

ACADIA PHARMACEUTICALS INC

Form 10-K

March 10, 2011

[Table of Contents](#)

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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 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)

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Delaware
(State or Other Jurisdiction of

06-1376651
(I.R.S. Employer

Incorporation or Organization)

Identification Number)

3911 Sorrento Valley Boulevard

San Diego, California
(Address of Principal Executive Offices)

92121
(Zip Code)

Registrant's telephone number, including area code:

(858) 558-2871

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

Title of each class	Name of each exchange on which registered
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 ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Accelerated filer ☐
Smaller reporting company ☒

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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.

Table of Contents

ACADIA PHARMACEUTICALS INC.

TABLE OF CONTENTS

FORM 10-K

For the Year Ended December 31, 2010

INDEX

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

Table of Contents

PART I

FORWARD-LOOKING STATEMENTS

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

Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plans, in estimates, could, should, would, continue, seeks, aims, projects, predicts, pro forma, anticipates, potential or other similar use in the negative), or by discussions of future matters such as the development of 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

Table of Contents

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-XXYY. 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.

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We maintain a website at 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.

Table of Contents

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

Table of Contents

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_{2A} 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

Table of Contents

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_{2A} 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

Table of Contents

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

Table of Contents

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:

Product Candidate	Indication	Stage of Development	Commercialization Rights
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_{2A} 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.

Table of Contents

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.

Table of Contents

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_{2A} 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.

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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.

Table of Contents

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.

Table of Contents

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,

Table of Contents

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.

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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.

Table of Contents

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.

Table of Contents

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

identifying and validating targets;

screening compounds against targets;

preclinical and clinical trials of potential pharmaceutical products; and

obtaining FDA and other regulatory clearances.

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

capital resources;

research and development resources;

manufacturing capabilities; and

sales and marketing.

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

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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

Table of Contents

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, warnin