ACADIA PHARMACEUTICALS INC
Form 10-K
February 29, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Form 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015

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	06-1376651
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

3611 Valley Centre Drive, Suite 300

San Diego, California	92130
(Address of Principal Executive Offices)	(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 Select 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 x 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 x

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 x 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 x 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. x

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 x	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 x

As of June 30, 2015, 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 $2.6 billion, based on the closing price of the registrant s common stock on the NASDAQ Global Select Market on June 30, 2015 of $41.88 per share.

As of January 29, 2016, 112,636,457 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 April 29, 2016 are incorporated by reference into Part III of this report.

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FORM 10-K

For the Year Ended December 31, 2015

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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 simil 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 and cause our results to differ materially from those expressed or implied by our forward-looking statements. 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.***

Company Overview

We are a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. We have a portfolio of product opportunities led by our novel drug candidate, NUPLAZID™ (pimavanserin), for which we have reported positive Phase III pivotal trial results in Parkinson s disease psychosis, or PDP, and which has the potential to be the first drug approved in the United States for this condition. NUPLAZID is a selective serotonin inverse agonist, or SSIA, preferentially targeting 5-HT_{2A} receptors. Through this novel mechanism, NUPLAZID has demonstrated significant efficacy in Parkinson s disease psychosis in our Phase III pivotal trial and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved for use in PDP patients. We hold worldwide commercialization rights to pimavanserin.

We are pursuing Parkinson s disease psychosis as our lead indication for NUPLAZID. In September 2015, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for NUPLAZID for the treatment of psychosis associated with Parkinson s disease, which was accepted for priority review by the FDA on October 30, 2015 with a Prescription Drug User Fee Act, or PDUFA, goal date of May 1, 2016. In January 2016, we announced that the FDA s Psychopharmacologic Drugs Advisory Committee will review data included in the NDA for NUPLAZID. At the Advisory Committee meeting, scheduled for March 29, 2016, the Advisory Committee will discuss and advise the FDA on the risk-benefit profile of NUPLAZID for the treatment of PDP. In September 2014, we announced that the FDA granted Breakthrough Therapy designation for NUPLAZID for the treatment of Parkinson s disease psychosis. The Breakthrough Therapy designation was created to expedite the development and review of drugs that are intended to treat serious or life-threatening

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conditions. If approved, we intend to commercialize NUPLAZID for Parkinson s disease psychosis in the United States by establishing a specialty sales force focused primarily on physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians.

Our NDA submission is based on data from a comprehensive development program assessing the safety and efficacy of NUPLAZID for Parkinson s disease psychosis. The NDA includes data from the pivotal Phase III -020 Study, in which NUPLAZID met all primary and secondary endpoints with statistical significance, along with supportive data from other studies with NUPLAZID. In the -020 Study, NUPLAZID significantly reduced psychosis compared to placebo in patients with Parkinson s disease psychosis with no worsening of motor function. These results were further supported by significant improvements in all secondary efficacy measures and by significant benefits in exploratory efficacy measures of nighttime sleep, daytime wakefulness and caregiver burden.

We believe that pimavanserin has the potential to address important unmet medical needs in neurological and psychiatric disorders beyond PDP and we plan to continue to study the use of pimavanserin in multiple disease states. We believe Alzheimer s disease represents one of our most important opportunities for further exploration. We are currently conducting a Phase II study exploring the utility of pimavanserin for the treatment of Alzheimer s disease psychosis, or ADP, a disorder for which no drug is currently approved by the FDA, and expect to complete enrollment of this study around mid-year 2016 and have top-line results of the study in the fourth quarter of 2016. We also plan to initiate a Phase II study in Alzheimer s disease agitation in the first half of 2016. We also believe that schizophrenia represents a disease with multiple unmet or ill-served needs and we are currently evaluating the most attractive development opportunities there. We have successfully completed a Phase II study of pimavanserin in the treatment of schizophrenia where we observed significant anti-psychotic effects when pimavanserin was co-administered with a low dose of risperidone, a generic drug currently approved for the treatment of schizophrenia.

We were originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. We reincorporated in Delaware in 1997 and our headquarters are in San Diego, California. 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 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.

We own or have rights to various trademarks, copyrights and trade names used in our business, including ACADIA® and NUPLAZID . 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 endorsement or sponsorship of us, by the trademark or trade dress owners.

Recent Events

In January 2016, we raised net proceeds of approximately $281.6 million from the sale of 10,344,827 shares of our common stock in a follow-on public offering.

In September 2015, we submitted an NDA to the FDA for NUPLAZID for the treatment of psychosis associated with Parkinson s disease. The NDA has been accepted for priority review by the FDA with a PDUFA goal date of May 1, 2016. In January 2016, we announced that the FDA s Psychopharmacologic Drugs Advisory Committee will review data included in the NDA for NUPLAZID. At the Advisory Committee meeting, scheduled for March 29, 2016, the Advisory Committee will discuss and advise the FDA on the risk-benefit profile of NUPLAZID for the treatment of PDP.

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Our Strategy

Our strategy is to discover, develop and commercialize innovative small molecule drugs that address unmet medical needs in central nervous system disorders. We have assembled a management team with significant industry experience to lead the discovery, development, and commercialization of our product opportunities. We complement our management team with scientific and clinical advisors, including recognized experts in the fields of Parkinson s disease psychosis, Alzheimer s disease, schizophrenia, and other central nervous system disorders. Key elements of our strategy are to:

Commercialize our lead product candidate, NUPLAZID, for Parkinson s disease psychosis. In September 2015, we submitted an NDA to the FDA for NUPLAZID for the treatment of psychosis associated with Parkinson s disease, which has been accepted for priority review by the FDA with a PDUFA goal date of May 1, 2016. If approved, NUPLAZID would be the first drug approved by the FDA for the treatment of Parkinson s disease psychosis. If approved, we intend to commercialize NUPLAZID for this indication in the United States by establishing a specialty sales force focused primarily on physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians. Outside of the United States, we may choose to commercialize NUPLAZID in selected markets by establishing one or more strategic alliances.

Leverage the commercial potential of pimavanserin by expanding to additional neurological and psychiatric disorders. We intend to pursue the development and commercialization of pimavanserin in additional neurological and psychiatric indications that are underserved by currently available antipsychotics and represent large unmet medical needs. In the second quarter of 2015, we initiated a significant life cycle planning project to assess and prioritize other medically important and attractive development opportunities for pimavanserin. In addition to the ongoing development of pimavanserin in Alzheimer s disease psychosis, we plan to initiate a Phase II study in Alzheimer s disease agitation in the first half of 2016. In addition, we have completed a Phase II study in schizophrenia and through our life cycle planning are assessing various areas of large unmet need in schizophrenia. We will also consider other indications that are a good strategic fit and which have large unmet medical needs.

Seek to in-license or acquire complementary products or product candidates. Although all of the product opportunities currently in our pipeline, including NUPLAZID (pimavanserin) emanate from internal discoveries, in the future we may in-license or acquire assets, which could include clinical-stage product candidates or commercial-stage products, to leverage the sales force that we intend to establish.

Continue to develop our other product candidates for the treatment of central nervous system and related disorders. We plan to continue developing other product candidates. While our resources are currently focused on the development and commercialization of pimavanserin, we plan to pursue additional product candidates in the future. These may be directed at neurological and related central nervous system disorders and may be developed independently or in partnerships. We believe that a diversified portfolio will mitigate risks inherent in drug development and increase the likelihood of our success.

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Our Product Candidates and Programs

Our portfolio of product opportunities includes product opportunities being explored in clinical development and in advanced preclinical testing. We believe that our product opportunities offer innovative therapeutic approaches and may provide significant advantages relative to current therapies. The following table summarizes our product opportunities and programs:

NUPLAZID (Pimavanserin)

Pimavanserin is a new chemical entity that we discovered and that has successfully completed Phase III development, positioning it to be potentially the first drug approved in the United States for the treatment of Parkinson s disease psychosis. During 2014, the FDA provisionally accepted NUPLAZID as the trade name for pimavanserin. NUPLAZID (pimavanserin) is a selective serotonin inverse agonist preferentially targeting the 5-HT_{2A} receptor, a key serotonin receptor that plays an important role in psychosis. Through this novel mechanism, NUPLAZID has demonstrated significant efficacy in Parkinson s disease psychosis in our Phase III pivotal trial and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved for use in PDP patients. We hold worldwide commercialization rights to NUPLAZID (pimavanserin) for all indications and have established a broad patent portfolio, which includes numerous issued patents in the United States, Europe, and several additional countries.

In September 2015, we submitted an NDA to the FDA for NUPLAZID for the treatment of psychosis associated with Parkinson s disease, which was accepted for priority review by the FDA on October 30, 2015 with a PDUFA goal date of May 1, 2016. In January 2016, we announced that the FDA s Psychopharmacologic Drugs Advisory Committee will review data included in the NDA for NUPLAZID and will hold a meeting, scheduled for March 29, 2016, to discuss and advise the FDA on the risk-benefit profile of NUPLAZID for the treatment of PDP. In 2014, the FDA granted Breakthrough Therapy designation for NUPLAZID for the treatment of Parkinson s disease psychosis. The Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs that are intended to treat serious or life-threatening conditions. If approved, we intend to commercialize NUPLAZID for Parkinson s disease psychosis in the United States by establishing a specialty sales force focused primarily on physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians. We have established our core commercial team, and we are currently expanding our commercial organization in preparation for the planned future launch of NUPLAZID. During 2015, we expanded our existing infrastructure to support the planned launch and commercialization of NUPLAZID by adding to our commercial level manufacturing, field sales management, managed markets, medical affairs, quality control and compliance capabilities. In addition, we plan to hire a commercial sales force to coincide approximately with a NUPLAZID approval, if any. It is anticipated that the recommended dosing of NUPLAZID, if approved, will be two 17 mg tablets taken together once a day.

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NUPLAZID as a Treatment for Parkinson s Disease Psychosis

Parkinson s disease is the second most common neurodegenerative disorder after Alzheimer s disease. According to the National Parkinson Foundation, about one million people in the United States and between four to six million people globally suffer from this disease. Parkinson s disease is more common in people over 60 years of age and the prevalence of this disease is expected to increase significantly as the population ages.

Parkinson s disease psychosis is a debilitating disorder commonly characterized by visual hallucinations and delusions that afflicts about 40 percent of the one million Parkinson s disease patients in the United States. The development of psychosis in patients with Parkinson s disease substantially contributes to the burden of Parkinson s disease and deeply affects their quality of life. Parkinson s disease psychosis is associated with a diminished quality of life, nursing home placement, and increased caregiver stress and burden.

The FDA has not approved any drug to treat Parkinson s disease psychosis. Therefore, despite substantial limitations, physicians frequently resort to off-label use of currently marketed antipsychotic drugs, including Seroquel and clozapine, to treat patients with Parkinson s disease psychosis. These drugs are associated with a number of side effects, which can be especially problematic for elderly patients with Parkinson s disease.

The only currently marketed antipsychotic drug that has demonstrated efficacy in reducing psychosis in patients with Parkinson s disease without further impairing motor function is clozapine when given at low doses. Studies suggest that this unique clinical utility of low-dose clozapine arises from its potent blocking of a key serotonin receptor, a protein that responds to the neurotransmitter serotonin, known as the $5\text{-}HT_{2A}$ 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, routine use of clozapine is limited by safety concerns, including its potential to cause a rare, and potentially fatal, blood disorder that necessitates stringent blood monitoring. Currently, there is a large unmet medical need for new therapies that will effectively treat psychosis in patients with Parkinson s disease without compromising motor control or causing other serious side effects in this elderly and fragile patient population.

NUPLAZID provides an innovative, non-dopaminergic approach and, we believe, has the potential to be the first safe and effective drug that will treat Parkinson s disease psychosis without compromising motor control, thereby significantly improving the quality of life for patients with Parkinson s disease.

In November 2012, we announced successful top-line results from our pivotal Phase III -020 Study, evaluating the efficacy, tolerability, and safety of NUPLAZID in patients with Parkinson s disease psychosis. Results from the -020 Study were presented at the American Academy of Neurology Meeting in March 2013, and published in The Lancet, a peer-reviewed medical journal, in November 2013. The -020 Study was a multi-center, double-blind, placebo-controlled clinical trial. A total of 199 patients were enrolled in the study and randomized on a one-to-one basis to receive either 34 mg of NUPLAZID (the equivalent of 40mg of pimavanserin tartrate) or placebo once-daily for six weeks, following a two-week screening period that included brief psycho-social therapy. Patients also received stable doses of their existing anti-Parkinson s therapy throughout the study.

NUPLAZID met the primary endpoint in the -020 Study by demonstrating a highly significant reduction in psychosis ($p=0.001$) as measured using the SAPS-PD, a scale consisting of nine items from the hallucinations and delusions domains of the Scale for the Assessment of Positive Symptoms. These results were further supported by highly significant improvements in all secondary efficacy measures, including the Clinical Global Impression Severity, or CGI-S, scale ($p<0.001$), the Clinical Global Impression Improvement, or CGI-I, scale ($p=0.001$), and a CGI-I responder analyses ($p=0.008$). In addition, statistically significant benefits were observed in exploratory efficacy measures of nighttime sleep, daytime wakefulness and caregiver burden. Consistent with previous studies, data from the -020 Study indicate that NUPLAZID was safe and well tolerated. Importantly, NUPLAZID met the key secondary endpoint for motor tolerability as measured using Parts II and III of the

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Unified Parkinson s Disease Rating Scale, or UPDRS, suggesting NUPLAZID did not affect motor function when given together with the therapies patients in the study were taking to treat their Parkinson s motor symptoms. Three deaths occurred in the -020 Study, one in the placebo group and two in the pimavanserin group; all were regarded as unrelated to study drug. Two deaths occurred in our earlier completed Phase III study with pimavanserin for Parkinson s disease psychosis, which tested two active arms, 8.5 mg and 34 mg, of pimavanserin versus placebo on a 1-1-1 basis. There was one death in each of the 8.5 mg and 34 mg arms, each of which was regarded as unrelated to study drug.

We also are continuing to conduct our open-label safety extension study, referred to as the -015 Study, involving patients with Parkinson s disease psychosis who have completed the -020 Study and our earlier Phase III studies. The -015 Study, together with a similar extension study from our earlier Phase II Parkinson s disease psychosis trial, has generated a considerable amount of long-term safety data on NUPLAZID. A total of over 250 patients have been treated with NUPLAZID for at least one year, and of those at least 170 patients have been treated for at least two years. Our longest single-patient exposure is greater than 10 years. We believe that our experience to date suggests that long-term administration of NUPLAZID is generally safe and well tolerated in this elderly and fragile patient population.

Pimavanserin as a Treatment for Alzheimer s Disease Psychosis

According to the Alzheimer s Association, an estimated 5.3 million people in the United States have Alzheimer s disease, with only half being diagnosed, and it is currently the fifth leading cause of death for people age 65 and older. Studies have suggested that approximately 25 to 50 percent of patients diagnosed with Alzheimer s disease 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 increased institutionalization.

The FDA has not approved any drug to treat Alzheimer s disease psychosis. As symptoms progress and become more severe, physicians often resort to off-label use of antipsychotic medications in these patients. In addition to the long-term safety risks, studies have shown the use of atypical antipsychotics doubles the expected rate of cognitive deterioration among Alzheimer s disease patients. There is a large unmet medical need for a safe and effective therapy to treat the psychosis in patients with Alzheimer s disease.

We are in Phase II development with pimavanserin as a potential new treatment for Alzheimer s disease psychosis. Patients with Alzheimer s disease psychosis and Parkinson s disease psychosis share many characteristics and often exhibit similar psychiatric symptoms associated with their respective underlying neurodegenerative disease. We have shown that pimavanserin attenuates psychosis-related behaviors in preclinical models of Alzheimer s disease psychosis. In preclinical models, pimavanserin also has been shown to positively interact with cholinesterase inhibitors to enhance their pro-cognitive effect. Because of its selective mechanism of action and its efficacy and 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.

In November 2013, we initiated a Phase II trial, referred to as the -019 Study, to examine the efficacy and safety of pimavanserin as a treatment for Alzheimer s disease psychosis. The -019 Study is a randomized, double-blind, placebo-controlled study designed to enroll 200 patients with Alzheimer s disease psychosis. Following a screening period that includes brief psycho-social therapy, patients are randomized on a one-to-one basis to receive either 34 mg of pimavanserin (the equivalent of 40mg of pimavanserin tartrate) or placebo once-daily for twelve weeks. The -019 study will assess several key efficacy endpoints, including use of the Neuropsychiatric Inventory Nursing Home scale to measure psychosis and other behavioral disorders. Key efficacy endpoints will be based on the change at week 6 from baseline. The study will also assess additional exploratory endpoints, including the cognitive status of patients and the durability of response to pimavanserin, through twelve weeks of therapy. We expect to complete enrollment of this study around mid-year 2016.

