 million in 2009 compared to an aggregate decrease of \$7.4 million in 2008. These decreases were primarily due to payments made for external service costs related to our clinical trials, the timing and amount of which may fluctuate significantly from period to period.

Net cash used in investing activities totaled \$1.1 million in 2010 compared to net cash provided by investing activities of \$9.4 million in 2009 and net cash provided by investing activities of \$69.7 million in 2008. Net cash used in or provided by investing activities 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 2010 relative to net cash provided by investing activities in 2009 was primarily due to increased purchases of investment securities, net of maturities of investment securities. The decrease in net cash provided by investing activities in 2009 relative to 2008 was primarily due to decreased maturities of investment securities, net of purchases of investment securities.

Net cash provided by financing activities totaled \$470,000 in 2010 compared to \$1.2 million in 2009 and net cash used in financing activities of \$374,000 in 2008. The decrease in net cash provided by financing activities in 2010 relative to 2009 was primarily attributable to reduced proceeds from the issuance of stock offset by decreased repayments of long-term debt. The increase in net cash provided by financing activities in 2009 relative to 2008 was primarily attributable to increased proceeds from the issuance of common stock, including sales under our CEFF. The net cash used in financing activities in 2008 was primarily due to repayments of our long-term debt, offset by net proceeds from stock option exercises and employee stock plan purchases.

The following table summarizes our contractual obligations, including interest, at December 31, 2010 (in thousands):

	<u>Total</u>	<u>Less than 1 Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
Operating leases .....	\$7,265	\$1,807	\$3,916	\$1,542	\$—
Long-term debt .....	117	84	33	—	—
Total .....	<u>\$7,382</u>	<u>\$1,891</u>	<u>\$3,949</u>	<u>\$1,542</u>	<u>\$—</u>

We have also entered into agreements with contract research organizations and other external service providers for services in connection with the development of our product candidates. We were contractually obligated for up to approximately \$8.7 million of future services under these agreements as of December 31, 2010. 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 on 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 progress and results of the underlying studies.

In addition, we have entered into an agreement with the Ipsen Group pursuant to which we licensed certain intellectual property rights that complement our patent portfolio. If certain conditions are met, we would be required to make future payments, including milestones, sublicensing fees and royalties. The amount of potential future milestone payments is \$10.5 million in the aggregate, which amount would be offset by any sublicensing fees we may pay under the agreement. Because these milestone payments would only be payable upon the achievement of specified regulatory events and it is uncertain when, or if, such events will occur, we cannot forecast with any degree of certainty when, or if, we will be required to make payments under the agreement. Accordingly, none of these amounts are included in the above table.

#### *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*

See Item 15 of Part IV, "Notes to Consolidated Financial Statements—Note 2—Summary of Significant Accounting Policies".

#### **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 a money

market fund, U.S. Treasury notes, and high quality marketable debt instruments of corporations and government sponsored enterprises 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, 2010, 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.

### **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, 2010, 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, 2010.

### *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, 2010, 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, 2010, our internal control over financial reporting was effective based on those criteria.

### *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 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.



### PART III

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

The information required by this Item and not set forth below will be set forth in the section headed "Proposal 1—Election of Directors" in our definitive Proxy Statement for our 2011 Annual Meeting of Stockholders to be filed with the SEC by May 2, 2011 (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 the section headed "Executive Compensation" 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 the section headed "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement and is incorporated in this report by reference.

Information regarding our equity compensation plans will be set forth in the section headed "Executive Compensation" 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 the section headed "Transactions With Related Persons" in our Proxy Statement and is incorporated in this report by reference.

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

The information required by this Item will be set forth in the section headed "Proposal 2—Ratification of Selection of Independent Registered Public Accounting Firm" in our Proxy Statement and is incorporated in this report by reference.

**PART IV**

**Item 15. Exhibits and 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:

	<u>Page Number</u>
Report of Independent Registered Public Accounting Firm .....	F-1
Consolidated Balance Sheets at December 31, 2010 and 2009 .....	F-2
Consolidated Statements of Operations for Each of the Three Years Ended December 31, 2010, 2009, and 2008 .....	F-3
Consolidated Statements of Cash Flows for Each of the Three Years Ended December 31, 2010, 2009, and 2008 .....	F-4
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for Each of the Three Years Ended December 31, 2010, 2009, and 2008 .....	F-5
Notes to Consolidated Financial Statements .....	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.

## 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 10, 2011

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ ULI HACKSELL Uli Hacksell	Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2011
/s/ THOMAS H. AASEN Thomas H. Aasen	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 10, 2011
/s/ LESLIE IVERSEN Leslie Iversen	Chairman of the Board	March 10, 2011
/s/ MICHAEL BORER Michael Borer	Director	March 10, 2011
/s/ LAURA BREGE Laura Brege	Director	March 10, 2011
/s/ MARY ANN GRAY Mary Ann Gray	Director	March 10, 2011
/s/ LESTER KAPLAN Lester Kaplan	Director	March 10, 2011
/s/ TORSTEN RASMUSSEN Torsten Rasmussen	Director	March 10, 2011

## 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, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express opinions on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP  
San Diego, California  
March 10, 2011

**ACADIA PHARMACEUTICALS INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except for par value and share data)

	December 31,	
	2010	2009
<b>Assets</b>		
Cash and cash equivalents .....	\$ 6,849	\$ 18,122
Investment securities, available-for-sale .....	30,238	28,938
Prepaid expenses, receivables and other current assets .....	762	1,413
Total current assets .....	37,849	48,473
Property and equipment, net .....	426	1,062
Other assets .....	119	145
Total assets .....	\$ 38,394	\$ 49,680
<b>Liabilities and stockholders' equity</b>		
Accounts payable .....	\$ 1,972	\$ 2,947
Accrued expenses .....	3,219	5,358
Current portion of deferred revenue .....	690	6,037
Current portion of long-term debt .....	78	365
Total current liabilities .....	5,959	14,707
Long-term portion of deferred revenue .....	2,623	22,579
Long-term debt, less current portion .....	32	98
Other long-term liabilities .....	92	182
Total liabilities .....	8,706	37,566
Commitments and contingencies (Note 12)		
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at December 31, 2010 and 2009; no shares issued and outstanding at December 31, 2010 and 2009 .....	—	—
Common stock, \$0.0001 par value; 75,000,000 shares authorized at December 31, 2010 and 2009; 39,350,561 and 38,332,119 shares issued and outstanding at December 31, 2010 and 2009, respectively .....	4	4
Additional paid-in capital .....	353,278	350,872
Accumulated deficit .....	(324,106)	(339,245)
Accumulated other comprehensive income .....	512	483
Total stockholders' equity .....	29,688	12,114
	\$ 38,394	\$ 49,680