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Pimavanserin as a Treatment for Alzheimer s Disease Agitation

While the diagnostic criteria for Alzheimer s disease focus mostly on the related cognitive deficits, it is the behavioral and neuropsychiatric symptoms that can be most troublesome for caregivers and lead to poor quality of life for patients. In addition to psychosis, these symptoms include agitation and aggressive behaviors. Alzheimer s disease agitation and aggression, or collectively AD agitation, is characterized by inappropriate verbal, vocal, or motor activity that can be independent of perceptible needs or confusion, and includes screaming, restlessness, wandering, and strange movements. Agitation and aggression in Alzheimer s disease patients are a major cause of acute care inpatient hospitalizations and pose a major challenge for patient care. Therefore, the detection, management, and treatment of these symptoms is critical to Alzheimer s disease patient care. Studies suggest that 40 to 50 percent of patients diagnosed with Alzheimer s disease in the United States exhibit AD agitation.

The FDA has not approved any drug for the treatment of agitation in Alzheimer s disease. Therefore, antipsychotics are frequently used off-label, despite their limited efficacy and associated long term safety risks. Preclinical and clinical studies suggest that blockade of the 5-HT_{2A} receptor is associated with decreased agitation and aggression. We believe pimavanserin s selective activity at the 5-HT_{2A} receptor may confer efficacy in AD agitation. In addition, pimavanserin s favorable side effect profile observed to date in treating elderly patients with PDP may make it an ideal therapy for AD agitation. We plan to initiate a Phase II study in AD agitation in the first half of 2016.

Pimavanserin as a Treatment for Schizophrenia

Schizophrenia is a severe chronic mental illness that involves disturbances in cognition, perception, emotion, and other aspects of behavior. The positive symptoms of schizophrenia include hallucinations and delusions, while the negative symptoms may manifest as loss of interest and emotional withdrawal. 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 schizophrenia. Antipsychotic drugs increasingly have been used by physicians to address a range of disorders in addition to schizophrenia, including 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.

Most schizophrenia patients in the United States today are treated with second-generation, or atypical, antipsychotics, which induce fewer motor disturbances than typical, or first-generation, 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, sleep disturbances, and motor disturbances. We believe that these side effects generally 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 2005, 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 improved side effect and efficacy profiles.

Pimavanserin s selective blockade of the 5-HT_{2A} receptor may enable it to be used in certain treatment approaches to improve the therapy for patients with schizophrenia. We published results in 2012 from an earlier multi-center, double-blind, placebo-controlled Phase II trial designed to evaluate pimavanserin as a co-therapy in

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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 efficacy comparable to that of a 6 mg, or standard, dose of risperidone, combined with a faster onset of antipsychotic action and an improved side effect profile, including significantly less weight gain, compared to the standard dose of risperidone. We are currently assessing areas of large unmet need in schizophrenia.

Adrenergic and Muscarinic Programs

In collaboration with Allergan, we have discovered 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. 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, 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.

Under our muscarinic collaboration with Allergan that terminated in 2015, we discovered small molecule product candidates for the treatment of glaucoma. Glaucoma is a chronic eye disease and is the second leading cause of blindness in the world. We identified a subtype of the muscarinic receptors that controls intraocular pressure and discovered lead compounds that selectively activate this target. In preclinical models, our product candidates have demonstrated a promising preclinical profile, including robust efficacy and a long duration of action. This program has reached Phase I development.

In November 2015, Allergan announced it entered into an agreement with Pfizer Inc. under which Pfizer will acquire Allergan. We do not know what impact, if any, Pfizer s acquisition of Allergan will have on our remaining chronic pain program with Allergan or Allergan s performance thereunder.

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, 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.

Even if we are successful in developing pimavanserin and gaining FDA approval of NUPLAZID, it would compete with a variety of established drugs in the areas of Parkinson s disease psychosis, Alzheimer s disease psychosis, Alzheimer s disease agitation, and schizophrenia. For example, NUPLAZID for the treatment of Parkinson s disease psychosis would compete with off-label use of antipsychotic drugs, including generic drugs quetiapine and clozapine.

Pimavanserin for Alzheimer s disease psychosis would compete with off-label use of antipsychotic drugs, including risperidone and quetiapine, and drugs indicated for the treatment of Alzheimer s disease and dementia in patients with Alzheimer s disease, including Aricept, marketed by Eisai Inc. and Pfizer Inc., and Namenda, marketed by Forest Laboratories, LLC, a wholly-owned subsidiary of Actavis. Pimavanserin for Alzheimer s disease agitation would compete with off-label use of antipsychotic drugs, including risperidone and quetiapine. Pimavanserin for the treatment of schizophrenia would compete with Rexulti, marketed by Otsuka Pharmaceutical Co., Ltd., Latuda, marketed by Sunovion Pharmaceuticals Inc., and generic drugs olanzapine, risperidone, aripiprazole and clozapine.

Our potential products for the treatment of chronic pain would compete with Lyrica, marketed by Pfizer Inc., and Cymbalta, marketed by Eli Lilly, as well as with a variety of generic or proprietary opioids. Currently,

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the leading drugs approved for chronic pain indications include Lyrica, the successor to Neurontin (gabapentin, now a generic drug), and Cymbalta, now generic in the United States.

Our potential products for the treatment of glaucoma would compete with Xalatan, marketed by Pfizer, and Lumigan and Alphagan, marketed by Allergan. Xalatan (latanoprost) is now generic.

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. Many of our competitors are using technologies or methods different or similar to ours 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 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 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 and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. 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, sales and marketing, 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. 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 effect on our business.

Intellectual Property

We currently hold 45 issued U.S. patents and 234 issued foreign patents. All of these patents originated from inventions made by us. In addition, we have 11 provisional and utility U.S. patent applications and 46 foreign patent applications.

Patents and other proprietary intellectual property 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 novel methods of screening and chemical synthetic methods, novel drug targets and novel compounds identified using our technology.

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We also rely upon trade secret rights to protect 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 by, among other things, requiring employees and third parties who have access to our proprietary information to sign confidentiality and nondisclosure 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, including pimavanserin. In connection with the FDA s acceptance of the filing of the NDA for NUPLAZID in the fourth quarter of 2015, we paid a $2.5 million milestone to Ipsen, adjusted for credits for prior payments made by us to Ipsen, pursuant to the terms of the 2006 license agreement. If the NDA is approved, an additional $8.0 million milestone would be payable to Ipsen pursuant to the terms of the 2006 license agreement. In addition, if we are able to successfully market and sell NUPLAZID, we would pay to Ipsen royalties of up to two percent of net product sales pursuant to the agreement. We are a party to various other license agreements that give us rights to use certain technologies in our research and development.

Pimavanserin

Twenty-two U.S. patents have been issued to us that provide protection for pimavanserin, including two that cover the compound generically and 13 that specifically cover pimavanserin, salts and polymorphs thereof, the use thereof for treating Parkinson s disease psychosis, Alzheimer s disease psychosis, Alzheimer s disease indications, schizophrenia, bipolar disorder, Lewy body disease, sleep disorders, and other methods of treatment. These patents also provide protection for certain methods of producing pimavanserin. 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. The patents that cover pimavanserin generically expire in 2021. Our estimation of the above patent terms includes patent term adjustments made by the U.S. Patent and Trademark Office, but not patent term extensions. These patent terms may be subject to change based on new interpretations of the law. We have 56 issued foreign patents that specifically cover pimavanserin, including patents in 38 European countries, Australia, Canada, China, Hong Kong, India, Japan, Mexico, New Zealand, Russia, Singapore and South Africa, which provide patent protection until 2024. We also have 53 issued foreign patents that cover polymorphs of pimavanserin and provide patent protection until 2025. 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.

Alpha Adrenergic Program

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.

Muscarinic Program

We have three U.S. patents that have been issued to us providing coverage for the compounds that were covered by our collaboration with Allergan for the treatment of glaucoma that terminated in 2015. These U.S. patents will expire in 2023. We have 51 issued foreign patents and 10 pending foreign applications that cover these compounds. The issued foreign patents for this program will expire in 2022 and 2025. In addition we have 14 U.S. and foreign patent applications recently filed covering additional compounds from the glaucoma collaboration.

Collaboration Agreements

Historically, we have been a party to various collaboration agreements with Allergan and other parties to leverage our drug discovery platform and related assets, and to advance development of and commercialize selected product candidates. These 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 future sales, if any, of drugs developed under the collaboration.

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In September 1997, we entered into a collaboration agreement with Allergan focused primarily on the discovery and development of new adrenergic therapeutics for pain and ophthalmic indications. This agreement, as amended, 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 payments, consisting of research funding and milestone payments, through December 31, 2015 under this agreement. We are eligible to receive additional milestone payments of up to $10.0 million in the aggregate upon the achievement of development and regulatory milestones as well as royalties on future net 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 term of this agreement with Allergan continues 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, our Allergan collaboration agreement includes a research term that is shorter but may be renewed if agreed to by the parties.

In November 2015, Allergan announced it entered into an agreement with Pfizer Inc. under which Pfizer will acquire Allergan. We do not know what impact, if any, Pfizer s acquisition of Allergan will have on our adrenergic program with Allergan or Allergan s performance thereunder.

Government Regulation

Our business activities, including 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, import, export, 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. Moreover, if our product candidates are approved by the FDA, government coverage and reimbursement policies will both directly and indirectly impact our ability to successfully commercialize our products, and such coverage and reimbursement policies will be impacted by recently enacted and any applicable future healthcare reform measures. In addition, we are subject to state and federal laws, including, among others, anti-kickback laws, false claims laws, data privacy and security laws, and transparency laws that restrict certain business practices in the pharmaceutical industry.

In the United States, drug product candidates intended for human use undergo laboratory and animal testing until adequate proof of safety is established. Clinical trials for new product candidates are then typically conducted in humans 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 an Investigational New Drug Application, or IND, to the FDA.

Regulatory authorities, Institutional Review Boards and Data Monitoring Committees may require additional data before allowing the clinical studies to commence, continue 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

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regulatory approval process for 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, or GCPs. Additionally, the manufacture of our drug product, must be done in accordance with current good manufacturing practices, or GMPs.

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 for which the product will be labeled. 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. Under applicable laws and FDA regulations, each NDA submitted for FDA approval is 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 eight months from submission for priority review of NDAs that cover product candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists, and 12 months from submission for the standard review of NDAs. However, the FDA is not legally required to complete its review within these periods, these performance goals may change over time and the review is often extended by FDA requests for additional information or clarification. Moreover, the outcome of the review, even if generally favorable, may not be an actual approval but a complete response letter that describes additional work that must be done before the NDA can be approved. Before approving an NDA, the FDA can choose to inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with GMPs. The FDA may also audit sites at which clinical trials have been conducted to determine compliance with GCPs and data integrity. The FDA s review of an NDA may also involve review and recommendations by an independent FDA advisory committee, particularly for novel indications, such as Parkinson s disease psychosis. The FDA is not bound by the recommendation of an advisory committee.

In addition, delays or rejections may be encountered based upon changes in regulatory policy, regulations or statutes governing product approval during the period of product development and regulatory agency review.

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 in the patient population that will be treated. In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless a waiver applies. 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 payment of significant annual fees and 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

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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.

In addition, as a condition of approval, the FDA may require an applicant to develop a risk evaluation and mitigation strategy, or REMS. A REMS uses risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

Any trade name that we intend to use for a potential product must be approved by the FDA irrespective of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA conducts a rigorous review of proposed product names, and may reject a product name if it believes that the name inappropriately implies medical claims or if it poses the potential for confusion with other product names. The FDA will not approve a trade name until the NDA for a product is approved. If the FDA determines that the trade names of other products that are approved prior to the approval of our potential products may present a risk of confusion with our proposed trade name, the FDA may elect to not approve our proposed trade name. If our trade name is rejected, we will lose the benefit of any brand equity that may already have been developed for this trade name, as well as the benefit of our existing trademark applications for this trade name.

We and our collaborators and contract manufacturers also are required to comply with the applicable FDA GMP regulations. GMP 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 GMP requirements and other FDA regulatory requirements, which may result in delay or failure to approve applications, warning letters, product recalls and/or imposition of fines or penalties.

If the product is approved, we must also comply with post-marketing requirements, including, but not limited to, compliance with advertising and promotion laws enforced by various government agencies, including the FDA s Office of Prescription Drug Promotion, through such laws as the Prescription Drug Marketing Act, federal and state anti-fraud and abuse laws, including anti-kickback and false claims laws, healthcare information privacy and security laws, post-marketing safety surveillance, and disclosure of payments or other transfers of value to healthcare professionals and entities. In addition, we are subject to other federal and state regulation including, for example, the implementation of corporate compliance programs.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain.

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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, centralized 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. In addition, foreign regulations may include applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals and entities.

Drugs for Serious or Life-Threatening Illnesses

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as breakthrough therapies . A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team, and taking other steps to design the clinical trials in an efficient manner. FDA regulations also provide certain mechanisms to expedite 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. Under accelerated approval regulations, NDAs may be approved on the basis of valid surrogate markers of product effectiveness, thus accelerating the normal approval process. As a condition of approval, the FDA may require that a sponsor of a product subject to accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. 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.

Coverage and Reimbursement

Sales of our product candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor s determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of our products candidates, once approved, and have a material adverse effect on our sales, results of operations and financial condition.

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In the United States, the Medicare Part D program provides a voluntary outpatient drug benefit to Medicare beneficiaries for certain products. We expect NUPLAZID, if approved, will be available for coverage under Medicare Part D, but the extent to which the individual Part D plans may offer coverage may be subject to various factors such as those described above. In addition, while Medicare Part D has historically required Medicare Part D plans to include all or substantially all drugs in the following designated classes of clinical concern on their formularies: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants, the Centers for Medicare and Medicaid Services, or CMS, recently proposed, but did not adopt, changes to this policy for coverage year 2015. If this policy is changed in the future and if CMS no longer considers the antipsychotic class to be of clinical concern , Medicare Part D plans would have significantly more discretion to reduce the number of products covered in that class. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own coverage policies.

Healthcare Laws and Regulations

We are currently or will in the future be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we will conduct our business once our product candidates are approved. The healthcare laws and regulations that may affect our ability to operate include the following:

The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term remuneration has been broadly interpreted to include anything of value.

Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.

The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, imposes obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government s and/or pharmaceutical industry s voluntary compliance guidelines, state laws that require drug manufacturers to report information related to payments and other

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transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. By way of example, in March 2010, the ACA was signed into law, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- extension of a manufacturer s 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 certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer s Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer s outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; 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.

There have been judicial and Congressional challenges to ACA and there may be additional challenges and amendments to ACA in the future. Other legislative changes have been proposed and adopted in the United States since the ACA. Through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to certain providers. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. For example, in 2015 several U.S. Congressional inquiries were initiated regarding certain drug manufacturers pricing practices and legislation proposed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and

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reform government program reimbursement methodologies for drugs. We expect that ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. We cannot predict what healthcare reform initiatives may be adopted in the future.

Research and Development Expenses

Our research and development expenses were $73.9 million, $60.6 million, and $26.7 million in 2015, 2014, and 2013, respectively.

Manufacturing and Distribution

We currently outsource, and plan to continue to outsource, manufacturing responsibilities for our existing and future product candidates, including NUPLAZID, for development and commercial purposes. We believe this manufacturing strategy will enable us to direct our financial resources to our commercialization efforts and to the ongoing development of pimavanserin without devoting the resources and capital required to build manufacturing facilities.

During the first half of 2015, we licensed worldwide intellectual property rights related to pimavanserin in certain indications to ACADIA Pharmaceuticals GmbH, our wholly-owned Swiss subsidiary. Our active pharmaceutical ingredient, or API, has been manufactured in Switzerland for over 10 years and we anticipate continuing to manufacture in Switzerland as we transition to a commercial organization. ACADIA Pharmaceuticals GmbH will manage the worldwide supply chain of pimavanserin API.

During 2015, ACADIA Pharmaceuticals GmbH contracted with BASF Pharma (Evionnaz) SA, which was subsequently acquired by Siegfried Pharma Evionnaz SA, or Siegfried, to manufacture API to be used in the manufacture of NUPLAZID drug product for commercial use. The term of the manufacturing agreement extends through December 31, 2020 and will automatically renew for subsequent one year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is terminated earlier pursuant to its terms. Either party may terminate the manufacturing agreement prior to expiration upon the uncured material breach by the other party or upon the dissolution or liquidation of the other party or if the other party makes an assignment for the benefit of its creditors. Additionally, ACADIA may terminate the manufacturing agreement in the event of a continuing force majeure event affecting Siegfried or if we cease development, marketing and sales of NUPLAZID. ACADIA also may terminate the manufacturing agreement for any reason on three months prior notice to Siegfried.

Also during 2015, we contracted with Patheon Pharmaceuticals Inc., or Patheon, to manufacture NUPLAZID drug product for commercial use in the United States following any commercial launch of NUPLAZID, if approved by the FDA. Under the manufacturing agreement, we have agreed to purchase from Patheon a specified percentage of our commercial requirements of NUPLAZID for the United States. The term of the manufacturing agreement extends through December 31, 2020 and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is terminated early pursuant to its terms. Each party may terminate the manufacturing agreement prior to expiration upon the uncured material breach by the other party, upon the bankruptcy or insolvency of the other party or in the event of a continuing force majeure event affecting the other party. The manufacturing agreement will also terminate if we provide notice to Patheon that we no longer require manufacturing services because NUPLAZID has been discontinued. Additionally, we may terminate the manufacturing agreement, subject to certain limitations, if any regulatory authority takes any action or raises any objection that prevents us from commercializing NUPLAZID or takes an enforcement action against Patheon s manufacturing site that relates to NUPLAZID or could reasonably be expected to adversely affect Patheon s ability to supply NUPLAZID, if we determine to discontinue development or commercialization of NUPLAZID for safety or efficacy reasons, or if Patheon uses any debarred person in performing its service obligations under the manufacturing agreement. We

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also may terminate the manufacturing agreement for any other reason on three years prior notice to Patheon. Additionally, Patheon may terminate the manufacturing agreement if we assign the manufacturing agreement or any of our rights under the manufacturing agreement to a Patheon competitor.

We have retained third-party service providers to perform a variety of functions related to the distribution of NUPLAZID, including warehousing, customer service, order-taking, invoicing, collections, and shipment and returns processing.

Sales and Marketing

We have established our core commercial team that is preparing our organization for the planned future launch of NUPLAZID. This commercial team is comprised of experienced professionals in marketing, access and reimbursement, managed markets, marketing research, commercial operations, and sales force planning and management. During 2015, we hired our sales leadership team, including 12 regional sales managers and 6 account managers.

We are preparing to build a specialty sales force in the United States of approximately 135 experienced sales professionals. If NUPLAZID is approved, this specialty sales force will focus on promoting NUPLAZID primarily to physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians.

In preparation for a planned launch of NUPLAZID, we launched an ongoing PDP disease awareness campaign in early 2015 that includes educational programs with health care professionals, neurology journal and digital placements, a PDP educational website targeting physicians, and a strong presence at neurology and psychiatric medical meetings. We have also conducted foundational access and reimbursement research with key decision makers for payors covering 300 million lives, of which approximately 30% are covered by each of commercial healthcare payors, Medicare Part D Standard and Medicare Part D Low Income Subsidy, with approximately 10% covered by Medicaid.

In selected markets outside of the United States in which NUPLAZID may be approved, if any, we may choose to commercialize NUPLAZID independently or by establishing one or more strategic alliances.

Long-Lived Assets

Our long-lived assets totaled $2.2 million and $553,000 as of December 31, 2015 and 2014, respectively. All of our long-lived assets are located in the United States.

Employees

At December 31, 2015, we had approximately 160 employees. Of our total workforce, 68 are engaged in research and development activities, 52 are engaged in administrative activities such as finance, legal, and information technology, and 40 are engaged in commercial operations and marketing. 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.

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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

Our prospects are highly dependent on the success of pimavanserin, our most advanced product candidate. To the extent regulatory approval of NUPLAZID (pimavanserin) is delayed or not granted or NUPLAZID is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

We currently have no product candidates approved for sale, and we may never be able to develop marketable products. The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical product candidates are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities in the United States and other countries, whose regulations differ from country to country. We are focusing a significant portion of our activities and resources on pimavanserin, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to obtain regulatory approval for and successfully commercialize NUPLAZID (pimavanserin) in the United States and potentially in additional territories. The regulatory approval and successful commercialization of NUPLAZID is subject to many risks, including the risks discussed in other risk factors, and NUPLAZID may not receive marketing approval from any regulatory agency. If the results or timing of regulatory filings, the regulatory process, regulatory developments, commercialization, clinical trials or preclinical studies, or other activities, actions or decisions related to pimavanserin do not meet our or others expectations, the market price of our common stock could decline significantly.

In April 2013, we announced that the FDA had agreed that the data from our -020 Study, together with supportive data from our other studies with NUPLAZID, are sufficient to support the filing of a New Drug Application, or NDA, for the treatment of Parkinson s disease psychosis, or PDP. In September 2015, we submitted our NDA for NUPLAZID for the treatment of PDP to the FDA, which was accepted for priority review by the FDA on October 30, 2015 with a Prescription Drug User Fee Act, or PDUFA, goal date of May 1, 2016. While the FDA has agreed to review our NDA for NUPLAZID on the basis of our positive pivotal -020 Study data, along with supportive efficacy and safety data from other NUPLAZID studies, the NDA will be subject to the FDA s substantive review of the entire NDA to assess whether it is adequate to support approval of NUPLAZID for PDP. Notwithstanding the guidance that we received in April 2013, the FDA retains complete discretion in deciding whether to approve an NDA for NUPLAZID and there are many components to an NDA filing beyond the efficacy and safety data provided to the FDA in 2013. For example, in addition to reviewing the safety and efficacy data for NUPLAZID, the FDA will review our internal systems and processes, as well as those of our vendors, related to our development of NUPLAZID, including those pertaining to our clinical trials and manufacturing processes. Further, we previously delayed the submission of our NDA for NUPLAZID to complete the preparation of manufacturing quality systems to support commercial manufacturing and supply of NUPLAZID, in order to support the FDA s review of the NDA, and we cannot be certain that our additional preparation of these quality systems will be sufficient to support the review of the NDA.

Even though our NDA submission was accepted for filing, the FDA retains complete discretion in deciding whether or not to approve an NDA and there is no guarantee that NUPLAZID will be approved for the treatment of PDP or any other indication. In addition, neither the receipt of priority review for the NDA nor the Breakthrough Therapy designation increases the likelihood that our NDA will be approved. There is no guarantee that the FDA will determine that our safety and efficacy data are sufficient to support approval for NUPLAZID for PDP or that the potential benefits associated with NUPLAZID outweigh any safety concerns. The FDA or any

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advisory committee may not agree that the change shown on the SAPS-PD scale used to measure the primary endpoint in our -020 Study demonstrates a clinically meaningful benefit to patients. While the FDA did not object to our use of the SAPS-PD scale for the primary endpoint in the -020 study prior to our commencement of the study, this scale, which is a 9-item subset of the full 20-item SAPS scale, had never previously been used in a clinical study. Additionally, any negative development for pimavanserin in clinical development for indications other than PDP may adversely impact the FDA s review of the NUPLAZID NDA. In addition, the FDA may determine that our manufacturing and quality systems, or those of our third-party suppliers, or that the clinical trials conducted with NUPLAZID are not sufficient to support approval of the NDA. Additionally, as part of the FDA s review, the FDA has and will continue to provide comments and ask questions about the NDA for NUPLAZID, including questions about our pre-clinical and clinical studies and our manufacturing processes for NUPLAZID. Whether the FDA approves the NDA may depend in part on our responses to these comments and questions. If the FDA does not find our responses to its comments and questions satisfactory, it may choose not to approve the NDA for NUPLAZID and issue a complete response letter.

In January 2016, we announced that the FDA s Psychopharmacologic Drugs Advisory Committee will review data included in the NDA for NUPLAZID. At the Advisory Committee meeting, scheduled for March 29, 2016, the Advisory Committee will discuss and advise the FDA on the risk-benefit profile of NUPLAZID for the treatment of PDP. In advance of the Advisory Committee meeting, both we and the FDA separately will submit briefing documents for the Advisory Committee s review and these briefing documents will be made available to the public. In its briefing documents, the FDA is free to discuss or otherwise highlight any data included in the NDA for NUPLAZID, including data that we may not believe to be material to the overall risk-benefit profile of NUPLAZID. Historically, for some companies, disclosure of information in this manner has led to increased volatility in their stock price. Additionally, the Advisory Committee and FDA may interpret nonclinical and clinical data differently than we and our experts have. Press coverage and public scrutiny of the materials that will be discussed at the Advisory Committee meeting may negatively affect our stock price and the potential for the NDA for NUPLAZID to be approved. Even if we ultimately obtain approval of the NDA for NUPLAZID, the matters discussed at the Advisory Committee meeting could limit our ability to successfully commercialize NUPLAZID and could adversely impact our stock price.

The FDA is not bound by the recommendations of the Advisory Committee, but it considers such recommendations carefully when making decisions. The FDA may choose not to approve our NDA for NUPLAZID for any of a variety of reasons, including a decision related to the safety or efficacy data for NUPLAZID or for any other issues that they may identify related to our development of NUPLAZID for the treatment of PDP.

Thus, significant uncertainty remains regarding the regulatory approval process for NUPLAZID.

Even if the FDA grants an approval for NUPLAZID for the treatment of PDP, the terms of the approval may limit its commercial potential. Additionally, even after receipt of FDA approval, NUPLAZID would be subject to substantial, ongoing regulatory requirements.

The FDA has complete discretion over the approval of NUPLAZID for the treatment of PDP. If it grants approval, the scope of the approval may limit our ability to commercialize NUPLAZID and, therefore, our ability to generate substantial sales revenues. For example, the FDA may not approve the labeling claims for NUPLAZID that we believe are necessary or desirable for successful commercialization as a treatment for PDP, or may grant approval contingent on the performance of costly post-approval clinical trials or subject to warnings or contraindications, including a Risk Evaluation and Mitigation Strategy, or REMS, to mitigate the risk of off-label use in populations where the FDA may believe that the potential risks of NUPLAZID use may outweigh its benefits. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for NUPLAZID will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing processes, good clinical practices, international conference on harmonization regulations and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our nonclinical

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and clinical development and for any clinical trials that we conduct post-approval. The FDA may decide to withdraw approval, add warnings or narrow the approved indications in the product label, or require or revise REMS that could restrict distribution. These actions could result from, among other things, safety concerns, including unexpected side effects or drug-drug interaction problems, or concerns over misuse or abuse of the product. If any of these actions were to occur following approval, we may have to discontinue the commercialization of NUPLAZID, limit our sales and marketing efforts, and/or conduct post-approval studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

Even if NUPLAZID is approved by the FDA for PDP, we may not be successful in its commercial launch.

We currently have a small commercialization group but have never, as an organization, launched or commercialized a product. In connection with any potential approval by the FDA of NUPLAZID for the treatment of PDP, in addition to building a sales force, we will need to successfully coordinate the commercialization of NUPLAZID. Prior to commercialization, NUPLAZID could also be subject to review and potential scheduling by the Drug Enforcement Administration of the U.S. Department of Justice, or DEA, which could delay and adversely impact its marketing and commercialization. There are numerous examples of unsuccessful product launches and, since we have never launched a product, there is no guarantee that we will be able to do so if granted marketing approval for NUPLAZID for the treatment of PDP. If any product launch of NUPLAZID is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product could be harmed.

We currently have no sales force and have no experience as a company in marketing or distributing pharmaceutical products. If we are unable to expand our marketing capabilities and establish our sales force or enter into agreements with third parties to distribute NUPLAZID, we may not be able to generate product revenues.

Our strategy is to build a fully-integrated biopharmaceutical company to successfully execute the commercial launch of NUPLAZID in the United States following regulatory approval. While we have established our core commercial team, we do not currently have a complete organization for the sales, marketing and distribution of NUPLAZID and, as an organization, we do not have any experience commercializing pharmaceutical products. In order to market any products that may be approved by the FDA, including NUPLAZID, we must continue to build our sales, marketing, managerial, compliance, 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 revenues and may not become profitable.

Included in our strategy in the United States is a plan to establish a specialty sales force to commercialize NUPLAZID for the treatment of PDP. The establishment and development of our own sales force to market NUPLAZID will be expensive and time consuming and could delay any product launch, and we cannot be certain that we will be able to successfully develop this capability. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. To the extent we rely on third parties to commercialize NUPLAZID, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in commercializing our products. In the event we are unable to develop our own sales force or collaborate with a third-party marketing and sales organization, we would not be able to effectively commercialize NUPLAZID which would negatively impact our ability to generate product revenues.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize NUPLAZID will be harmed.

If approved, NUPLAZID will be a newly-marketed drug and, therefore, none of the members of our sales force will have ever promoted NUPLAZID prior to its launch. As a result, we will be required to expend significant time and resources to train our sales force to be credible, persuasive, and compliant with applicable laws in marketing NUPLAZID for the treatment of PDP to neurologists, select psychiatrists, and pharmacists and

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physicians in long-term care facilities. In addition, we must train our sales force to ensure that a consistent and appropriate message about NUPLAZID is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of NUPLAZID and its proper administration, our efforts to successfully commercialize NUPLAZID could be put in jeopardy, which would negatively impact our ability to generate product revenues.

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

Even if a product is 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 adequate reimbursement levels.

If a product does not provide a treatment regimen that is at least 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.

With respect to NUPLAZID specifically, even if approved by the FDA for the treatment of PDP, successful commercialization will depend on whether and to what extent physicians, long-term care facilities and pharmacies, over whom we have no control, determine to utilize NUPLAZID. NUPLAZID, if approved by the FDA, would be made available to treat PDP, an indication for which the FDA has not approved a pharmaceutical treatment. Because of this, it is particularly difficult to estimate NUPLAZID s market potential. Industry sources and analysts have a divergence of estimates for the near- and long-term market potential of NUPLAZID, and a variety of assumptions directly impact the estimates for NUPLAZID s market potential, including assumptions regarding the prevalence of PDP, the rate of diagnosis of PDP, the rate of physician adoption of NUPLAZID, and patient adherence and compliance rates. Small differences in these assumptions can lead to widely divergent estimates of the market potential of NUPLAZID. For example, certain research suggests that patients with Parkinson s disease may be hesitant to report symptoms of PDP to their treating physicians for a variety of reasons, including apprehension about societal stigmas relating to mental illness. Research also suggests that physicians who typically treat patients with Parkinson s disease may not ask about or identify symptoms of PDP. For these reasons, even if PDP occurs in high rates among patients with Parkinson s disease, it may be underdiagnosed. Even if PDP is diagnosed, physicians may not prescribe treatment for it, and if they do prescribe treatment, they may prescribe other drugs to treat it, even though they are not approved for PDP, instead of NUPLAZID. In addition, even if NUPLAZID is prescribed for the treatment of PDP, issues may arise with respect to patient adherence and compliance rates. It is anticipated that the recommended dosing of NUPLAZID, if approved, will be two 17 mg tablets taken together once a day. Patients may elect, whether at the direction of their physician or otherwise, to take only one tablet a day instead of two, to take tablets at different times during the day, or to otherwise not adhere to the recommended dosing, any of which could result in far lower efficacy. If patients do not adhere to the recommended dosing of NUPLAZID, patients and physicians

may believe that NUPLAZID is less effective, and as a result they may stop taking it and prescribing it. The commercial success of NUPLAZID depends on acceptance by patients and physicians, and there are a number of factors that could skew our or others estimates about whether and to what extent NUPLAZID will be prescribed for the treatment of PDP.

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Our ability to generate product revenues will be diminished if NUPLAZID does not receive coverage from payors or sells for inadequate prices, or if patients have unacceptably high co-pay amounts.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for NUPLAZID, or other products we may market, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may not use NUPLAZID if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost of those products.

In addition, the market for NUPLAZID will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. Selling NUPLAZID at less than an optimized price could impact our revenues and overall success as a company. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of any approved products to each payor separately, with no assurance that coverage will be obtained. If we are unable to obtain coverage of, and adequate payment levels for, NUPLAZID or any other products we may market to third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize NUPLAZID, or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

We are subject to federal, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our potential products, including NUPLAZID, as described in greater detail in the Government Regulation section of this Annual Report. If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management s attention away from the operation of our business.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the

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range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with any products we may market, including NUPLAZID, which could negatively impact our profitability.

We expect that the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, 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 may receive for any approved product, including NUPLAZID. An expansion in the government s role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other anticipated developments resulting from the federal healthcare reform legislation, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset fees enacted under the ACA on certain drug product sales, subject to limited exceptions. It is possible that these fees, if applicable, would adversely affect our financial performance. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any products for which we receive regulatory approval, including NUPLAZID.

If our operations are found to be in violation of any of the laws or regulations described above, comparable laws and regulations of non-U.S. jurisdictions or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any marketed products, if we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs and constrain the business or financial arrangements with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to

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induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

the U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which impose criminal and civil penalties, through civil whistleblower or qui tam actions, on individuals or entities for, among other things, knowingly presenting, or causing to be presented to the U.S. federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;

the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;

the U.S. Federal Food, Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

the U.S. federal physician payment transparency requirements, sometimes referred to as the Physician Payments Sunshine Act , which was enacted as part of the ACA and its implementing regulations and requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children s Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value made to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to

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healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. Moreover, while we do not bill third-party payors directly and our customers make the ultimate decision on how to submit claims, from time-to-time, after approval of our product candidates, we may provide reimbursement guidance to patients and healthcare providers. If a government authority were to conclude that we provided improper advice and/or encouraged the submission of a false claim for reimbursement, we could face action against us by government authorities. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we receive marketing approval from the FDA for NUPLAZID for the treatment of PDP, we could face liability if a regulatory authority determines that we are promoting the product for off-label uses.