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

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

	<u>Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
<b>Revenues</b>			
Collaborative revenues .....	\$42,135	\$ 6,399	\$ 1,590
<b>Operating expenses</b>			
Research and development (includes stock-based compensation of \$599, \$874, and \$1,325, respectively) .....	20,579	41,585	56,750
General and administrative (includes stock-based compensation of \$984, \$1,260, and \$1,662, respectively) .....	6,462	10,282	11,818
Total operating expenses .....	<u>27,041</u>	<u>51,867</u>	<u>68,568</u>
Income (loss) from operations .....	15,094	(45,468)	(66,978)
Interest income, net .....	45	323	2,734
Net income (loss) .....	<u>\$15,139</u>	<u>\$(45,145)</u>	<u>\$(64,244)</u>
Net income (loss) per common share, basic .....	<u>\$ 0.39</u>	<u>\$ (1.20)</u>	<u>\$ (1.73)</u>
Net income (loss) per common share, diluted .....	<u>\$ 0.39</u>	<u>\$ (1.20)</u>	<u>\$ (1.73)</u>
Weighted average common shares outstanding, basic .....	<u>38,593</u>	<u>37,476</u>	<u>37,113</u>
Weighted average common shares outstanding, diluted .....	<u>38,720</u>	<u>37,476</u>	<u>37,113</u>

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

**ACADIA PHARMACEUTICALS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Years Ended December 31,		
	2010	2009	2008
<b>Cash flows from operating activities</b>			
Net income (loss) .....	\$ 15,139	\$(45,145)	\$(64,244)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization .....	607	1,111	1,043
Stock-based compensation .....	1,583	2,134	2,987
Amortization of investment premium/discount .....	(117)	260	911
Other .....	(94)	323	5
Changes in operating assets and liabilities:			
Prepaid expenses, receivables and other current assets .....	671	1,013	1,966
Other assets .....	26	47	83
Accounts payable .....	(990)	656	(276)
Accrued expenses .....	(2,135)	(2,282)	(7,075)
Deferred revenue .....	(25,303)	28,178	(268)
Other long-term liabilities .....	(90)	(22)	(1)
Net cash used in operating activities .....	(10,703)	(13,727)	(64,869)
<b>Cash flows from investing activities</b>			
Purchases of investment securities .....	(54,674)	(50,265)	(79,972)
Maturities of investment securities .....	53,486	59,750	149,912
Purchases of property and equipment .....	—	(41)	(226)
Proceeds from sales of property and equipment .....	128	—	—
Net cash provided by (used in) investing activities .....	(1,060)	9,444	69,714
<b>Cash flows from financing activities</b>			
Proceeds from issuance of common stock, net of issuance costs .....	823	1,923	535
Repayments of long-term debt .....	(353)	(762)	(909)
Net cash provided by (used in) financing activities .....	470	1,161	(374)
Effect of exchange rate changes on cash .....	20	73	(287)
Net increase (decrease) in cash and cash equivalents .....	(11,273)	(3,049)	4,184
<b>Cash and cash equivalents</b>			
Beginning of year .....	18,122	21,171	16,987
End of year .....	\$ 6,849	\$ 18,122	\$ 21,171
<b>Supplemental schedule of cash flow information</b>			
Interest paid .....	\$ 37	\$ 96	\$ 171

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

ACADIA PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS)  
(in thousands, except share data)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Comprehensive Income (Loss)
<b>Balances at December 31, 2007</b>	37,035,389	\$ 4	\$343,293	\$(229,856)	\$ 493	\$113,934	\$(56,137)
Issuance of common stock from exercise of stock options	70,548	—	187	—	—	187	—
Issuance of common stock pursuant to employee stock purchase plan	71,937	—	348	—	—	348	—
Net loss	—	—	—	(64,244)	—	(64,244)	\$(64,244)
Noncash compensation related to stock options granted	—	—	2,987	—	—	2,987	—
Unrealized loss on investment securities	—	—	—	—	(104)	(104)	(104)
Cumulative translation adjustment	—	—	—	—	(116)	(116)	(116)
<b>Balances at December 31, 2008</b>	37,177,874	\$ 4	\$346,815	\$(294,100)	\$ 273	\$ 52,992	\$(64,464)
Issuance of common stock from exercise of stock options	62,189	—	74	—	—	74	—
Issuance of common stock pursuant to employee stock purchase plan	176,785	—	193	—	—	193	—
Issuance of common stock under Committed Equity Financing Facility, net of issuance costs	785,271	—	1,147	—	—	1,147	—
Issuance of common stock upon exercise of warrant	130,000	—	509	—	—	509	—
Net loss	—	—	—	(45,145)	—	(45,145)	(45,145)
Noncash compensation related to stock options granted	—	—	2,134	—	—	2,134	—
Unrealized loss on investment securities	—	—	—	—	(98)	(98)	(98)
Cumulative translation adjustment	—	—	—	—	308	308	308
<b>Balances at December 31, 2009</b>	38,332,119	\$ 4	\$350,872	\$(339,245)	\$ 483	\$ 12,114	\$(44,935)
Issuance of common stock from exercise of stock options	10,820	—	11	—	—	11	—
Issuance of common stock pursuant to employee stock purchase plan	81,032	—	65	—	—	65	—
Issuance of common stock under Committed Equity Financing Facility, net of issuance costs	926,590	—	747	—	—	747	—
Net income	—	—	—	15,139	—	15,139	15,139
Noncash compensation related to stock options granted	—	—	1,583	—	—	1,583	—
Unrealized loss on investment securities	—	—	—	—	(5)	(5)	(5)
Cumulative translation adjustment	—	—	—	—	34	34	34
<b>Balances at December 31, 2010</b>	39,350,561	\$ 4	\$353,278	\$(324,106)	\$ 512	\$ 29,688	\$ 15,168

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



**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. The Company is focused on the development and commercialization of small molecule drugs for the treatment of central nervous system disorders. The Company's primary operations are based in San Diego, California and it has two wholly owned subsidiaries located in Europe.

The Company has incurred substantial operating losses since its inception due in large part to expenditures for its research and development activities. As of December 31, 2010, the Company had an accumulated deficit of \$324.1 million. The Company expects to incur operating losses for at least the next several years as it pursues the development of its product candidates.