A company may not promote off-label uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product s FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician s choice of drug treatment made in the physician s independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. If we begin marketing NUPLAZID, or any other product, we intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of our products, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management s attention could be diverted to handle any such alleged violations. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the federal False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the

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promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

We expect our net losses to continue for at least the next few 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, 2015, we had an accumulated deficit of approximately $662.6 million. We expect to incur net losses over the next few years as we advance our programs and incur significant development and commercialization costs.

We have not received any revenues from the commercialization of our product candidates. In September 2015, we submitted our NDA for NUPLAZID for the treatment of PDP to the FDA, which was accepted for priority review by the FDA on October 30, 2015 with a PDUFA goal date of May 1, 2016. The regulatory approval process is time consuming and uncertain and there is no guarantee that our NDA for NUPLAZID will be approved for marketing. Even if our NDA for NUPLAZID is approved, we would still expect to incur significant expenses and net losses for at least the next few years as we begin our first ever commercialization efforts and pursue the development and commercialization of NUPLAZID and other product candidates. Substantially all of our revenues for the twelve months ended December 31, 2015 were from reimbursement of patent costs under our agreements with third parties. The research term of our 2003 research collaboration with Allergan concluded in 2013 and we no longer recognize revenues from this collaboration. In addition, our 1999 muscarinic collaboration focused on glaucoma terminated in 2015 and we will not be receiving any further payments under that agreement. Thus, any payments from Allergan pursuant to our continuing collaboration in chronic pain are dependent upon the advancement of an applicable product candidate. Until such time as we may gain regulatory approval for, and generate revenues from, product sales, we anticipate that collaborations, which provide us with research funding and potential milestone payments and royalties, and grant funding will continue to be our primary sources of revenues.

We cannot be certain that the milestones required to trigger payments under any ongoing 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, 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.

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize NUPLAZID or any of our other product candidates.

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents and investment securities totaled $215.1 million at December 31, 2015. In January 2016, we raised net proceeds of approximately $281.6 million in a follow-on public offering. While we believe that our existing cash resources will be sufficient to fund our cash requirements through at least the next twelve months, we may 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:

- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin, planned commercialization activities for NUPLAZID, and other research and development programs;

- the costs of preparing applications for regulatory approvals for NUPLAZID and other product candidates, as well as the costs required to support review of such applications;

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- the costs of establishing, or contracting for, sales and marketing capabilities for NUPLAZID or other product candidates;
- our ability to obtain regulatory approval for, and generate product sales from, NUPLAZID or other product candidates;
- the costs of acquiring additional product candidates or 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 or license agreements, or our collaborators ability to make payments under these agreements;
- our ability to enter into new, and to maintain existing, collaboration and license agreements;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under 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 NUPLAZID or other product candidates; and
- the costs associated with litigation, including the costs incurred in defending against claims made in the consolidated putative class action that was commenced following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID and the subsequent decline of the price of our common stock in March 2015.

Unless and until we can generate significant cash from our operations, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, public or private sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. These events, coupled with other factors, may limit our access to additional financing in the future. This could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we will be required to delay, 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. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

If we do not obtain regulatory approval from foreign jurisdictions, we will not be able to market our products in those jurisdictions, which will limit our commercial revenues.

In order to market our products in foreign jurisdictions, we must obtain foreign regulatory approval in each of those jurisdictions. We currently plan to submit our Marketing Authorization Application for NUPLAZID in Europe later this year, following approval in the United States, if obtained. Even if we obtain regulatory approval in the United States, approval by the FDA does not ensure that foreign jurisdictions will also approve our products for commercial distribution. The regulations in foreign jurisdictions vary. We will be required to comply with different regulations and policies of the jurisdictions where we seek approval for our product candidates, and we have not yet identified all of the requirements that we will need to satisfy to submit NUPLAZID for approval in foreign jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work beyond the work that we have

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conducted to support our NDA submission for PDP. Furthermore, we may not be able to obtain approval for foreign sales. This will restrict our ability to market our products and would limit their commercial potential and value, including that of NUPLAZID.

The pivotal Phase III study with NUPLAZID for PDP, the results of which were announced in November 2012, was our first successful pivotal Phase III trial and there is no guarantee that future studies with pimavanserin will be successful.

The historical rate of failures for product candidates in clinical development is extremely high. In November 2012, we announced results from our successful pivotal -020 Phase III trial with NUPLAZID for the treatment of PDP. Even though we successfully completed the -020 Study, those results are not predictive of the results of any additional studies that we may undertake with pimavanserin, including any post-approval studies that we may undertake if NUPLAZID is approved for marketing by the FDA. We believe that pimavanserin also may have utility in indications other than PDP, such as Alzheimer s disease psychosis, or ADP, other indications related to Alzheimer s disease, and schizophrenia. However, prior to the first efficacy study that we commenced in late 2013, we had never tested pimavanserin in clinical studies for ADP or any Alzheimer s disease indication, and we have only conducted a Phase II trial for pimavanserin as a co-therapy treatment in schizophrenia. There is no guarantee that we will have the same level of success with pimavanserin in other indications that we had with the -020 Study or that we will be successful at all in future studies for additional indications or that future results of studies of NUPLAZID for the treatment of PDP will be consistent with those from the -020 Study.

If we do not successfully complete development of NUPLAZID, we will be unable to market and sell NUPLAZID or products derived from it, or to generate related product revenues.

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 and, if approved for marketing, commercialization of the product.

We have full responsibility for the pimavanserin program throughout the world. We expect our research and development costs for continued development of pimavanserin to be substantial. While we currently are undertaking the ongoing development work for pimavanserin, including clinical trials of pimavanserin for indications other than PDP, in the future we would need to add resources and raise additional funds in order to take this product candidate to market and to conduct the necessary sales and marketing activities, and to conduct further development activities, if we do not secure a partner. Following any potential approval by the FDA, our current strategy is to commercialize NUPLAZID for PDP in the United States by establishing a specialty sales force focused primarily on neurologists, a small group of psychiatrists, and pharmacists and physicians in long-term care facilities who treat PDP patients. In addition, if we commercialize NUPLAZID in select markets outside of the United States, we will more than likely need to establish one or more strategic alliances in the future for that purpose. Without future collaboration partners in the United States and abroad, we might not be able to realize the full value of NUPLAZID.

We have conducted an initial life cycle planning project for pimavanserin that was initiated in the second quarter of 2015 and through which we expect to formulate a multi-year plan to develop pimavanserin in indications beyond PDP. Given the unique profile of pimavanserin, together with the list of potential indications we could pursue, this is a substantial and a very important undertaking. Our life cycle planning process will be ongoing as we evaluate appropriate indications for pimavanserin to pursue as we seek to maximize the opportunities for this compound. If our life-cycle planning and execution is not conducted successfully, then we may not realize the full value from pimavanserin or may devote substantial resources to develop pimavanserin for indications that are ultimately not successful or do not yield adequate returns. Furthermore, even if NUPLAZID is approved for PDP, a failure in a subsequent study for another indication could harm our ability to successfully market NUPLAZID for PDP or could lead to it being withdrawn from the market. If we are unable to develop pimavanserin for other indications, we may not be able to maximize the potential of the compound and that could have a material adverse effect on our future revenues and our success as a company.

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Our most advanced product candidates are in development, which is a long, expensive and unpredictable process, 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 ended Phase I testing of AM-831 in 2012 and had previously had an unsuccessful Phase III trial with our most advanced product candidate, NUPLAZID. Following the reporting of successful results from the Phase III -020 Study with NUPLAZID in November 2012 and our meeting with the FDA in April 2013, we submitted our NDA for NUPLAZID for PDP in September 2015 that was accepted for priority review by the FDA on October 30, 2015 with a PDUFA goal date of May 1, 2016. An unfavorable outcome in any of the ongoing or future development efforts for NUPLAZID, including any unfavorable decisions related to our NDA, would be a major set-back for the program and for us, generally. In particular, an unfavorable outcome in our NUPLAZID program may require us to delay, devote additional substantial resources to, reduce the scope of, or eliminate this program and could have a material adverse effect on us and the value of our common stock. In addition to our PDP program, we commenced a Phase II study with pimavanserin for patients with ADP in November 2013 and we are planning additional studies in other indications, including those within schizophrenia and Alzheimer s disease. We have a continuing clinical collaboration with Allergan with separate product candidates for the treatment of chronic pain that has reached Phase II development.

In connection with clinical trials, we face risks that:

- a product candidate may not prove to be efficacious or safe;
- 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 be consistent with positive results of earlier trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies.

If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our 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 an 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 clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application;

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

patient recruitment, 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;

imposition of clinical holds by regulatory authorities or institutional review boards;

failure to conduct clinical trials in accordance with regulatory requirements;

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.

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.

We depend on collaborations with third parties to develop and commercialize selected product candidates other than pimavanserin, and we have limited control over how those third parties conduct development and commercialization activities for such product candidates.

One 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, other than pimavanserin, and we have limited control over the amount and timing of resources that our collaborators may devote to our product candidates. We may choose to rely on collaborations in the future for certain portions of our pimavanserin program or for the commercialization of NUPLAZID in certain territories outside of the United States. The research term of our 2003 research collaboration with Allergan concluded in 2013 and we no longer recognize revenues from this collaboration. In addition, our 1999 muscarinic collaboration focused on glaucoma terminated in 2015 and we will not be receiving any further payments under that agreement. Any additional payments from our continuing collaboration agreement with Allergan in chronic pain are dependent upon further advancement of an applicable product candidate. Unless these milestones are met, we will not receive future revenues from our continuing collaboration with Allergan.

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.

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In July 2014, Allergan announced that it would be reducing its worldwide headcount by approximately 13% and that it would be restructuring its operations. In March 2015, Actavis plc acquired Allergan. Then, in November 2015, Allergan announced it entered into an agreement with Pfizer Inc. under which Pfizer will acquire Allergan. Allergan also previously has announced that it was seeking a partner for further development and commercialization of drug candidates in our chronic pain program under our continuing collaboration. In connection with Actavis acquisition of Allergan, and any related restructuring, Allergan elected to terminate our collaboration focused on muscarinic product candidates, including the glaucoma program covered by such collaboration, and, in connection with Actavis and subsequently Pfizer s acquisition of Allergan, it may choose to devote substantially less resources to the chronic pain program or could discontinue such program entirely. If Allergan is unable to successfully partner our chronic pain 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 this program to date. In addition, Allergan can terminate our existing chronic pain collaboration upon prior notice to us, as it has done with the glaucoma collaboration. Allergan may be more likely to terminate, or decline to continue, our chronic pain collaboration in connection with Actavis and Pfizer s acquisition of Allergan.

If Allergan elects to devote substantially less resources to the chronic pain program, absent circumstances giving rise to our right to terminate, our remedies against Allergan are limited, and we may not be able to regain rights to such program. If Allergan elects to discontinue the chronic pain program and terminates our collaboration agreement, as was the case with the glaucoma program, the discontinued program may revert to us, in which case we would need to evaluate whether to continue advancing such program alone or with a new collaborator. Either advancing such program alone or seeking a new collaborator would divert our management s attention and involve expending additional resources that are currently devoted to our other programs, including our pimavanserin program. We have not yet made a determination with regard to any further development of the glaucoma program that will be returning to us under the collaboration focused on muscarinic product candidates.

We also face competition in our search for new collaborators, if we seek a new partner for our pimavanserin program or other programs, including any programs that may revert to us from Allergan. Given the current economic and industry environment, it is possible that competition for new collaborators may increase. If we are unable to find new collaborations, we may not be able to continue advancing our programs alone.

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 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 or reduction of a collaborator s development or commercialization efforts with respect to our product candidates; or
- termination or non-renewal of the collaboration.

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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 collaborators 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 a continuing collaboration with Allergan for the development of product candidates related to chronic pain. Allergan may also pursue other research programs related to pain management that are independent from our collaboration in this therapeutic area. In March 2015, Actavis acquired Allergan and, in November 2015, Allergan announced it entered into an agreement with Pfizer under which Pfizer will acquire Allergan. Actavis and Pfizer may have, or acquire rights to, additional programs related to chronic pain, which could impact the strategy with respect to the development of product candidates covered by our continuing collaboration.

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.

Of the large number of product candidates in development, only a small percentage result in the submission of an NDA to the FDA or comparable regulatory filing to regulatory authorities in other jurisdictions, and even fewer are approved for marketing. We cannot assure you that, even if clinical trials are completed, either we or our collaborators 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

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timely manner, if at all. Even if we or our collaborators successfully complete the clinical trials of product candidates and apply for such required authorizations, the product candidates, such as pimavanserin, 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.

We currently depend, and will in the future continue to depend, on third parties to manufacture NUPLAZID and our other product candidates. If these manufacturers fail to provide us or our collaborators with adequate supplies of clinical trial materials and commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize NUPLAZID or our other product candidates.

We have no manufacturing facilities and only limited experience as an organization 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, including NUPLAZID, for clinical trials. If any of our product candidates, including NUPLAZID, are approved by the FDA or other regulatory agencies for commercial sale, we will need to contract with a third party to manufacture them in larger quantities.

In August 2015, we contracted with Patheon Pharmaceuticals Inc. to manufacture NUPLAZID drug product for commercial use in the United States following any commercial launch of NUPLAZID, if approved by the FDA. Additionally, in August 2015 we contracted with BASF Pharma (Evionnaz) SA, which was subsequently acquired by Siegfried Pharma Evionnaz SA in October 2015, to manufacture active pharmaceutical ingredient, or API, to be used in the manufacture of NUPLAZID drug product for commercial use. However, we have not entered into any agreements with any alternate suppliers for NUPLAZID drug product or NUPLAZID API. Even if we are able to enter into other long-term agreements with manufacturers for commercial supply on reasonable terms, we may be unable to do so with sufficient time prior to launch of NUPLAZID, which would expose us to substantial supply risk and potentially jeopardize our launch.

Even though we entered into an agreement with Patheon for the manufacture of NUPLAZID drug product and with Siegfried for the manufacture of NUPLAZID API for commercial use, and even if we successfully enter into long-term agreements with other manufacturers, the FDA may not approve the facilities of such manufacturers, the manufacturers may not perform as agreed, or the manufacturers may terminate their agreements with us. Presently, we only have one supplier of API and one supplier of drug product for our NUPLAZID (pimavanserin) program. If any of the foregoing circumstances occur, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market NUPLAZID or any of our other product candidates. While we believe that there will be alternative sources available to manufacture our product candidates, including NUPLAZID, 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, including Patheon and Siegfried, are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs, and we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel to ensure compliance with cGMPs. In addition, the facilities used by our third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted prior to any grant of regulatory approval by the FDA. If any of our third-party manufacturers are unable to

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successfully manufacture material that conforms to our specifications and the FDA s strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain approval for the manufacturing facilities. Additionally, a failure by any of our third-party manufacturers to establish and follow cGMPs or to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates, including NUPLAZID, or the ultimate launch of NUPLAZID or any other products based on our product candidates. 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.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly-enforced federal, state and foreign regulations. We cannot assure you that any issues relating to the manufacture of any of our product candidates, including NUPLAZID, will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize NUPLAZID in the United States, or provide any product candidates to patients in clinical trials, would be jeopardized. Any delay or interruption in our ability to meet commercial demand for our products will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are unable to attract, retain, and motivate key management, research and development, and sales and marketing personnel, our drug development programs, our research and discovery efforts, and our commercialization plans may be delayed and we may be unable to successfully develop or commercialize our product candidates, including NUPLAZID.

Our success depends on our ability to attract, retain, and motivate highly qualified management, scientific, and commercial 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 expect to need to hire additional personnel as we expand our research and development efforts and commercial activities for pimavanserin from our current levels. We face competition for experienced scientists, clinical operations personnel, commercial and other personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates will be limited. If we are unable to attract and retain the necessary personnel, it will significantly impede the achievement of our research and development objectives, our commercialization efforts for NUPLAZID, and our ability to meet the demands of our collaborators in a timely fashion.

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

As of December 31, 2015, we employed approximately 160 employees. Although we have already added several capabilities, we will need to add additional qualified personnel and resources if the NDA for NUPLAZID is approved for marketing and we establish a commercial sales force. Our current infrastructure will be inadequate to support these future efforts and expected growth. In particular, we will have to develop internal sales, marketing, and distribution capabilities if we decide to market any drug that we may successfully develop, including NUPLAZID. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates.

Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. In particular, as our commercialization plans and strategies develop, we will need to recruit and train a substantial number of sales and marketing personnel and expect to need to expand the size of our employee base for managerial, operational, financial and other resources. To that end, we must be able to:

manage our development efforts effectively;

integrate additional management, administrative and manufacturing personnel;

build a marketing and sales organization; and

maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals. Our failure to accomplish any of these goals could harm our financial results and prospects.

As we grow as an organization and expand from a development to a commercial-stage company, we may make certain changes to our organization in order to properly manage our growth, which may include changes to the composition of our board of directors and management. Any such changes may be disruptive to us as an organization, which could harm our business.

As we continue to grow as an organization, including by expanding our development efforts and building out our commercial capabilities in anticipation of commercial launch of NUPLAZID, if approved, we will evaluate, and may implement, changes to our organization that may be appropriate in order to properly manage and direct our growth and transformation into a commercial-stage company. These changes may include changes to the size and composition of our management and/or board of directors, as appropriate, to include individuals with substantial experience in managing or serving on the boards of directors of commercial-stage pharmaceutical companies. For example, two long-standing board members resigned in November and December 2015, and our board recently elected three new board members, Dr. Edmund Harrigan, Julian Baker and Jim Daly. Additionally, in September 2015, we named Steve Davis, who had been serving as our Interim CEO since March 2015, to be our President and Chief Executive Officer and to be a member of our Board of Directors. We also recently named Dr. Serge Stankovic as our new Executive Vice President, Head of Research and Development, to replace our previous Executive Vice President, Development and Chief Medical Officer who resigned in November 2015. We also hired a new Chief Medical Officer in January 2016. We currently are

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recruiting for a new Chief Financial Officer and may decide to hire other executive level employees as we grow. Any such significant changes to the organization may distract management or otherwise be disruptive to us as a company, which could harm our business.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited. Even if we obtain rights to other product candidates or products, we will incur a variety of costs and may never realize the anticipated benefits.

A key element of our strategy is to develop, acquire or in-license businesses, technologies, product candidates or products that we believe are a strategic fit with our business. The success of this strategy depends in large part on the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically-enabled product candidates for the treatment of neurological disorders, or for therapeutic indications that complement or augment our current product candidates, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise, and 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. Efforts to do so may not result in the actual acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management s time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited. In particular, if NUPLAZID is approved for marketing and we are unable to add additional commercial products to our portfolio, we may not be able to successfully leverage our commercial organization.

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. Moreover, any product candidate we identify, select and acquire or license may require additional, time-consuming development or regulatory efforts prior to commercial sale, including preclinical studies, if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop NUPLAZID or our other product candidates, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates, and our business and prospects would therefore be harmed.

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 unproven methods to identify and develop product candidates, including NUPLAZID. 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, as noted above, we will likely find it necessary to license the technology of others or

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

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

- whether and when we obtain FDA approval of NUPLAZID for the treatment of PDP;
- the success of our launch and commercialization of NUPLAZID, if approved, in the United States for the treatment of PDP;
- the status of development and commercialization of pimavanserin for indications other than PDP and in jurisdictions other than the United States;
- the status of development and commercialization of our other product candidates, including compounds being developed under our collaborations;
- whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates or products;
- 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 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, other internal research and development efforts, and pre-commercial and commercial efforts;

the effect of competing technologies and products and market developments;

the costs associated with litigation, including the costs incurred in defending against claims made in the two putative class action complaints, which have now been consolidated into one action, filed following our March 2015 announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID and the subsequent decline of the price of our common stock; and

general and industry-specific economic conditions.

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We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

Future changes to U.S. and non-U.S. tax laws could materially adversely affect us.

During the first half of 2015, we licensed worldwide intellectual property rights related to pimavanserin in certain indications to ACADIA Pharmaceuticals GmbH, our wholly-owned Swiss subsidiary. Our goals for the establishment of ACADIA Pharmaceuticals GmbH, and the licensing of worldwide intellectual property rights for pimavanserin, include building a platform for long-term operational and financial efficiencies, including tax-related efficiencies. Future changes in U.S. and non-U.S. tax laws, including implementation of international tax reform relating to the tax treatment of multinational corporations, if enacted, may reduce or eliminate any potential financial efficiencies that we hope to achieve by establishing this operational structure. Additionally, taxing authorities, such as the U.S. Internal Revenue Service, may audit and otherwise challenge these types of arrangements, and have done so with other companies in the pharmaceutical industry. If any such changes in tax law are enacted, or our licensing of worldwide intellectual property rights for pimavanserin to our Swiss subsidiary is otherwise challenged, this could materially adversely affect our business.

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 Stock 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 this 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.

We will need to obtain final FDA approval of our proposed product name for pimavanserin, NUPLAZID, and the failure or any delay in receiving this approval may adversely impact the timing and success of our sales and marketing efforts.

The FDA will need to provide final approval of the NUPLAZID product name regardless of our trademark registration from the United States Patent and Trademark Office. Typically, the FDA conducts an extensive review of proposed product names, including an evaluation for possible confusion with other existing product names. If the FDA does not approve the name NUPLAZID, we will need to adopt an alternative name. As a result, we would lose the benefit of any existing trademark applications and may need to spend significant

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resources in an effort to select another product name that will meet FDA approval, qualify under existing trademark laws and not infringe on the existing rights of third parties. Additionally, if the FDA does not approve our proposed trade name, and we are unable to adopt an alternative name in a timely manner, we may be required to launch without a brand name, and our efforts to build a successful brand identity for, and commercialize, the product may be adversely impacted. In addition, we will need to develop brand loyalty for any product name in order to commercialize pimavanserin effectively. If we fail to do this, it could negatively impact our future revenues from sales of pimavanserin.

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 intellectual property rights to our product candidates, including NUPLAZID, and technologies, as well as successfully defending these rights against third-party challenges. Any misappropriation of our intellectual property could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. To protect our intellectual property, we rely on a combination of patents, trade secret protection and contracts requiring confidentiality and nondisclosure.

With regard to patents, although we have filed numerous patent applications worldwide with respect to pimavanserin, not all of our patent applications resulted in an issued patent, or they resulted in an issued patent that is susceptible to challenge by a third party. Our ability to obtain, maintain, and/or defend our patents covering 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 develop similar or alternative technologies or design around our patent claims to produce competitive products that fall outside of the scope of our patents;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- 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 are easily susceptible to challenges by third parties;

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- our proprietary technologies may not be patentable;
- changes to patent laws that limit the exclusivity rights of patent holders or make it easier to render a patent invalid;
- recent decisions by the United States Supreme Court limiting patent-eligible subject matter;
- the passage of the America Invents Act (2012) introduced new procedures for challenging pending patent applications and issued patents; and
- technology that we may in-license may become important to some aspects of our business, however, we generally would not control the patent prosecution, maintenance or enforcement of any such in-licensed technology.

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 freedom to operate. Moreover, 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. For applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or United States PTO, to determine who was the first to invent the invention at issue. It is difficult to determine how such disputes would be resolved. Applications containing a claim not entitled to priority before March 16, 2013, are not subject to interference proceedings due the change brought by the America Invents Act (2012) to a first to file system. However, a derivation proceeding can be brought by a third-party alleging that the inventor derived the invention from another.

Periodic maintenance fees on any issued patent are due to be paid to the United States PTO and foreign patent agencies in several stages over the lifetime of the patent. The United States PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators from disclosing scientific discoveries until we have the opportunity to file patent applications on such discoveries, but in some cases, we are limited to relatively short periods to review a proposed publication and file a patent

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application. 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 may be impaired.

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, nondisclosure, 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. We also have not entered into any noncompete agreements with any of our employees. 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 future employment with any of our competitors. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

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 a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including post-issuance review proceedings before the United States PTO or oppositions and other comparable proceedings in foreign jurisdictions.

Central provisions of The Leahy-Smith America Invents Act, or the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the United States PTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can petition the United States PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, United States PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. The United States Supreme Court is currently

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reviewing whether it is proper for the United States PTO to give claims their broadest reasonable meaning in post-issuance proceedings. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus, a challenger s burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the United States PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the United States PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the United States PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

While we are not currently subject to any pending intellectual property litigation or patent challenges, and are not aware of any such threatened litigation or patent challenges, 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, and such patents are held to be valid and enforceable, 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, and such patents are held to be valid and enforceable, 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, which could potentially be trebled 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, or at all.

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

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

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

The strength of patents in the pharmaceutical and biotechnology field can be highly uncertain and involve complex legal and factual questions. For example, some of our patent applications may cover the uses of gene sequences. The patentability of gene sequences and the use of gene sequences has been seriously undermined by recent decisions of the United States Supreme Court. The United States PTO s interpretation of the Supreme Court s decisions and the standards for patentability it sets forth 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 as mentioned above, and U.S. patents may be subject to reexamination and post-issuance proceedings in the United States PTO (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. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. In addition, such interference, reexamination, post-issuance 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. For example, the America Invents Act (2012) included a number of significant changes to U.S. patent law. These included changes to transition from a first-to-invent system to a first-to-file system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. It is still not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

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, including NUPLAZID, 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, including NUPLAZID, 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

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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, including NUPLAZID, 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, the use of NUPLAZID for the treatment of PDP would compete with off-label use of antipsychotic drugs, including generic drugs quetiapine and clozapine. Pimavanserin for the treatment of ADP would compete with off-label use of antipsychotic drugs, including risperidone and quetiapine, and drugs indicated for the treatment of Alzheimer s disease and dementia in patients with Alzheimer s disease, including Aricept, marketed by Eisai Inc. and Pfizer Inc., and Namenda, marketed by Forest Laboratories, LLC, a wholly-owned subsidiary of Actavis. Pimavanserin for the treatment of Alzheimer s disease agitation would compete with off-label use of antipsychotic drugs, including risperidone and quetiapine. Pimavanserin for the treatment of schizophrenia would compete with Rexulti, marketed by Otsuka Pharmaceutical Co., Ltd., Latuda, marketed by Sunovion Pharmaceuticals Inc., and generic drugs olanzapine, risperidone, aripiprazole and clozapine. In the area of chronic pain, potential products would compete with 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.

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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 effect 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 if 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 historically has been, and is likely to remain, highly volatile.

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 development and commercialization efforts in our pimavanserin development program;

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the timing, or developments regarding the timing, of submission and review of filings for our product candidates, including NUPLAZID, for approval by regulatory authorities in the United States and abroad and the results of any applications for marketing approval of product candidates;

any other communications or guidance from the FDA or other regulatory authorities that pertain to our product candidates, including NUPLAZID;

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 products, or other material events by our competitors or us, including any new products that we may acquire or in-license;

disputes or other developments concerning our proprietary and intellectual property 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 Stock 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; and

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

In the past, following periods of volatility in the market price of a particular company s securities, securities class action litigation has often been brought against that company. For example, in March 2015, following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID for the treatment of PDP and the subsequent decline of the price of our common stock, two putative securities class action complaints were filed against us and certain of our current and former officers, which complaints were subsequently consolidated into one complaint. The complaint generally alleges that the defendants violated Sections 10(b) and 20(a) of the Securities

Exchange Act of 1934 by making materially false and misleading statements regarding the timing of our planned NDA submission to the FDA for NUPLAZID, thereby artificially inflating the price of our common stock. If we are not successful in defense of these claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such claims are not successful, the litigation could result in substantial costs and divert our management s attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

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. We filed registration statements in connection with private financings that we concluded in January 2011 and December 2012, which registrations cover

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approximately 17.0 million shares and 19.5 million shares of our common stock, respectively. In addition, in connection with our March 2014 public offering of common stock, we agreed to provide resale registration rights for the shares of our common stock held by entities affiliated with one of our principal stockholders and two of our directors, Julian C. Baker and Dr. Stephen R. Biggar, which we refer to as the Baker Entities. In connection with our January 2016 public offering of common stock, we entered into a formal registration rights agreement with the Baker Entities to provide for these rights. Based on information available to us, the Baker Entities collectively beneficially owned approximately 20.8% of our common stock as of January 8, 2016. Under the registration rights agreement we have agreed that, if at any time and from time to time after the expiration of an initial period of approximately 90 days, the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act, we would be obligated to effect such registration. Our registration obligations under this registration rights agreement cover all shares now held or later acquired by the Baker Entities, will be in effect for up to 10 years, and include our obligation to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future. If the Baker Entities, by exercising these registration and/or underwriting rights or otherwise, sell a large number of our shares, or the market perceives that the Baker Entities intend to sell a large number of our shares, this could adversely affect the market price 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 statement, or an indeterminate number of shares pursuant to a new registration statement or in a private placement, 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 or future financings.

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 our 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;

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prohibit our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with 66 $^{2}/_{3}$ 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 three 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 may significantly affect our ability to raise capital.

Historically, turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. These events, coupled with other factors, may limit our access to financing in the future. This could have a material adverse effect on our ability to access funding on acceptable terms, or at all, and our stock price may suffer further as a result.

We do not intend to pay dividends on our common stock in the foreseeable future; as such, you must rely on stock appreciation for any return on your investment.

To date, we have not paid any cash dividends on our common stock, and we do not intend to pay any dividends in the foreseeable future. Instead, we intend to retain any future earnings to fund the development and growth of our business. For this reason, the success of an investment in our common stock, if any, will depend on the appreciation of our common stock, which may not occur. There is no guarantee that our common stock will appreciate, and therefore, a holder of our common stock may not realize a return on his or her investment.

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

This item is not applicable.

Item 2. ***Properties.***

As of December 31, 2015, our primary facility consists of approximately 51,000 square feet of leased office space located in San Diego, California, which is leased through February 2019. We lease two facilities in San Diego related to our research and development activities that cover an aggregate of approximately 11,000 square feet of laboratory and office space. We believe that our existing facilities are adequate for our current needs.

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

In March 2015, following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID for the treatment of PDP and the subsequent decline of the price of our common stock, two putative securities class action complaints (captioned *Rihn v. ACADIA Pharmaceuticals Inc.*, Case No. 15-cv-0575-BTM-DHB, and *Wright v. ACADIA Pharmaceuticals Inc.*, Case No. 15-cv-0593-BTM-DHB) were filed in the U.S. District Court for the Southern District of California, or the Court, against us and certain of our current and former officers. The complaints generally alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding the timing of our planned NDA submission to the FDA for NUPLAZID, thereby artificially inflating the price of our common stock. The complaints sought unspecified monetary damages and other relief. On April 10 and June 1, 2015, the Court entered orders deferring the defendants response to the Rihn and Wright complaints until after the Court appointed a lead plaintiff and assigned lead counsel. On May 12, 2015, several putative stockholders

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filed separate motions to consolidate the two actions and be appointed lead plaintiff. On September 8, 2015, the Court issued an order consolidating the two actions, appointing lead plaintiff, and assigning lead counsel. On November 16, 2015, lead plaintiff filed a consolidated complaint with the Court which, like the prior complaints, accuses the defendants of making materially false and misleading statements regarding the anticipated timing of our planned NDA submission to the FDA for NUPLAZID. On January 15, 2016, we filed a motion to dismiss the consolidated complaint. Subject to court approval, the parties stipulated that plaintiffs shall file their opposition to our motion to dismiss on March 22, 2016 and that we shall file our reply to plaintiffs opposition on April 21, 2016. The hearing on our motion to dismiss is scheduled for May 20, 2016. We plan to continue to vigorously defend against the claims advanced.

Item 4. ***Mine Safety Disclosures.***

This item is not applicable.

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PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.***

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

2015	**High**	**Low**
First Quarter	$ 46.48	$ 29.45
Second Quarter	$ 43.24	$ 31.00
Third Quarter	$ 51.99	$ 30.03
Fourth Quarter	$ 43.30	$ 30.51
2014	**High**	**Low**
First Quarter	$ 32.00	$ 21.20
Second Quarter	$ 25.50	$ 15.64
Third Quarter	$ 29.31	$ 19.21
Fourth Quarter	$ 33.49	$ 22.04

As of January 29, 2016, there were 112,636,457 shares of common stock outstanding held by approximately 40 stockholders of record. Many stockholders hold their shares in street name and we believe that there are approximately 33,000 beneficial owners of our common stock. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future.

Performance Graph

The following graph shows a comparison of the total cumulative returns of an investment of $100 in cash from December 31, 2010 through December 31, 2015 in (i) our common stock, (ii) the NASDAQ Biotechnology Index, and (iii) the NASDAQ U.S. Benchmark TR Index. 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).

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Item 6. ***Selected Financial Data.***

The following data has been derived from our audited financial statements, including the consolidated balance sheets at December 31, 2015 and 2014 and the related consolidated statements of operations for each of the three years ended December 31, 2015 and related notes appearing elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2012 and 2011 and the consolidated balance sheet data as of December 31, 2013, 2012 and 2011 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 consolidated financial statements and related notes included elsewhere in this report.

	Years Ended December 31,				
	2015	2014	2013	2012	2011
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Revenues:					
Collaborative revenues	$ 61	$ 120	$ 1,145	$ 4,907	$ 2,067
Operating expenses:					
License fees	2,500				
Research and development	73,869	60,602	26,722	18,794	17,309
General and administrative	88,304	32,748	12,720	6,999	7,610
Total operating expenses	164,673	93,350	39,442	25,793	24,919
Loss from operations	(164,612)	(93,230)	(38,297)	(20,886)	(22,852)
Interest income, net	499	755	349	37	87
Loss before income taxes	(164,113)	(92,475)	(37,948)	(20,849)	(22,765)
Income tax expense	330				
Net loss	$ (164,443)	$ (92,475)	$ (37,948)	$ (20,849)	$ (22,765)
Net loss per common share, basic and diluted	$ (1.63)	$ (0.95)	$ (0.44)	$ (0.38)	$ (0.44)
Weighted average common shares outstanding, basic and diluted	100,630	97,248	85,715	55,116	52,183

	At December 31,				
	2015	2014	2013	2012	2011
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investment securities	$ 215,132	$ 322,486	$ 185,790	$ 107,967	$ 31,048
Working capital	197,087	308,784	181,381	102,600	25,784
Total assets	221,896	325,458	189,118	108,590	32,114
Total stockholders equity	199,762	309,489	182,131	84,984	23,362

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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, products or product candidates, 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, contin 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 innovative medicines to address unmet medical needs in central nervous system disorders. We have a portfolio of product opportunities led by our novel drug candidate, NUPLAZID (pimavanserin), for which we have reported positive Phase III pivotal trial results in Parkinson s disease psychosis, or PDP, and which has the potential to be the first drug approved in the United States for this condition. NUPLAZID is a selective serotonin inverse agonist, or SSIA, preferentially targeting 5-HT_{2A} receptors. Through this novel mechanism, NUPLAZID has demonstrated significant efficacy in Parkinson s disease psychosis in our Phase III pivotal trial and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved for use in PDP patients. We hold worldwide commercialization rights to pimavanserin.

We are pursuing Parkinson s disease psychosis as our lead indication for NUPLAZID. In September 2015, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for NUPLAZID for the treatment of psychosis associated with Parkinson s disease, which was accepted for priority review by the FDA on October 30, 2015 with a Prescription Drug User Fee Act, or PDUFA, goal date of May 1, 2016. In January 2016, we announced that the FDA s Psychopharmacologic Drugs Advisory Committee will review data included in the NDA for NUPLAZID. At the Advisory Committee meeting, scheduled for March 29, 2016, the Advisory Committee will discuss and advise the FDA on the risk-benefit profile of NUPLAZID for the treatment of PDP. In September 2014, we announced that the FDA granted Breakthrough Therapy designation for NUPLAZID for the treatment of PDP. The Breakthrough Therapy designation was created to expedite the development and review of drugs that are intended to treat serious or life-threatening conditions. If approved, we intend to commercialize NUPLAZID for Parkinson s disease psychosis in the United States by establishing a specialty sales force focused primarily on physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians.

We believe that pimavanserin has the potential to address important unmet medical needs in neurological and psychiatric disorders beyond PDP and we plan to continue to study the use of pimavanserin in multiple disease states. We believe Alzheimer s disease represents one of our most important opportunities for further exploration. We are currently conducting a Phase II study exploring the utility of pimavanserin for the treatment of Alzheimer s disease psychosis, or ADP, a disorder for which no drug is currently approved by the FDA, and expect to complete enrollment of this study around mid-year 2016 and have top-line results of the study in the fourth quarter of 2016. We also plan to initiate a Phase II study in Alzheimer s disease agitation in the first half

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of 2016. We believe schizophrenia represents a disease with multiple unmet or ill-served needs and we are currently evaluating the most attractive development opportunities there for pimavanserin. We have successfully completed a Phase II study of pimavanserin in the treatment of schizophrenia where we observed significant anti-psychotic effects when pimavanserin was co-administered with a low dose of risperidone, a generic drug currently approved for the treatment of schizophrenia.

During the first half of 2015, we licensed worldwide intellectual property rights related to pimavanserin in certain indications to ACADIA Pharmaceuticals GmbH, our wholly-owned Swiss subsidiary. Our active pharmaceutical ingredient, or API, for our NUPLAZID (pimavanserin) program has been manufactured in Switzerland for over 10 years and we anticipate continuing to manufacture our API in Switzerland as we transition to a commercial organization. ACADIA Pharmaceuticals GmbH will manage the worldwide supply chain of pimavanserin API. We believe the establishment of ACADIA Pharmaceuticals GmbH, as well as the licensing of worldwide intellectual property rights for pimavanserin, will allow us to build a platform for long-term operational and financial efficiencies.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. As of December 31, 2015, we had an accumulated deficit of $662.6 million. We expect to continue to incur operating losses for at least the next few years as we advance our programs and incur significant development and commercialization costs.

Revenues

We have not generated any revenues from product sales to date. Our revenues to date have been generated substantially from payments under our current and past collaboration agreements. Our collaboration agreement with Allergan focused on muscarinic product candidates for the treatment of glaucoma terminated in 2015 and we will not be receiving any further payments under that agreement. Our continuing collaboration agreement with Allergan involves the development of product candidates in the area of chronic pain. Under this continuing agreement, we are eligible to receive payments upon achievement of development and regulatory milestones, as well as royalties on future product sales, if any. We no longer receive research funding from this agreement and additional payments are dependent upon the advancement of an applicable product candidate. Our continuing collaboration agreement with Allergan in chronic pain is subject to termination upon notice by Allergan.

License Fees

License fees consist of our milestone payments due to the Ipsen Group under our 2006 license agreement, pursuant to which we licensed certain intellectual property rights that complement our patent portfolio for our serotonin platform, including NUPLAZID. In connection with the FDA s acceptance of the filing of the NDA for NUPLAZID in the fourth quarter of 2015, we paid a $2.5 million milestone to the Ipsen Group, and a potential future milestone payment of $8.0 million would be payable upon obtaining regulatory approval from the FDA of our NDA for NUPLAZID. If NUPLAZID is approved, then we would also make royalty payments to the Ipsen Group of up to two percent on future net product sales, if any.

Research and Development Expenses

Our research and development expenses have consisted 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 candidate, NUPLAZID (pimavanserin). We currently are responsible for all costs incurred in the development of pimavanserin.

We use external service providers to manufacture our product candidates and for the majority of the services performed in connection with the preclinical and clinical development of pimavanserin. Historically, we have used our internal research and development resources, including our employees and discovery infrastructure,

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across several projects and many of our costs have not been attributable to a specific project. Accordingly, we have not reported our internal research and development costs on a project basis. To the extent that external expenses are not attributable to a specific project, they are included in other programs. The following table summarizes our research and development expenses by project for the years ended December 31, 2015, 2014, and 2013 (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Costs of external service providers:			
NUPLAZID (pimavanserin)	$ 40,506	$ 43,161	$ 16,625
Other programs	890	723	709
Subtotal	41,396	43,884	17,334
Internal costs	20,302	11,527	7,180
Stock-based compensation	12,171	5,191	2,208
Total research and development	$ 73,869	$ 60,602	$ 26,722

Although our NDA for NUPLAZID has been accepted for filing by the FDA, at this time, due to the risks in the regulatory and approval processes, we are unable to estimate with any certainty the costs we will incur for the continued development of NUPLAZID for Parkinson s disease psychosis, including work necessary to support the review of the NDA. Due to the risks inherent in clinical development, we also are unable to estimate with certainty the costs we will incur for the development of pimavanserin for other indications, including those within Alzheimer s disease and schizophrenia. Due to these same factors, we are unable to determine with any certainty the anticipated completion dates for our current research and development programs. Clinical development and regulatory approval timelines, probability of success, and development costs vary widely. While our current focus is primarily on supporting a review of the NDA by the FDA and advancing the development of pimavanserin for other indications, 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 the commercial potential of each opportunity and our financial position. We cannot forecast with any degree of certainty which product opportunities will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree any such arrangements would affect our development plans and capital requirements.

We expect our research and development expenses to increase and continue to be substantial as we pursue the development of pimavanserin, including supporting the FDA s review of our NDA for NUPLAZID, our ongoing open-label safety extension study, our ongoing Phase II trial for Alzheimer s disease psychosis, and potential studies in other indications, including those within schizophrenia and other Alzheimer s disease indications. The lengthy process of completing clinical trials and supporting development activities and seeking regulatory approval for our product opportunities 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. In addition, starting in the second half of 2013, we began to hire the senior leadership of our commercial organization that is helping us prepare for the planned launch of NUPLAZID and we are currently expanding our commercial organization and preparing to build a specialty sales force in the United States that will focus on promoting NUPLAZID, if approved by the FDA. We expect our general and

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administrative expenses to increase in future periods to support activities associated with our planned launch of NUPLAZID and our further development of pimavanserin in indications other than Parkinson s disease psychosis.

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.

Research and Development Accruals

We estimate certain costs and expenses and accrue for these liabilities as part of our process of preparing financial statements. Examples of areas in which subjective judgments may be required include, among other things, costs associated with services provided by contract organizations for, preclinical development, manufacturing of our product candidates, and clinical trials. We accrue for costs incurred as the services are being provided by monitoring the status of the trial or services provided, and the invoices received from our external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. Other indirect costs are generally recognized on a straight-line basis over the estimated period of the study. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed materially 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 valuation 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.

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, the progress and timing of expenditures related to our development and commercialization efforts, and the extent to which we generate revenues from product sales, if any. 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, 2015 and 2014

License Fees

We incurred license fees of $2.5 million in connection with the FDA s acceptance of the filing of the NDA for NUPLAZID in the fourth quarter of 2015, adjusted for credits for prior payments made by us, pursuant to our 2006 license agreement with the Ipsen Group. We did not incur any similar license fees in 2014. A potential

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future milestone payment of $8.0 million would be payable upon obtaining regulatory approval from the FDA of our NDA for NUPLAZID. If NUPLAZID is approved, then we would also make royalty payments to the Ipsen Group of up to two percent on future net product sales, if any.

Research and Development Expenses

Research and development expenses increased to $73.9 million in 2015, including $12.2 million in stock-based compensation, from $60.6 million in 2014, including $5.2 million in stock-based compensation. This increase was primarily due to an increase of $15.8 million in personnel and related costs and stock compensation expense associated with our expanded research and development organization, partially offset by pimavanserin manufacturing development costs incurred in 2014 not incurred in 2015. We expect our research and development expenses to increase in future periods as we continue to pursue the development of pimavanserin, including supporting the FDA s review of our NDA for NUPLAZID, our ongoing open-label safety extension study, our ongoing Phase II trial for Alzheimer s disease psychosis, and potential studies in other indications, including those within Alzheimer s disease and schizophrenia, as well as the development of our other product candidates.

General and Administrative Expenses

General and administrative expenses increased to $88.3 million in 2015, including $28.0 million in stock-based compensation, from $32.7 million in 2014, including $10.8 million in stock-based compensation. This increase was due to increases in personnel and related costs of $35.3 million and increases in external services costs of $20.3 million. Contributing to the increase in personnel costs was $9.6 million in expense incurred in connection with the transition agreement we entered into with our former Chief Executive Officer upon his retirement in the first quarter of 2015. Included in this compensation expense of $9.6 million was $9.0 million in stock-based compensation expense representing the fair value of the outstanding options expected to vest over the term of the transition agreement as valued on his retirement date. Excluding the expense incurred in connection with the transition agreement with our former Chief Executive Officer, the increases in personnel costs and external services costs were largely related to our commercial preparations for the planned launch of NUPLAZID. We anticipate that our general and administrative expenses will increase in future periods to support our planned development and commercial activities for NUPLAZID.

Comparison of the Years Ended December 31, 2014 and 2013

Revenues

Revenues decreased to $120,000 in 2014 from $1.1 million in 2013. This decrease was partially due to the conclusion of our 2003 research collaboration with Allergan in March 2013. Revenues from our collaborations with Allergan decreased to $40,000 in 2014 from $571,000 in 2013. Additionally, revenues from agreements with other parties, including research grants, decreased to $80,000 in 2014 compared to $574,000 in 2013 due to decreased activities under research grants.

Research and Development Expenses

Research and development expenses increased to $60.6 million in 2014, including $5.2 million in stock-based compensation, from $26.7 million in 2013, including $2.2 million in stock-based compensation. This increase was primarily due to an increase of $26.6 million in external service costs as well as an increase in costs associated with our expanded research and development organization, including $4.2 million in increased personnel costs, and $3.0 million in increased stock-based compensation. External service costs totaled $43.9 million in 2014, compared to $17.3 million in 2013. The increase in external service costs was largely attributable to increased third-party costs related to our development of, and NDA submission for, NUPLAZID.

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General and Administrative Expenses

General and administrative expenses increased to $32.7 million in 2014, including $10.8 million in stock-based compensation, from $12.7 million in 2013, including $3.5 million in stock-based compensation. The increase in general and administrative expenses was primarily due to an increase in costs associated with additional administrative and commercial personnel, including $7.3 million in increased stock-based compensation, and $4.7 million in increased personnel expenses, as well as an increase of $6.7 million in external service costs. The increase in external service costs was largely attributable to increased consulting and professional fees related to our pre-commercial activities.

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. For example, in January 2016, we raised net proceeds of approximately $281.6 million in a follow-on public offering, and in 2014 and 2013 we raised net proceeds of $196.8 million and $107.9 million, respectively, in public offerings of our common stock. We anticipate that the level of cash used in our operations will increase in future periods in order to fund our planned commercial activities for NUPLAZID and our ongoing and planned development activities for pimavanserin for other indications. We expect that our cash, cash equivalents, and investment securities will be sufficient to fund our planned operations through at least the next twelve months.

We may 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:

- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin, planned commercialization activities for NUPLAZID, and other research and development programs;
- the costs of preparing applications for regulatory approvals for NUPLAZID and other product candidates, as well as the costs required to support review of such applications;
- the costs of establishing, or contracting for, sales and marketing capabilities for NUPLAZID or other product candidates;
- our ability to obtain regulatory approval for, and generate product sales from, NUPLAZID or other product candidates;
- the costs of acquiring additional product candidates or research and development programs;
- the scope, prioritization and number of research and development programs;
- the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators ability to make payments under these agreements;
- our ability to enter into new, and to maintain existing, collaboration and license agreements;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under 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 NUPLAZID or other product candidates; and

the costs associated with litigation, including the costs incurred in defending against claims made in the consolidated putative class action that was commenced following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID and the subsequent decline of the price of our common stock in March 2015.

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Unless and until we can generate significant cash from our operations, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, public or private sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. These events, coupled with other factors, may limit our access to additional financing in the future. This could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we will be required to delay, 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. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock

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 in accordance with our investment policy. Our investment policy defines allowable investments and establishes 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 A3/A- or better, or P-1/A-1 or better, as determined by Moody s Investors Service or Standard & Poor s. Our investment portfolio has not been adversely impacted by the disruptions in the credit markets that have occurred in the past. However, if there are future disruptions in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected.

At December 31, 2015, we had $215.1 million in cash, cash equivalents, and investment securities, compared to $322.5 million at December 31, 2014. This $107.4 million decrease in cash, cash equivalents, and investment securities during 2015 was primarily due to the $121.8 million of cash used in operations, partially offset by $14.5 million received from stock option exercises and purchases under our employee stock purchase plan. Net cash used in operating activities increased to $121.8 million in 2015 compared to $66.4 million in 2014 and $31.8 million in 2013. The increase in net cash used in operating activities in 2015 relative to 2014 was primarily due to the increase in our net loss, offset by an increase of $24.2 million in non-cash stock-based compensation expense, together with changes in our operating assets and liabilities, including accounts payable and accrued liabilities. Accounts payable and accrued liabilities increased by $5.9 million in 2015 compared to an increase of $8.9 million during 2014. The increases in accounts payable and accrued liabilities were due to increases in external service costs related to our commercial preparations for the planned launch of NUPLAZID.

The increase in net cash used in operating activities in 2014 relative to 2013 was primarily due to the increase in our net loss, offset by an increase of $10.3 million in non-cash stock-based compensation expense, together with changes in our operating assets and liabilities, including accounts payable and accrued expenses. Accounts payable and accrued liabilities increased by $8.9 million in 2014 compared to an increase of $1.4 million during 2013. The increase in accounts payable and accrued expenses was primarily due to an increase in external service costs associated with our expanded research and development activities.

Net cash provided by investing activities totaled $147.6 million in 2015 compared to net cash used in investing activities of $87.3 million in 2014 and $126.1 million in 2013. Net cash used in investing activities has fluctuated significantly from period to period primarily due to the timing of purchases and maturities of investment securities.