The Company will require significant additional financing in the future to fund its operations. Future capital requirements will depend on many factors, including the progress in, the outcome of and the costs of the Company's clinical trials, the scope, prioritization and number of its research and development programs, and the ability of its collaborators and the Company to reach the milestones, and other events or developments under its collaboration agreements. Until the Company can generate significant continuing revenues, it expects to fund its operations through its existing cash, cash equivalents and investment securities, payments from existing and potential future collaborations, proceeds from private or public sales of its securities, debt financing, or by licensing all or a portion of its product candidates or technology. The Company cannot be certain that additional funding will be available on acceptable terms, or at all. Conditions in the financial markets and other factors could have a material adverse effect on the Company's ability to access sufficient funding on acceptable terms, or at all. If the Company cannot raise adequate additional capital, it will be required to delay, further reduce the scope of, or eliminate one or more of its research or development programs or its commercialization efforts. In addition, the Company may be required to relinquish greater, or even all, rights to product candidates at earlier stages of development or on less favorable terms than it would otherwise choose.

**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.

## ACADIA PHARMACEUTICALS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *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 other observable inputs.

#### *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, 2010, 2009 and 2008, gains or losses from disposals of property and equipment were not material.

#### *Revenues*

The Company recognizes revenues in accordance with authoritative guidance established by U.S. generally accepted accounting principles ("GAAP"). The Company's revenues are primarily related to its collaboration agreements, which may provide for various types of payments, including upfront payments, funding of research and development, milestone payments, and licensing fees. The Company's collaboration agreements also include potential payments for product royalties; however, the Company has not received any product royalties to date.

The Company considers a variety of factors in determining the appropriate method of accounting under its collaboration agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting. Where there are multiple deliverables identified within a collaboration agreement that are combined into a single unit of accounting, revenues are deferred and recognized over the expected period of performance. The specific methodology for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances applicable to each agreement.

Upfront, non-refundable payments that do not have stand-alone value are recorded as deferred revenue once received and recognized as revenues over the expected period of performance. 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. When non-refundable license fees do not meet all of these criteria, the license revenues are recognized over the expected period of performance. Non-refundable payments for research funding are generally recognized as revenues over the period as the related research activities are performed. Payments for reimbursement of external development costs are generally recognized as revenues using a contingency-adjusted performance model over the expected period of performance based on the nature of the related agreement.

The Company evaluates milestone payments on an individual basis and recognizes revenues from non-refundable milestone payments 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 associated 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 milestone event. Where separate milestone payments do not meet these criteria, the Company recognizes revenue using a contingency-adjusted performance model over the period of performance.

## ACADIA PHARMACEUTICALS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *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 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 programs are funded under agreements with collaboration partners, and the Company's 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 currently invests its excess cash primarily in a money market fund, U.S. Treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises. The Company has adopted an investment policy that includes guidelines relative to diversification and maturities to preserve principal 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, 2010, 2009, and 2008, revenues from two of the Company's collaborative partners comprised 97 percent, 89 percent, and 88 percent of total revenues, respectively. Revenue related to the Biovail collaboration comprised 94 percent and 72 percent of total revenues for the years ended December 31, 2010 and 2009, respectively. Revenues from Allergan, Inc. comprised 3 percent, 17 percent, and 64 percent of total revenues for the years ended December 31, 2010, 2009, and 2008, respectively. Another collaborative partner comprised 24 percent of total revenues for the year ended December 31, 2008.

#### *Foreign Currency Translation*

The functional currencies of the Company's subsidiaries located in Europe 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, 2010 and 2009, the balance within accumulated other comprehensive income from foreign currency translation was \$516,000 and \$482,000, respectively. Foreign currency transaction gains and losses are included in the results of operations and, to date, have not been significant.

**ACADIA PHARMACEUTICALS INC.**

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

***Stock-Based Compensation***

The fair 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 model. The estimated fair values of the stock option or purchase rights, including the effect of estimated forfeitures, are then expensed over the vesting period. The following assumptions were used to estimate the fair value of employee stock options:

	<u>Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Expected volatility .....	101%	74-96%	68-81%
Risk-free interest rate .....	1-3%	2-3%	2-3%
Expected forfeiture rate .....	11%	5-10%	5-6%
Expected dividend yield .....	0%	0%	0%
Expected life of options in years .....	5.7	5.7	5.5-5.7

*Expected Volatility.* In 2010, the Company considered its historical volatility and implied volatility when determining the volatility factor. In prior years, the Company also utilized the historical volatility of peer companies due to a lack of trading history. Peer companies were selected based upon similar 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.

*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 the end of the contractual term of all outstanding options.

The following assumptions were used to estimate the fair value for the offerings under the employee stock purchase plan that commenced during the indicated year:

	<u>Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Expected volatility .....	58-152%	123-179%	50-164%
Risk-free interest rate .....	0-1%	0-1%	0-3%
Expected dividend yield .....	0%	0%	0%
Expected life of offering in years .....	0.5-2.0	0.5-2.0	0.5-2.0

***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.

ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

*Use of Estimates*

The preparation of financial statements in conformity with U.S. GAAP 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.

*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 consisted of the following:

	<u>December 31,</u>	
	<u>2010</u>	<u>2009</u>
	<u>(in thousands)</u>	
Unrealized gain (loss) on investment securities .....	\$ (4)	\$ 1
Foreign currency translation adjustments .....	516	482
	<u>\$512</u>	<u>\$483</u>

**ACADIA PHARMACEUTICALS INC.**

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

***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. For the year ended December 31, 2010, outstanding stock options to purchase an aggregate of 127,000 common shares were included in the weighted average common shares outstanding on a diluted basis and, therefore, are not included in the table below. The Company has excluded all outstanding stock options and warrants from the calculation of diluted net loss per common share for the years ended December 31, 2009 and 2008 because all such securities were antidilutive. Shares used in calculating basic and diluted net loss per common share exclude these potential common shares:

	<u>Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
	(in thousands)		
Antidilutive options to purchase common stock .....	4,066	3,612	3,291
Antidilutive warrants to purchase common stock .....	848	1,691	1,539
	<u>4,914</u>	<u>5,303</u>	<u>4,830</u>

***Segment Reporting***

Management has determined that the Company operates in one operating segment. All revenues for the years ended December 31, 2010 and 2009 were generated in the United States. Information regarding long-lived assets by geographic area is as follows:

	<u>December 31,</u>	
	<u>2010</u>	<u>2009</u>
	(in thousands)	
United States .....	\$282	\$ 738
Europe .....	144	324
	<u>\$426</u>	<u>\$1,062</u>

***Recently Issued Accounting Standards***

In October 2009, the Financial Accounting Standards Board (“FASB”) issued authoritative guidance which amends existing guidance related to revenue recognition for arrangements with multiple deliverables. The guidance provides accounting principles and application guidance for arrangements that contain multiple deliverables, including how the arrangement should be separated, and the consideration allocated to each deliverable. Assuming other criteria are met, this guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management’s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The Company will adopt this guidance prospectively on January 1, 2011 for any new or materially modified agreements after the date of adoption.