Net cash provided by financing activities decreased to $14.5 million in 2015 compared to $203.9 million in 2014 and $111.7 million in 2013. The decrease in net cash provided by financing activities in 2015 relative to 2014 was primarily attributable to $196.8 million in net proceeds received from our public offering of common stock in March 2014. The increase in net cash provided by financing activities in 2014 relative to 2013 was

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primarily attributable to the additional proceeds received from our public offering of common stock in March 2014 as compared to our public offering of common stock in May 2013 which raised net proceeds of $107.9 million.

Contractual Obligations

The following is a summary of our long-term contractual obligations as of December 31, 2015 (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases	$ 6,024	$ 2,336	$ 3,428	$ 260	$
Other long-term contractual obligations	2,562	808	1,660	94	
Total	$ 8,586	$ 3,144	$ 5,088	$ 354	$

In addition to operating leases, we enter into certain other long-term commitments for goods and services that are outstanding for periods greater than one year. To the extent these long-term commitments are noncancelable, they are reflected in the above table. We also enter into short-term agreements with various vendors and suppliers of goods and services in the normal course of operations through purchase orders or other documentation, or that are undocumented except for an invoice. Such short-term agreements are generally outstanding for periods less than a year and are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements 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 agreement and therefore are not reflected in the above table.

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 for our serotonin platform, including NUPLAZID. If certain conditions are met, we would be required to make future payments, including milestones, sublicensing fees, and royalties. In connection with the FDA s acceptance of the filing of the NDA for NUPLAZID in the fourth quarter of 2015, we paid a $2.5 million milestone to the Ipsen Group, adjusted for credits for prior payments made by us to Ipsen, and a potential future milestone payment of $8.0 million would be payable upon obtaining regulatory approval from the FDA. If NUPLAZID is approved, then we would also make royalty payments to Ipsen of up to two percent on future net product sales, if any. Because the remaining milestone payment would only be payable upon obtaining regulatory approval from the FDA and it is uncertain when, or if, such event will occur, we cannot forecast with any degree of certainty when, or if, we will be required to make this payment under this agreement. Similarly, royalty payments would be contingent upon any net product sales. 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.

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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 A3/A- or better, or P-1/A-1 or better, as determined by Moody s Investors Service 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, 2015, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

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 principal executive officer and principal 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 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, controls 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, 2015, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer, who serves as our principal executive, financial and accounting 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 concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2015.

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 principal executive officer and principal financial officer, to

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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, 2015, 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 (COSO) in Internal Control-Integrated Framework (2013). In adopting the 2013 Framework, management assessed the applicability of the principles within each component of internal control and determined whether or not they have been adequately addressed within the current system of internal control and adequately documented. Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer, concluded that, as of December 31, 2015, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report, which is included herein.

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, of any changes 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.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

ACADIA Pharmaceuticals Inc.

We have audited ACADIA Pharmaceuticals Inc. s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) (the COSO criteria). ACADIA Pharmaceuticals Inc. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

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

In our opinion, ACADIA Pharmaceuticals Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of ACADIA Pharmaceuticals Inc. as of December 31, 2015, and the related consolidated statements of operations, comprehensive loss, stockholders equity and cash flows for the year ended December 31, 2015 of ACADIA Pharmaceuticals Inc. and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

February 29, 2016

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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 Election of Directors and Information Regarding the Board of Directors and Corporate Governance in our definitive Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the SEC by April 29, 2016 (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 chief compliance officer, Ryan E. Brown c/o ACADIA Pharmaceuticals Inc., 3611 Valley Centre Drive, Suite 300, San Diego, CA 92130.

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 Ratification of Selection of Independent Registered Public Accounting Firm in our Proxy Statement and is incorporated in this report by reference.

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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 Reports of Ernst & Young LLP and PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firms, are included in this report:

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.

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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/ Stephen R. Davis
Stephen R. Davis

Chief Executive Officer

(on behalf of the registrant and as the registrant s
Principal Executive, Financial and Accounting Officer)

Date: February 29, 2016

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Stephen R. Davis, his true and lawful attorney-in-fact and agent 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 attorney-in-fact and agent, 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 attorney-in-fact and agent, 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.

Signature	Title	Date
/s/ Stephen R. Davis **Stephen R. Davis**	Chief Executive Officer and Director (Principal Executive, Financial and Accounting Officer)	February 29, 2016
/s/ Leslie Iversen **Leslie Iversen**	Chairman of the Board	February 29, 2016
/s/ Julian Baker **Julian Baker**	Director	February 29, 2016
/s/ Stephen Biggar **Stephen Biggar**	Director	February 29, 2016
/s/ Laura Brege **Laura Brege**	Director	February 29, 2016
/s/ James Daly **James Daly**	Director	February 29, 2016
/s/ Mary Ann Gray	Director	February 29, 2016

Mary Ann Gray		
/s/ Edmund Harrigan	Director	February 29, 2016
Edmund Harrigan		
/s/ Daniel Soland	Director	February 29, 2016
Daniel Soland		
/s/ William M. Wells	Director	February 29, 2016
William M. Wells		

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

ACADIA Pharmaceuticals Inc.

We have audited the accompanying consolidated balance sheet of ACADIA Pharmaceuticals Inc. as of December 31, 2015, and the related consolidated statements of operations, comprehensive loss, stockholders equity and cash flows for the year ended December 31, 2015. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ACADIA Pharmaceuticals Inc. at December 31, 2015, and the consolidated results of its operations and its cash flows for the year ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), ACADIA Pharmaceuticals Inc. s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

February 29, 2016

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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, 2014, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2014, 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 an opinion 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

San Diego, California

February 26, 2015

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ACADIA PHARMACEUTICALS INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31, 2015	December 31, 2014
Assets		
Cash and cash equivalents	$ 102,138	$ 61,854
Investment securities, available-for-sale	112,994	260,632
Interest and other receivables	1,638	964
Prepaid expenses and other current assets	2,219	1,168
Total current assets	218,989	324,618
Property and equipment, net	2,203	553
Restricted cash	375	
Other assets	329	287
Total assets	$ 221,896	$ 325,458
Liabilities and stockholders equity		
Accounts payable	$ 1,672	$ 2,016
Accrued liabilities	20,230	13,818
Total current liabilities	21,902	15,834
Long-term liabilities	232	135
Total liabilities	22,134	15,969
Commitments and contingencies (Note 10)		
Stockholders equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at December 31, 2015 and 2014; no shares issued and outstanding at December 31, 2015 and 2014		
Common stock, $0.0001 par value; 225,000,000 shares and 150,000,000 shares authorized at December 31, 2015 and December 31, 2014, respectively; 101,938,702 shares and 100,047,331 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	10	10
Additional paid-in capital	862,327	807,631
Accumulated deficit	(662,586)	(498,143)
Accumulated other comprehensive income (loss)	11	(9)
Total stockholders equity	199,762	309,489
Total liabilities and stockholders equity	$ 221,896	$ 325,458

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

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ACADIA PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Years Ended December 31,		
	2015	2014	2013
Revenues			
Collaborative revenues	$ 61	$ 120	$ 1,145
Operating expenses			
License fees	2,500		
Research and development	73,869	60,602	26,722
General and administrative	88,304	32,748	12,720
Total operating expenses	164,673	93,350	39,442
Loss from operations	(164,612)	(93,230)	(38,297)
Interest income, net	499	755	349
Loss before income taxes	(164,113)	(92,475)	(37,948)
Income tax expense	330		
Net loss	$ (164,443)	$ (92,475)	$ (37,948)
Net loss per common share, basic and diluted	$ (1.63)	$ (0.95)	$ (0.44)
Weighted average common shares outstanding, basic and diluted	100,630	97,248	85,715

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

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ACADIA PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	Years Ended December 31,		
	2015	2014	2013
Net loss	$ (164,443)	$ (92,475)	$ (37,948)
Other comprehensive gain (loss):			
Unrealized gain (loss) on investment securities	13	(60)	45
Foreign currency translation adjustments	7	3	(1)
Comprehensive loss	$ (164,423)	$ (92,532)	$ (37,904)

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

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ACADIA PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2015	**2014**	**2013**
Cash flows from operating activities			
Net loss	$ (164,443)	$ (92,475)	$ (37,948)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	40,194	16,039	5,711
Amortization of premiums and accretion of discounts on investment securities, available for sale	(2,060)	484	1,528
Depreciation	647	206	79
Income tax benefit from exercise of stock options	(247)		
Gain on disposal of assets			(10)
Changes in operating assets and liabilities:			
Interest and other receivables	(674)	(214)	(505)
Prepaid expenses and other current assets	(804)	652	(1,484)
Restricted cash	(375)		
Other assets	(42)	(108)	(179)
Accounts payable	(344)	1,644	(1,003)
Accrued liabilities	6,256	7,266	2,413
Deferred revenue		(55)	(379)
Long-term liabilities	97	127	8
Net cash used in operating activities	(121,795)	(66,434)	(31,769)
Cash flows from investing activities			
Purchases of investment securities	(269,486)	(335,361)	(211,585)
Maturities of investment securities	419,197	248,268	86,087
Purchases of property and equipment	(2,141)	(180)	(618)
Proceeds from sales of property and equipment			12
Net cash provided by (used in) investing activities	147,570	(87,273)	(126,104)
Cash flows from financing activities			
Proceeds from issuances of equity securities, net of issuance costs	14,547	203,851	111,682
Deferred offering costs	(292)		
Income tax benefit from exercise of stock options	247		
Net cash provided by financing activities	14,502	203,851	111,682
Effect of exchange rate changes on cash	7	3	(1)
Net increase (decrease) in cash and cash equivalents	40,284	50,147	(46,192)
Cash and cash equivalents at beginning of period	61,854	11,707	57,899
Cash and cash equivalents at end of period	$ 102,138	$ 61,854	$ 11,707
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 415	$	$

Supplemental disclosure of noncash investing information:				
Property and equipment purchases in accrued liabilities	$	156	$	$

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

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ACADIA PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount				
Balances at December 31, 2012	73,334,216	$ 7	$ 452,693	$ (367,720)	$ 4	$ 84,984
Issuance of common stock in public offering, net of issuance costs	9,200,000	1	107,882			107,883
Issuance of common stock from exercise of stock options	1,455,406		3,441			3,441
Issuance of common stock pursuant to employee stock purchase plan	122,853		358			358
Issuance of common stock from exercise of warrants on a net issuance basis	1,643,006					
Reclassification from redeemable common stock	5,347,137	1	17,657			17,658
Net loss				(37,948)		(37,948)
Stock-based compensation			5,711			5,711
Other comprehensive income					44	44
Balances at December 31, 2013	91,102,618	$ 9	$ 587,742	$ (405,668)	$ 48	$ 182,131
Issuance of common stock in public offering, net of issuance costs	7,360,000	1	196,778			196,779
Issuance of common stock from exercise of stock options	1,486,802		6,408			6,408
Issuance of common stock pursuant to employee stock purchase plan	97,911		664			664
Net loss				(92,475)		(92,475)
Stock-based compensation			16,039			16,039
Other comprehensive loss					(57)	(57)
Balances at December 31, 2014	100,047,331	$ 10	$ 807,631	$ (498,143)	$ (9)	$ 309,489
Issuance of common stock from exercise of stock options	1,822,578		12,991			12,991
Issuance of common stock pursuant to employee stock purchase plan	68,793		1,556			1,556
Income tax benefit from exercise of stock options			247			247
Deferred offering costs			(292)			(292)
Net loss				(164,443)		(164,443)
Stock-based compensation			40,194			40,194
Other comprehensive income					20	20
Balances at December 31, 2015	101,938,702	$ 10	$ 862,327	$ (662,586)	$ 11	$ 199,762

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

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

ACADIA Pharmaceuticals Inc. (the Company), based in San Diego, California, is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. The Company was originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. and reincorporated in Delaware in 1997.

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 located in Europe. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of 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.

Cash and Cash Equivalents

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

Investment Securities

The Company has classified all of its investment securities as available-for-sale as the sale of such securities may be required prior to maturity to implement management strategies, and accordingly, carries these investments at fair value. Unrealized gains and losses, if any, are reported as a separate component of stockholders equity. The cost of investment securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses, if any, are also included in interest income. The cost of securities sold is based on the specific identification method.

Fair Value of Financial Instruments

The carrying values of the Company s financial instruments, consisting of cash and cash equivalents, interest and other receivables, restricted cash, and accounts payable and accrued liabilities, approximate fair value due to the relative short-term nature of these instruments.

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As disclosed in Note 4, the Company classifies its cash equivalents and available-for-sale investment securities within the fair value hierarchy as defined by authoritative guidance:

Level 1 Inputs	Quoted prices for identical instruments in active markets.
Level 2 Inputs	Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable.
Level 3 Inputs	Valuation derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight line method. Leasehold improvements are amortized over the shorter of their estimated useful lives or the term of the lease by use of the straight line method. Construction-in-process reflects amounts incurred for property, equipment or improvements that have not been placed in service. 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.

Estimated useful lives by major asset category are as follows:

	Useful Lives
Machinery and equipment	5 to 7 years
Computers and software	3 years
Furniture and fixtures	10 years

Impairment of Long-Lived Assets

The Company reviews its long lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. No such impairment losses have been recorded by the Company.

License Fees

The Company expenses amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expense or capitalized based upon management s assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale.

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, pre-commercialization manufacturing expenses, and clinical trials. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or services

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 based on the number of patients enrolled in the trial. Other indirect costs are generally recognized on a straight-line basis over the estimated period of the study. As actual costs become known, the Company adjusts its accruals. Certain research and development programs have been 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 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 in accordance with the Company s investment policy. The Company s investment policy defines allowable investments and establishes 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 A3/A- or better, or P-1/A-1 or better, as determined by Moody s Investors Service or Standard & Poor s.

The Company does not currently have any of its own manufacturing facilities, and therefore relies on third-party manufacturers to produce its product candidates for clinical trials. Although there are potential sources of supply other than the Company s existing suppliers, any new supplier would be required to qualify under applicable regulatory requirements.

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 valuation model. The estimated fair value of each stock option and purchase right, including the effect of estimated forfeitures, is then expensed over the requisite service period, which is generally the vesting period. The following assumptions were used during these periods:

	Years Ended December 31,		
	2015	2014	2013
Stock Options:			
Expected volatility	89%	93%	94%
Risk-free interest rate	1-2%	1-2%	1-2%
Expected dividend yield	0%	0%	0%
Expected life of options in years	5.7	5.7	6.0

	Years Ended December 31,		
	2015	2014	2013
Employee Stock Purchase Plan:			
Expected volatility	51-59%	44-95%	69-118%
Risk-free interest rate	0.1-0.9%	0.1-0.5%	0.1-0.3%
Expected dividend yield	0%	0%	0%
Expected life in years	0.5-2.0	0.5-2.0	0.5-2.0

Stock-based awards issued to non-employees other than directors are accounted for under the fair value method using the Black-Scholes valuation model 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

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

obtained. The stock-based compensation expense related to the grant of stock options to non-employees was $584,000 for the year ended December 31, 2013, and was not significant for the years ended December 31, 2015 and 2014. In 2015, stock options were granted to a non-employee that vest upon the attainment of Company-specific performance criteria. Through December 31, 2015, no expense was recognized related to these performance-based stock options as future vesting was uncertain.

Expected Volatility. The Company considers its historical volatility and implied volatility when determining the expected volatility.

Risk-Free Interest Rate. The Company determines its risk-free interest rate assumption based on the U.S. Treasury yield for obligations with contractual terms similar to the expected term of the stock option or purchase right being valued.

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

Expected Life. In determining the expected life for stock 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 estimated life for the Company s employee stock purchase rights is based upon the terms of each offering period.

The table below summarizes the total stock-based compensation expense included in the Company s statements of operations for the periods presented (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Research and development	$ 12,171	$ 5,191	$ 2,208
General and administrative	28,023	10,848	3,503
	$ 40,194	$ 16,039	$ 5,711

During the first quarter of 2015, the Company entered into a transition agreement with its former Chief Executive Officer, in connection with his retirement from the Company in March 2015. Stock-based compensation expense for the year ended December 31, 2015 includes a one-time $9.0 million charge representing the fair value of the outstanding options expected to vest over the term of the transition agreement as valued on the retirement date.

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.

The Company recognizes excess tax benefits associated with stock-based compensation to stockholders equity only when realized. When assessing whether excess tax benefits relating to stock-based compensation have been realized, the Company follows the with-and-without approach excluding any indirect effects of the excess tax deductions. Under this approach, excess tax benefits related to stock-based compensation are not deemed to be realized until after the utilization of all other tax benefits available to the Company.

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company recognizes the impact of a tax position in the financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options and warrants are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be antidilutive. The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. More specifically, at December 31, 2015, 2014 and 2013, options, employee stock purchase rights, and warrants totaling approximately 11,525,000 shares, 9,902,000 shares and 9,314,000 shares, respectively, were excluded as their effect would have been anti-dilutive.

Segment Reporting

Management has determined that the Company operates in one business segment which is the development and commercialization of innovative medicines. All revenues for the years ended December 31, 2015, 2014 and 2013 were generated in the United States.