In April 2010, the FASB issued an accounting standards update which provides guidance in applying the milestone method of revenue recognition to research or development arrangements. Under this guidance, management may recognize revenue contingent upon the achievement of a milestone in its entirety, in the period

**ACADIA PHARMACEUTICALS INC.**

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

in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered substantive. The Company will adopt this guidance prospectively on January 1, 2011 for any milestones which may be achieved subsequent to adoption.

**3. Investment Securities**

Investment securities, available-for-sale, consisted of the following:

	December 31, 2010			Estimated Fair Value
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	
	(in thousands)			
U.S. Treasury notes .....	\$ 4,291	\$—	\$—	\$ 4,291
Government sponsored enterprise securities .....	23,432	2	(6)	23,428
Corporate debt securities .....	2,519	—	—	2,519
	\$30,242	\$ 2	\$ (6)	\$30,238
	December 31, 2009			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
	(in thousands)			
U.S. Treasury notes .....	\$ 3,790	\$—	\$—	\$ 3,790
Government sponsored enterprise securities .....	25,147	7	(6)	25,148
	\$28,937	\$ 7	\$ (6)	\$28,938

**4. Fair Value Measurements**

Authoritative guidance defines fair value, establishes a framework for measuring fair value in U.S. GAAP and expands disclosures about fair value measurements. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

*Level 1.* Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

*Level 2.* Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.

*Level 3.* Inputs that are unobservable for the asset or liability.

As of December 31, 2010, the Company held \$37.1 million of cash equivalents and available-for-sale investment securities consisting of a money market fund, U.S. Treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises. The Company has adopted an investment policy and established guidelines relating to credit quality, diversification and maturities of its 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.

**ACADIA PHARMACEUTICALS INC.**

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

The Company's cash equivalents and available-for-sale investment securities are classified within Level 1 or Level 2 of the fair value hierarchy. The Company's investment securities classified as Level 1 are valued using quoted market prices and the Company's investment securities classified as Level 2 are valued using other observable inputs such as recent trades for the securities or similar securities, interest rates on similar securities, or yield curves or benchmark interest rates observable at commonly quoted intervals. The fair value measurements of the Company's cash equivalents and available-for-sale investment securities are identified in the following tables (in thousands):

	December 31, 2010	Fair Value Measurements at Reporting Date using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund .....	\$ 6,403	\$ 6,403	\$ —	\$—
U.S. Treasury notes .....	4,291	4,291	—	—
Government sponsored enterprise securities .....	23,428	—	23,428	—
Corporate debt securities .....	2,519	—	2,519	—
	<u>\$36,641</u>	<u>\$10,694</u>	<u>\$25,947</u>	<u>\$—</u>

	December 31, 2009	Fair Value Measurements at Reporting Date using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund .....	\$17,038	\$17,038	\$ —	\$—
U.S. Treasury notes .....	3,790	3,790	—	—
Government sponsored enterprise securities .....	25,148	—	25,148	—
	<u>\$45,976</u>	<u>\$20,828</u>	<u>\$25,148</u>	<u>\$—</u>

**5. Balance Sheet Components**

Property and equipment, net, consisted of the following:

	Estimated Useful Lives (Years)	December 31,	
		2010	2009
		(in thousands)	
Machinery and equipment .....	5-7	\$ 5,480	\$ 5,711
Computers and software .....	3	1,162	1,368
Furniture and fixtures .....	3-10	256	266
Leasehold improvements .....	3-10	1,148	1,150
		8,046	8,495
Accumulated depreciation and amortization .....		(7,620)	(7,433)
		<u>\$ 426</u>	<u>\$ 1,062</u>



**ACADIA PHARMACEUTICALS INC.**

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

Depreciation and amortization of property and equipment was \$607,000, \$1.1 million, and \$1.0 million for the years ended December 31, 2010, 2009, and 2008, respectively.

Accrued expenses consisted of the following:

	December 31,	
	2010	2009
	(in thousands)	
Accrued clinical and research services .....	\$2,339	\$3,623
Accrued compensation and benefits .....	537	1,375
Other .....	343	360
	\$3,219	\$5,358

**6. 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 9.95 percent to 10.27 percent per annum. At December 31, 2010 and 2009, the Company had \$110,000 and \$463,000, respectively, in outstanding borrowings under these agreements. At December 31, 2010, a total of \$78,000 of the outstanding borrowings was classified as current and \$32,000 was classified as long-term.

**7. Collaborative Research and Licensing Agreements**

In May 2009, the Company entered into a collaboration and license agreement with Biovail Laboratories International SRL (“Biovail”), a subsidiary of Biovail Corporation, to co-develop and commercialize pimavanserin for neurological and psychiatric indications in the United States and Canada. Under the terms of the agreement, the Company received an upfront non-refundable cash payment of \$30 million and was eligible to receive potential development, regulatory and sales milestone payments as well as royalties on future net sales of pimavanserin. The upfront non-refundable cash payment of \$30 million received from Biovail was deferred and was being recognized as revenue on a straight line basis over the estimated period of the Company’s performance under the agreement. Payments received from Biovail for the reimbursement of specified development costs also were deferred and recognized as revenue using a contingency-adjusted performance model. In October 2010, the Company and Biovail entered into an agreement pursuant to which the parties agreed to conclude their collaboration. Under this agreement, the Company regained all rights to pimavanserin and received a one-time cash payment of \$8.75 million. As a result of the conclusion of the collaboration pursuant to this agreement, during the fourth quarter of 2010, the Company recorded an aggregate of \$34.7 million in revenue, consisting of the \$8.75 million cash payment and recognition of \$25.9 million of deferred revenue remaining from this collaboration. The Company has no ongoing involvement with or future obligations to Biovail and will no longer recognize revenue from this collaboration. The Company recognized revenues relating to the Biovail collaboration of \$39.5 million and \$4.6 million during the years ended December 31, 2010 and 2009, respectively. At December 31, 2009, \$26.1 million of revenue was deferred under this agreement, of which \$5.3 million was included in current liabilities and \$20.8 million was included in long-term liabilities. At December 31, 2010, the Company had no deferred revenue balance related to this collaboration.

In March 2009, the Company entered into a collaboration and license agreement with Meiji Seika Kaisha, Ltd. (“Meiji Seika”) to develop and commercialize a novel class of pro-cognitive drugs to treat patients with schizophrenia in Japan and several other Asian countries. Under the agreement, the Company is eligible to receive up to \$25 million in aggregate payments, including \$3 million in license fees and up to \$22 million in

## ACADIA PHARMACEUTICALS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

potential development and regulatory milestone payments, in addition to royalties on product sales, if any, in the Asian territory. Meiji Seika also is responsible for the first \$15 million of development expenses, of which approximately \$1.1 million had been incurred through December 31, 2010. The companies will share remaining expenses through clinical proof-of-concept, subject to possible adjustment in the event the Company further licenses the program outside of the licensed Asian territory. Meiji Seika is responsible for all costs associated with the development, manufacturing and commercialization of the product candidate in the Asian territory. Meiji Seika is eligible to share a portion of any product-related revenues received by the Company in the rest of the world. Payments received from Meiji Seika for license fees and the reimbursement of specified development costs have been deferred and are being recognized as revenue using a contingency-adjusted performance model over the estimated period of the Company's performance. The Company recognized revenues relating to this collaboration of \$472,000 and \$161,000 during the years ended December 31, 2010 and 2009, respectively. At December 31, 2010, \$3.0 million of revenue was deferred under this agreement, of which \$362,000 was included in current liabilities and \$2.6 million was included in long-term liabilities. At December 31, 2009, \$2.0 million of revenue was deferred under this agreement, of which \$215,000 was included in current liabilities and \$1.8 million was included in long-term liabilities.

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 that has been extended by the parties through March 2011. As of December 31, 2010, the Company had received an aggregate of \$17.4 million under the agreement, consisting of an upfront payment, research funding and related fees. The Company also may receive license fees and milestone payments as well as royalties on future product sales worldwide, if any. The Company recognized \$1.0 million in revenue related to this agreement during each of the years ended December 31, 2010, 2009, and 2008.

In July 1999, the Company entered into a collaboration agreement with Allergan to discover, develop and commercialize drugs for the treatment of glaucoma. Under the agreement, the Company provided its drug discovery expertise to enable the selection by Allergan of a product candidate for development and commercialization. Allergan was granted exclusive worldwide rights to products based on this product candidate for the treatment of ocular disease. As of December 31, 2010, the Company had received an aggregate of \$9.4 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, 2010, 2009, and 2008 totaled \$45,000, \$50,000, and \$23,000, respectively.

In September 1997, the Company entered into a collaboration agreement with Allergan focused primarily on the discovery and development of new therapeutics for pain and ophthalmic indications. This agreement was subsequently amended in conjunction with the execution of the March 2003 collaboration. 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, 2010 under this agreement. The Company is also eligible to receive additional milestone payments 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 the Company. The Company recognized no revenue under this agreement during the years ended December 31, 2010, 2009, and 2008.

#### **8. Restructurings**

In October 2009, the Company implemented a restructuring designed to further streamline its operations, reduce its internal operating expenses, and extend its cash runway. In connection with the restructuring, the

## ACADIA PHARMACEUTICALS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Company reduced its total workforce by about half. The Company provided cash severance payments, continuation of benefits and outplacement services to employees directly affected by the workforce reductions. The Company incurred charges of \$1.3 million in connection with the workforce reductions, of which \$905,000 is included in research and development expenses and \$382,000 is included in general and administrative expenses in the statement of operations for the year ended December 31, 2009. As of December 31, 2009, the Company had accrued remaining restructuring costs totaling \$719,000, which amount was included in accrued compensation and benefits (Note 5).

In August 2008, the Company implemented a restructuring designed to focus resources on its most advanced product candidates and provide additional financial flexibility and strength. In connection with the restructuring, the Company reduced its total workforce by about half. The Company provided cash severance payments, continuation of benefits and outplacement services to employees directly affected by the workforce reductions. The Company incurred charges of approximately \$2.1 million in connection with the workforce reductions, of which \$1.7 million is included in research and development expenses and \$454,000 is included in general and administrative expenses in the statement of operations for the year ended December 31, 2008.

There have been no significant changes in estimates or reversals of amounts previously accrued for either of these restructurings. The Company had paid all of the restructuring costs as of December 31, 2010.

#### **9. Stockholders' Equity**

##### ***Committed Equity Financing Facility***

In August 2008, the Company entered into a Committed Equity Financing Facility ("CEFF") with Kingsbridge Capital Limited that provides the Company with access, at its discretion, to capital during a three-year period through the sale of newly-issued shares of the Company's common stock. Pursuant to its terms, the CEFF will expire in August 2011. The funds that can be raised under the CEFF will depend on the then-current price of the Company's common stock and the number of shares actually sold, which may not exceed an aggregate of approximately 7 million shares. The aggregate amount raised under the CEFF may not exceed \$60 million. The Company may access capital under the CEFF in tranches of up to a maximum of between 2.0 and 3.5 percent of its market capitalization at the time of the draw down of each tranche, subject to certain conditions, including a minimum share price threshold of \$0.90. The shares would be sold at discounts ranging from 6 percent to 12 percent, depending on the average market price of the Company's common stock during the applicable pricing period. As of December 31, 2010, the Company had raised \$1.9 million through the issuance of 1.7 million shares of its common stock pursuant to the CEFF.

##### ***Warrants***

In connection with the CEFF, the Company issued a warrant to Kingsbridge in August 2008 to purchase 350,000 shares of common stock at an exercise price of \$3.915 per share. The warrant is exercisable through February 2014, subject to certain exceptions. The warrant's value of \$576,000 was determined on the date of grant using the Black-Scholes model with the following assumptions: risk free interest rate of 3.23 percent, volatility of 74.33 percent, a 5.5 year term and no dividend yield. This warrant was recorded as a component of stockholders' equity with an equal offsetting amount to stockholders' equity because the value of the warrant is considered a financing cost. In August 2009, Kingsbridge exercised the warrant with respect to 130,000 shares, and 220,000 shares remain outstanding as of December 31, 2010. In addition, the Company had warrants outstanding at December 31, 2010 to purchase an aggregate of 74,073 shares of its common stock that were issued in connection with a secured promissory note in 2002. These warrants have an exercise price of \$8.10 per share and will expire in May 2012.

**ACADIA PHARMACEUTICALS INC.**

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

**Stock Option Plans**

The Company's 2010 Equity Incentive Plan (the "2010 Plan") became effective upon approval of the stockholders in June 2010. The 2010 Plan permits the grant of options to directors, officers, other employees, and consultants. In addition, the 2010 Plan permits the grant of stock bonuses, rights to purchase restricted stock, and other stock awards. The exercise price of options granted under the 2010 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 2010 Plan generally vest over a four-year period. All shares that remained eligible for grant under the Company's 2004 Equity Incentive Plan (the "2004 Plan") at the time of approval of the 2010 Plan were transferred to the 2010 Plan. The 2010 Plan share reserve also has been, and may be, increased by the number of shares that otherwise would have reverted to the 2004 Plan reserve after June 2010. At December 31, 2010, there were 8,314,234 shares of common stock authorized for issuance and 3,992,574 shares of common stock available for new grants under the 2010 Plan.

The 2004 Plan became effective upon the closing of the Company's initial public offering in June 2004. The 2004 Plan provided for the grant of options to directors, officers, other employees, and consultants. The exercise price of options granted under the 2004 Plan was at 100 percent of the fair market value of the common stock on the date of grant and the maximum term of any option was ten years. Options granted under the 2004 Plan generally vested over a four-year period.

The Company's 1997 stock option 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 prior to the Company's initial public offering. 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 vested over a four-year period. Stock option transactions under the 2010 Plan, 2004 Plan and 1997 Plan during the years ended December 31, 2010, 2009, and 2008 are presented below:

	<u>Number of Shares</u>	<u>Weighted- Average Exercise Prices</u>	<u>Weighted Average Remaining Contractual Term</u>
<b>Outstanding at December 31, 2007</b> .....	2,811,343	\$7.46	
Granted .....	1,360,434	\$5.09	
Exercised .....	(70,548)	\$2.66	
Canceled/forfeited .....	<u>(547,595)</u>	<u>\$9.21</u>	
<b>Outstanding at December 31, 2008</b> .....	3,553,634	\$6.37	
Granted .....	537,086	\$1.47	
Exercised .....	(62,189)	\$1.20	
Canceled/forfeited .....	<u>(773,085)</u>	<u>\$4.58</u>	
<b>Outstanding at December 31, 2009</b> .....	3,255,446	\$6.09	
Granted .....	1,760,382	\$1.44	
Exercised .....	(10,820)	\$1.01	
Canceled/forfeited .....	<u>(689,910)</u>	<u>\$6.70</u>	
<b>Outstanding at December 31, 2010</b> .....	<u>4,315,098</u>	<u>\$4.11</u>	7.0
Vested and expected to vest at December 31, 2010 .....	<u>4,094,623</u>	<u>\$4.24</u>	6.9
Exercisable at December 31, 2010 .....	<u>2,446,730</u>	<u>\$5.87</u>	5.5

**ACADIA PHARMACEUTICALS INC.**

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

At December 31, 2010, 2009, and 2008, there were 2,446,730, 2,311,808, and 2,013,495 options exercisable, respectively.

The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2010 is calculated as the difference between the exercise price of the underlying options and the closing market price of the Company's common stock of \$1.20 on that date. The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2010 was \$45,000. The aggregate intrinsic value of options exercised during the years ended December 31, 2010, 2009, and 2008 was approximately \$4,000, \$186,000, and \$380,000, respectively, determined as of the date of exercise. The Company received \$11,000 in cash from options exercised during the year ended December 31, 2010.

The weighted average fair value of options granted during the years ended December 31, 2010, 2009, and 2008 was approximately \$1.13, \$1.07, and \$3.21, respectively. As of December 31, 2010, total unrecognized compensation cost related to stock options and purchase rights was approximately \$1.9 million, and the weighted average period over which this cost is expected to be recognized is 2.3 years.

The following table summarizes information about stock options outstanding at December 31, 2010:

<u>Options Outstanding</u>				<u>Options Exercisable</u>	
<u>Range of Exercise Prices</u>	<u>Number of Shares</u>	<u>Weighted-Average Remaining Contractual Life</u>	<u>Weighted-Average Exercise Price</u>	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price</u>
\$ 0.95–\$ 1.35	1,163,213	7.5	\$1.22	533,672	\$1.15
\$ 1.36–\$ 1.80	1,059,250	8.6	\$1.55	84,875	\$1.51
\$ 1.81–\$ 4.00	682,455	7.2	\$2.24	489,697	\$2.23
\$ 4.01–\$ 6.95	370,176	4.9	\$6.69	360,546	\$6.69
\$ 6.96–\$ 8.50	490,345	5.8	\$8.28	433,724	\$8.27
\$ 8.51–\$12.00	302,685	4.3	\$9.59	302,685	\$9.59
\$12.01–\$15.43	246,974	5.3	\$14.98	241,531	\$14.98
	<u>4,315,098</u>		\$4.11	<u>2,446,730</u>	\$5.87

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 model with the following assumptions for the year ended December 31, 2010: dividend yield of 0 percent; volatility of 74 to 76 percent; risk free interest rate of 3 to 4 percent and remaining contractual life of 7 to 9 years. For the year ended December 31, 2009, the following assumptions were used: dividend yield of 0 percent; volatility of 76 percent; risk free interest rate of 3 to 4 percent and remaining contractual life of 7 to 8 years. For the year ended December 31, 2008, the following assumptions were used: dividend yield of 0 percent; volatility of 72 to 76 percent; risk free interest rate of 2 to 4 percent and remaining contractual life of 7 to 9 years. During the years ended December 31, 2010, 2009, and 2008, in connection with the grant of stock options to non-employees, the Company recorded expense (benefit) of \$6,000, \$16,000, and (\$39,000), 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 in June 2004. The Purchase Plan includes an "evergreen"

## ACADIA PHARMACEUTICALS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 925,000 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, 2010, 2009, and 2008, 81,032, 176,785, and 71,937 shares of common stock were issued at average prices of \$0.81, \$1.09, and \$4.83 under the Purchase Plan, respectively. The weighted average fair value of purchase rights granted during the years ended December 31, 2010, 2009, and 2008 was \$0.42, \$1.09, and \$1.49, respectively. During the years ended December 31, 2010, 2009, and 2008, the Company recorded cash received from the exercise of purchase rights of \$65,000, \$193,000, and \$348,000, respectively.

#### *Common Stock Reserved For Future Issuance*

At December 31, 2010, 4,315,098 and 294,073 shares of common stock were reserved for issuance upon the exercise of stock options and warrants, respectively.

#### **10. 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 \$133,000, \$271,000, and \$458,000 for the years ended December 31, 2010, 2009 and 2008, respectively.

#### **11. Income Taxes**

At December 31, 2010, the Company had both federal and state net operating loss ("NOL") carryforwards of approximately \$283.4 million and \$214.2 million, respectively. The federal and state NOL carryforwards begin to expire in 2012 and 2016, respectively. The Company has \$7.3 million of federal research and development ("R&D") credit carryforwards that will begin to expire in 2012. In addition, the Company has \$3.6 million of state R&D credit carryforwards that have no expiration date. The Company also has foreign NOL carryforwards of approximately \$5.2 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.

**ACADIA PHARMACEUTICALS INC.**

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

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 authoritative accounting guidance. 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 with no net effect on income tax expense or the effective tax rate.

Approximately \$2.6 million of the NOL carryforwards relate 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.

The components of the deferred tax assets are as follows:

	2010	2009
	(in thousands)	
NOL carryforwards .....	\$ 108,805	\$ 108,567
R&D credit carryforwards .....	9,604	9,257
Deferred revenue .....	1,189	11,196
Capitalized R&D .....	6,250	3,412
Other .....	3,674	3,325
	129,522	135,757
Valuation allowance .....	(129,522)	(135,706)
	\$ —	\$ 51

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 in 2010. The valuation allowance decreased by approximately \$6.2 million in 2010 primarily due to the reversal of deferred tax assets used to offset 2010 net income.

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

	2010	2009	2008
	(in thousands)		
Amounts computed at statutory federal rate .....	\$ 5,144	\$(15,238)	\$(21,868)
Permanent differences, including stock-based compensation .....	274	333	1,131
Federal R&D credits .....	(350)	(1,237)	(1,687)
Change in valuation allowance .....	(6,080)	18,809	25,971
State taxes .....	972	(2,499)	(3,488)
Foreign taxes .....	108	(99)	(87)
Other .....	(56)	220	(46)
	\$ 12	\$ 289	\$ (74)

**ACADIA PHARMACEUTICALS INC.**

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

The net income tax expense (benefit) for the years ended December 31, 2010, 2009 and 2008 are recorded in the Company's statement of operations in general and administrative expenses. The Company's policy is to recognize interest and penalties, if any, as a component of income tax expense.

The tax years 1997-2010 remain open to examination by the major taxing jurisdictions to which the Company is subject.

**12. Commitments and Contingencies**

The Company and its Swedish subsidiary lease 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 primary U.S. lease provides for early termination.

Future noncancelable minimum payment obligations under operating lease arrangements are as follows at December 31, 2010:

<u>Year Ending</u>	<u>(in thousands)</u>
2011 .....	\$1,807
2012 .....	1,738
2013 .....	1,089
2014 .....	1,089
Thereafter .....	<u>1,542</u>
	<u>\$7,265</u>

Rent expense was \$2.0 million, \$2.5 million, and \$2.6 million for the years ended December 31, 2010, 2009, and 2008, 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 entered into agreements with contract research organizations and other external service providers for services in connection with the development of its product candidates. The Company was contractually obligated for up to approximately \$8.7 million of future services under these agreements as of December 31, 2010. 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 progress and results of the underlying studies.

In November 2006, the Company entered into an agreement with the Ipsen Group pursuant to which it licensed certain intellectual property rights that complement its patent portfolio. If certain conditions are met, the Company would be required to make future payments, including milestones, sublicensing fees and royalties. The amount of potential future milestones payments is \$10.5 million in the aggregate, which amount would be offset by any sublicensing fees the Company may pay under the agreement. Because these milestone payments would only be payable upon the achievement of specified regulatory events and it is uncertain when, or if, such events will occur, the Company cannot forecast with any degree of certainty when, or if, it will be required to make payments under the agreement.



**ACADIA PHARMACEUTICALS INC.**

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

**13. Subsequent Events**

In January 2011, the Company raised net proceeds of \$13.8 million from the sale of approximately 12.6 million units at a price of \$1.19375 per unit to a select group of institutional investors in a private equity financing. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.35 shares of common stock. The warrants have an exercise price per share equal to \$1.38 and are exercisable beginning in July 2011 through January 2018. The common stock and warrants issued in this financing are not included in basic or diluted common shares outstanding as of December 31, 2010.

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

<u>2010</u>	<u>March 31,</u>	<u>June 30,</u>	<u>September 30,</u>	<u>December 31, (1)</u>
	(in thousands, except per share data)			
Revenues .....	\$ 2,133	\$ 2,297	\$ 2,301	\$35,404
Net income (loss) .....	\$ (5,487)	\$ (4,288)	\$ (4,227)	\$29,141
Net income (loss) loss per common share, basic .....	\$ (0.14)	\$ (0.11)	\$ (0.11)	\$ 0.74
Net income (loss) loss per common share, diluted .....	\$ (0.14)	\$ (0.11)	\$ (0.11)	\$ 0.74
 <u>2009</u>	 <u>March 31,</u>	 <u>June 30,</u>	 <u>September 30,</u>	 <u>December 31,</u>
Revenues .....	\$ 374	\$ 1,820	\$ 2,435	\$ 1,769
Net loss .....	\$(15,001)	\$(12,728)	\$(8,728)	\$(8,688)
Net loss per common share, basic and diluted .....	\$ (0.40)	\$ (0.34)	\$ (0.23)	\$ (0.23)

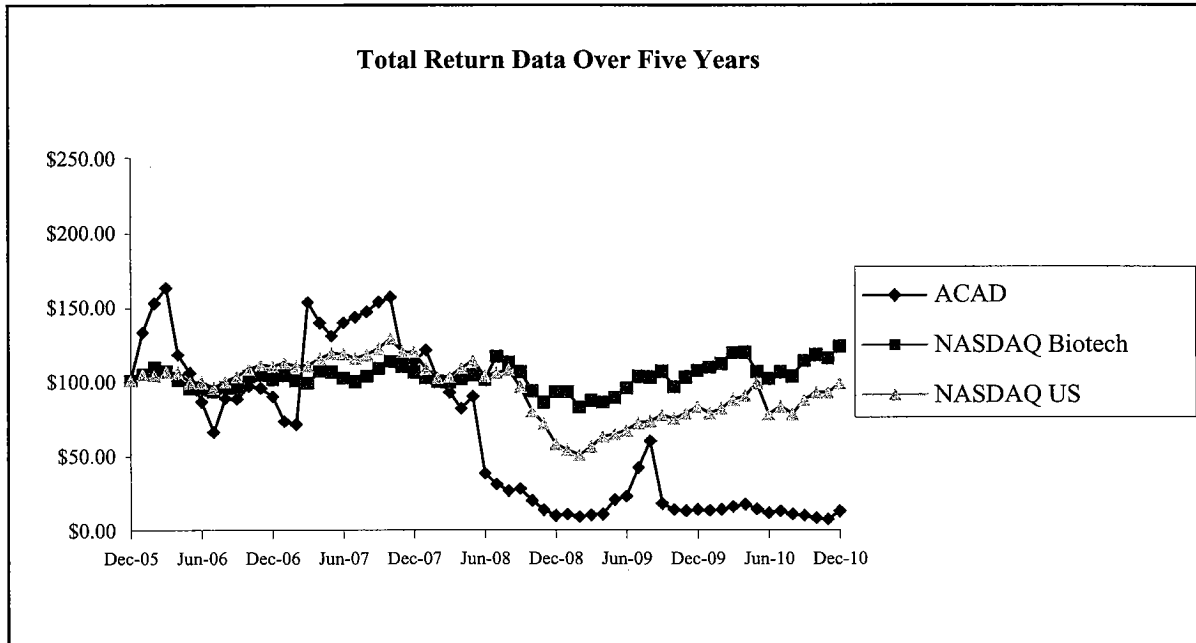
(1) As described in Note 7, during the fourth quarter of 2010, the Company ended its collaboration agreement with Biovail. In connection with concluding this collaboration, the Company recognized \$34.7 million in revenues during the fourth quarter of 2010, which resulted in the Company reporting net income for the fourth quarter and year ended December 31, 2010.

Revenues and net loss are rounded to thousands each quarter. Therefore, the sum of the quarterly amounts may not equal the annual amounts reported. Net income (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 income (loss) per common share amounts may not equal the annual amounts reported.

## PERFORMANCE MEASUREMENT COMPARISON

*The material in this section is not "soliciting material," is not deemed "filed" with the United States Securities and Exchange Commission, and is not to be incorporated into any filing of ACADIA Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language contained in such filing.*

The following graph shows a comparison of the total cumulative returns of an investment of \$100 in cash from December 30, 2005 through December 31, 2010 in (i) our common stock, (ii) the Nasdaq Biotechnology Index, and (iii) the Nasdaq Stock Market U.S. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of the possible future performance of our common stock. The graph assumes that all dividends have been reinvested (to date, we have not declared any dividends).



# CORPORATE INFORMATION

## EXECUTIVE OFFICERS

### **Uli Hacksell, Ph.D.**

Chief Executive Officer and Director

### **Thomas H. Aasen**

Executive Vice President, Chief Financial Officer and Chief Business Officer

### **Glenn F. Baity**

Vice President, General Counsel, Secretary

### **Roger G. Mills, M.D.**

Executive Vice President, Development

## BOARD OF DIRECTORS

### **Leslie L. Iversen, Ph.D.**

Chairman of the Board  
Professor of Pharmacology  
University of Oxford, England

### **Michael T. Borer**

Former Chief Executive Officer and President, Xcel Pharmaceuticals, Inc.

### **Laura A. Brege**

Executive Vice President  
Onyx Pharmaceuticals, Inc.

### **Mary Ann Gray, Ph.D.**

President  
Gray Strategic Advisors, LLC

### **Uli Hacksell, Ph.D.**

Chief Executive Officer  
ACADIA Pharmaceuticals Inc.

### **Lester J. Kaplan, Ph.D.**

Former Executive Vice President and President, Research and Development, Allergan, Inc.

### **Torsten Rasmussen**

President and Chief Executive Officer  
Morgan Management ApS

## CORPORATE HEADQUARTERS

ACADIA Pharmaceuticals Inc.  
3911 Sorrento Valley Blvd.  
San Diego, CA 92121  
Telephone: (858) 558-2871  
Fax: (858) 558-2872  
www.acadia-pharm.com

## COMMON STOCK LISTING

Ticker Symbol: ACAD, The Nasdaq Global Market

## ANNUAL STOCKHOLDERS' MEETING

ACADIA Pharmaceuticals' Annual Stockholders' Meeting will be held on Friday, June 10, 2011 at the offices of Cooley LLP at 4401 Eastgate Mall, San Diego, CA.

## STOCK TRANSFER AGENT AND REGISTRAR

BNY Mellon Shareowner Services  
480 Washington Boulevard  
Jersey City, NJ 07310-1900  
Telephone: (800) 851-3061  
www.bnymellon.com/shareowner/equityaccess

## COMPANY COUNSEL

Cooley LLP  
4401 Eastgate Mall  
San Diego, CA 92121-1909

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PricewaterhouseCoopers LLP  
5375 Mira Sorrento Place, Ste. 300  
San Diego, CA 92121

## STOCKHOLDERS' INQUIRIES

Stockholders may obtain copies of our news releases, Securities and Exchange Commission filings, including Forms 10-K, 10-Q, and 8-K, and other company information by accessing our website at [www.acadia-pharm.com](http://www.acadia-pharm.com). Stockholders may also contact Investor Relations at (858) 558-2871.

## FORWARD-LOOKING STATEMENTS

Statements in this report that are not strictly historical in nature are forward-looking statements. These statements include but are not limited to statements related to the progress and timing of our drug development programs and related trials, the utility, safety and efficacy of our product candidates, any future clinical trials, and our future results. These statements are only predictions representing ACADIA's expectations and beliefs as of the date this report was prepared based on current information. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in drug discovery, development and commercialization and the risk that past results of clinical trials may not be indicative of future results. For a discussion of these and other factors, please refer to ACADIA's Annual Report on Form 10-K for the year ended December 31, 2010, as well as other subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and ACADIA undertakes no obligation to revise or update this report to reflect future events or circumstances.



ACADIA  
Pharmaceuticals

ACADIA PHARMACEUTICALS INC.  
3911 SORRENTO VALLEY BLVD., SAN DIEGO, CA 92121  
[www.acadia-pharm.com](http://www.acadia-pharm.com)