Recently Issued Accounting Standards

In November 2015, the Financial Accounting Standards Board (FASB) issued authoritative accounting guidance related to the balance sheet classification of deferred taxes. This guidance requires deferred tax liabilities and assets to be classified as noncurrent in a classified statement of financial position. This guidance may be applied on either a prospective or retrospective basis and is effective for annual reporting periods beginning after December 15, 2016, with early adoption permitted. The Company adopted this standard prospectively in the fourth quarter of 2015, and as the Company s deferred tax assets are fully offset by a valuation allowance, there was no impact to the Company s financial position or results of operations upon its adoption of this standard.

In May 2014, the FASB issued authoritative accounting guidance related to revenue from contracts with customers. This guidance is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. The original guidance was effective for annual reporting periods beginning after December 15, 2016. However, in July 2015, the FASB agreed to delay the effective date by one year, with early adoption permitted, but not before the original effective date of the standard. In accordance with the agreed upon delay, the Company will adopt this guidance on January 1, 2018. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance. The Company is evaluating which transition approach to use and its impact, if any, on its consolidated financial statements.

In August 2014, the FASB issued authoritative accounting guidance related to an entity s ability to continue as a going concern. This guidance will explicitly require management to assess an entity s ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard is effective for annual reporting periods ending after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption permitted. The Company intends to adopt this guidance at the beginning of its first quarter of fiscal year 2016 and does not expect it to have a material impact on its consolidated financial statements and related disclosures.

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Investment Securities

Investment securities, all classified as available-for-sale, consisted of the following (in thousands):

	December 31, 2015			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 9,000	$	$ (1)	$ 8,999
Government sponsored enterprise securities	103,996	12	(13)	103,995
	$ 112,996	$ 12	$ (14)	$ 112,994

	December 31, 2014			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 2,748	$ 2	$	$ 2,750
Government sponsored enterprise securities	97,237	8	(10)	97,235
Corporate debt securities	137,682	3	(37)	137,648
Commercial paper	22,980	19		22,999
	$ 260,647	$ 32	$ (47)	$ 260,632

At each reporting date, the Company performs an evaluation of impairment to determine if the unrealized losses are other-than-temporary. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, and the Company s intent and ability to hold the investment until recovery of its amortized cost basis. The Company intends, and has the ability, to hold its investments in unrealized loss positions until their amortized cost basis has been recovered. Based on its evaluation, the Company determined that its unrealized losses were not other-than-temporary at December 31, 2015 and 2014. As of December 31, 2015 and 2014, all of the Company s available-for-sale investment securities had contractual maturity dates of less than one year.

4. Fair Value Measurements

As of December 31, 2015, the Company held $213.1 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 government sponsored enterprises in accordance with the Company s investment policy. The Company s investment policy defines allowable investments and establishes 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 A3/A- or better, or P-1/A-1 or better, as determined by Moody s Investors Service or Standard & Poor s.

The Company s cash equivalents and available-for-sale investment securities are classified within the fair value hierarchy as defined by authoritative guidance. The Company s investment securities classified as Level 1 are valued using quoted market prices. The Company obtains the fair value of its Level 2 financial instruments from third party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other

market-related data, are observable. The Company validates the prices provided by the third-party pricing services by reviewing their pricing methods and matrices, and obtaining market values from other pricing sources. After completing the validation procedures, the Company did not adjust or override any fair value measurements provided by these pricing services as of December 31, 2015 and 2014, respectively.

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company does not hold any securities classified as Level 3, which are securities valued using unobservable inputs. The Company has not transferred any investment securities between the classifications.

The fair value measurements of the Company s cash equivalents and available-for-sale investment securities are identified in the following tables (in thousands):

		Fair Value Measurements at Reporting Date Using		
	December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$ 46,437	$ 46,437	$	$
U.S. Treasury notes	8,999	8,999		
Government sponsored enterprise securities	157,623		157,623	
	$ 213,059	$ 55,436	$ 157,623	$

		Fair Value Measurements at Reporting Date Using		
	December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$ 48,423	$ 48,423	$	$
U.S. Treasury notes	2,750	2,750		
Government sponsored enterprise securities	110,235		110,235	
Corporate debt securities	137,648		137,648	
Commercial paper	22,999		22,999	
	$ 322,055	$ 51,173	$ 270,882	$

5. Balance Sheet Components

Property and equipment, net, consisted of the following (in thousands):

	December 31,	
	2015	2014
Machinery and equipment	$ 1,017	$ 896
Computers and software	1,336	862
Leasehold improvements	1,413	627
Furniture and fixtures	724	244
Construction-in-process	500	64
	4,990	2,693
Accumulated depreciation	(2,787)	(2,140)
	$ 2,203	$ 553

Depreciation of property and equipment was $647,000, $206,000, and $79,000 for the years ended December 31, 2015, 2014, and 2013, respectively. During 2015, 2014 and 2013, the Company retired $72,000, $40,000 and $2.8 million, respectively, of fully depreciated property and equipment.

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accrued liabilities consisted of the following (in thousands):

	December 31, 2015	December 31, 2014
Accrued research and development services	$ 8,805	$ 7,814
Accrued compensation and benefits	5,722	4,167
Accrued consulting and professional fees	4,508	1,497
Other	1,195	340
	$ 20,230	$ 13,818

6. Collaborative Research Agreements

The Company has been a party to three collaboration agreements with Allergan. The 2003 collaboration originally provided for a three-year research term, which was extended by the parties through 2013. The 1999 collaboration with Allergan for the development of product candidates in the area of glaucoma was terminated in 2015. The Company s continuing 1997 collaboration agreement with Allergan involves the development of product candidates in the area of chronic pain. Under the chronic pain collaboration, the Company is eligible to receive up to an aggregate of $10.0 million in payments upon the achievement of development and regulatory milestones. The Company also is eligible to receive royalties on future net product sales worldwide, if any, under the continuing collaboration agreement with Allergan. The Company recognized revenues, consisting of research funding, milestone and related fees, from its collaboration agreements with Allergan of $61,000, $40,000, and $571,000 during each of the years ended December 31, 2015, 2014, and 2013.

7. Stockholders Equity

Authorized Shares

In June 2015, following approval by the Company s stockholders, the Company filed a Certificate of Amendment of its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, which increased the number of authorized shares of common stock of the Company from 150,000,000 to 225,000,000.

Public Offerings

In March 2014, the Company raised net proceeds of $196.8 million from the sale of 7,360,000 shares of its common stock in a public offering, including 960,000 shares sold pursuant to the exercise in full of the underwriters over-allotment option.

In May 2013, the Company raised net proceeds of $107.9 million from the sale of 9,200,000 shares of its common stock in a public offering, including 1,200,000 shares sold pursuant to the exercise in full of the underwriters over-allotment option.

Private Equity Financings

In December 2012, the Company raised net proceeds of $80.5 million through the sale of 19,000,000 shares of its common stock at a price of $4.43 per share and the sale of warrants to purchase 500,000 shares of its common stock at a price of $4.42 per warrant share in a private equity financing. The warrants have an exercise price of $0.01 per share and will expire on December 17, 2019. In accordance with authoritative accounting guidance, the warrants value of $2.2 million was determined on the date of grant using the Black-Scholes model with the following assumptions: risk free interest rate of 1.1 percent, volatility of 105.8 percent, a 7.0 year term

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

and no dividend yield. These warrants were recorded as a component of stockholders equity within additional paid-in capital. Per their terms, the outstanding warrants to purchase 500,000 shares of common stock may not be exercised if the holder s ownership of the Company s common stock would exceed 19.99 percent following such exercise. Pursuant to the terms of the private financing, the Company has an effective resale registration statement on file with the SEC covering shares of common stock sold and shares of common stock issuable upon the exercise of the warrants.

In January 2011, the Company raised net proceeds of $13.9 million through the sale of 12,565,446 units at a price of $1.19375 per unit 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 of $1.38 per share and will expire on January 11, 2018. In accordance with authoritative accounting guidance, the warrants value of $3.3 million was determined on the date of grant using the Black-Scholes model with the following assumptions: risk free interest rate of 2.8 percent, volatility of 99.0 percent, a 7.0 year term and no dividend yield. These warrants were recorded as a component of stockholders equity with an equal offsetting amount to stockholders equity because the value of the warrants was considered a financing cost. During the year ended December 31, 2013, warrants to purchase 1,759,162 shares of common stock were exercised on a net issuance basis, resulting in the issuance of 1,643,006 shares of common stock. During the year ended December 31, 2012, warrants to purchase 1,172,774 shares of common stock were exercised on a net issuance basis, resulting in the issuance of 874,719 shares of common stock. At December 31, 2015, warrants to purchase 1,465,968 shares of common stock remained outstanding. Pursuant to the terms of the private financing, the Company has an effective resale registration statement on file with the SEC covering shares of common stock sold and shares of common stock issuable upon the exercise of the warrants.

Stock Option Plans

The Company s 2010 Equity Incentive Plan, as amended to date (the 2010 Plan), permits the grant of options to employees, directors 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 10 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. In June 2015, the Company s stockholders approved an amendment to its 2010 Plan to, among other things, increase the aggregate number of shares of common stock authorized for issuance under the plan by 5,000,000 shares, and at December 31, 2015, there were 15,738,857 shares of common stock authorized for issuance, of which 6,195,781 shares were available for new grants under the 2010 Plan.

The 2004 Plan provided for the grant of options to employees, directors 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 10 years. Options granted under the 2004 Plan generally vested over a four-year period.

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock option transactions during the year ended December 31, 2015 are presented below:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2014	7,930,530	$ 12.65		
Granted	4,242,000	$ 35.73		
Exercised	(1,822,578)	$ 7.13		
Cancelled/forfeited	(806,876)	$ 28.33		
Outstanding at December 31, 2015	9,543,076	$ 22.64	7.55	$ 130,308
Vested and expected to vest at December 31, 2015	8,878,145	$ 21.87	7.48	$ 127,714
Exercisable at December 31, 2015	4,053,885	$ 10.41	5.77	$ 102,509

The aggregate intrinsic value of options exercisable as of December 31, 2015 is calculated as the difference between the exercise price of the underlying options and the closing market price of the Company s common stock on that date, which was $35.65. The aggregate intrinsic value of options exercised during the years ended December 31, 2015, 2014, and 2013 was approximately $55.9 million, $30.6 million, and $20.7 million, respectively, determined as of the date of exercise. The Company received $13.0 million in cash from options exercised during the year ended December 31, 2015.

The weighted average fair value of options granted during the years ended December 31, 2015, 2014, and 2013 was approximately $25.80, $18.90, and $12.66, respectively. As of December 31, 2015, total unrecognized compensation cost related to stock options and purchase rights was approximately $93.5 million, and the weighted average period over which this cost is expected to be recognized is approximately 3.0 years.

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 included an evergreen provision providing that a limited number of additional shares may be added to the shares authorized for issuance on the date of each annual meeting of stockholders for a period of 10 years, which ended with the meeting in 2014. Through December 31, 2015, a total of 1,525,000 shares of common stock had been reserved for issuance under the Purchase Plan. At December 31, 2015, 316,696 shares of common stock remained available for issuance pursuant to 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, 2015, 2014, and 2013, a total of 68,793, 97,911, and 122,853 shares of common stock were issued under the Purchase Plan at average prices of $22.62, $6.78, and $2.92, respectively. The weighted average fair value of purchase rights granted during the years ended December 31, 2015, 2014, and 2013 was $14.31, $11.09, and $10.96, respectively. During the years ended December 31, 2015, 2014, and 2013, the Company recorded cash received from the exercise of purchase rights of $1.6 million, $664,000, and $358,000, respectively.

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. 401(k) Plan

Effective January 1997, the Company established a deferred compensation plan (the 401(k) Plan) pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended (the Code), whereby substantially all employees are eligible to contribute up to 60 percent of their pretax earnings, not to exceed amounts allowed under the Code. The Company makes discretionary 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, subject to limitations under the Code. The Company s total contributions to the 401(k) Plan were $993,000, $489,000, and $240,000 for the years ended December 31, 2015, 2014, and 2013, respectively.

9. Income Taxes

Domestic and foreign pre-tax income (loss) is as follows (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Domestic	$ 25,854	$ (92,447)	$ (37,938)
Foreign	(189,967)	(28)	(10)
	$ (164,113)	$ (92,475)	$ (37,948)

At December 31, 2015, the Company had federal, state, and foreign net operating loss (NOL) carryforwards of approximately $449.9 million, $413.8 million, and $187.9 million, respectively. For the year ended December 31, 2015, the Company recognized a state income tax provision of $330,000. This tax liability was associated with California state alternative minimum tax obligations and the apportionment of income to certain state jurisdictions in which the Company did not have corresponding NOLs. No similar state income tax provision was recognized for the years ended December 31, 2014 and 2013. Utilization of the domestic NOL and research and development (R&D) credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 of 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.

The Company previously completed a study to assess whether an ownership change, as defined by Section 382 of the Code, had occurred from the Company s formation through December 31, 2013. Based upon this study, the Company determined that several ownership changes had occurred. Accordingly, the Company reduced its deferred tax assets related to the federal NOL carryforwards and the federal R&D credit carryforwards that are anticipated to expire unused as a result of these ownership changes. These tax attributes were excluded 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. The Company completed a study through December 31, 2015 and concluded no additional ownership changes occurred. Future ownership changes may further limit the Company s ability to utilize its remaining tax attributes.

Federal and state NOL carryforwards of $2.3 million and $36.3 million will expire in 2018 and 2016, respectively, unless utilized. The remaining federal and state NOL carryforwards will begin to expire in 2019 and 2017, respectively. At December 31, 2015, the Company had $12.3 million of federal R&D credit carryforwards of which $119,000 will expire in 2018 unless utilized, and the remaining federal R&D credit carryforwards will begin to expire in 2019. At December 31, 2015, the Company had $8.1 million of state R&D credit

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

carryforwards that have no expiration date. At December 31, 2015, the Company had foreign NOL carryforwards of approximately $184.6 million that will expire in 2022 and $3.3 million that have no expiration date. The Company continues to record the deferred tax assets related to these attributes, subject to valuation allowance, until expiration occurs.

Approximately $79.9 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 (in thousands):

	December 31,	
	2015	2014
NOL carryforwards	$ 161,277	$ 168,778
R&D credit carryforwards	17,624	13,668
Capitalized R&D	4,901	6,548
Stock-based compensation	15,260	6,630
Other	2,126	1,615
	201,188	197,239
Valuation allowance	(201,188)	(197,239)
	$	$

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $3.9 million in 2015 primarily due to an increase in deferred tax assets generated from net operating losses, R&D credits and stock-based compensation expense, partially offset by the expiration of NOL carryforwards in 2015.

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

	Years Ended December 31,		
	2015	2014	2013
Amounts computed at statutory federal rate	$ (55,799)	$ (31,441)	$ (12,902)
Stock-based compensation and other permanent differences	1,752	1,417	244
Reduction of deferred tax assets under Section 382 of the Code			2,781
R&D credits	(3,782)	(2,420)	(1,269)
Change in valuation allowance	4,580	37,106	13,509
State taxes	742	(5,092)	(2,140)
Contingencies	2,247		
Foreign rate differential	48,456	4	
Other	2,134	426	(223)
Income tax expense	$ 330	$	$

The tax years 1998-2014 remain open to examination by the major taxing jurisdictions to which the Company is subject.

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination. For the year ended December 31, 2015, the Company recorded an uncertain tax position reserve of $2.3 million. No similar reserve was recorded for the years ended December 31, 2014 and 2013. Due to the valuation allowance recorded against the Company s deferred tax assets, none of the total unrecognized tax benefits as of December 31, 2015 would reduce the annual effective tax rate if recognized. The Company does not anticipate that the amount of unrecognized tax benefits as of December 31, 2015 will significantly change within the next twelve months. The Company s practice is to recognize interest and/or penalties related to uncertain income tax positions in income tax expense. The Company had no interest and/or penalties accrued on the Company s consolidated balance sheets at December 31, 2015 and 2014, and the Company did not recognize any interest and/or penalties in the statement of operations for the years ended December 31, 2015, 2014 and 2013 related to uncertain tax positions.

The following table provides a reconciliation of changes in unrecognized tax benefits (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Balance at beginning of period	$	$	$
Additions related to current period tax positions	2,301		
Additions related to prior period tax positions			
Reductions related to prior period tax positions			
Reductions related to lapse of statute of limitations			
Balance at end of period	$ 2,301	$	$

10. Commitments and Contingencies

Leases and Other Long-Term Commitments

The Company leases facilities and certain equipment under noncancelable operating leases that expire at various dates through February 2019. Under the terms of the facilities leases, the Company is required to pay its proportionate share of property taxes, insurance and normal maintenance costs. Rent expense for operating leases is recorded on a straight-line basis over the life of the lease term. If an operating lease contains fixed and determinable escalation clauses, the difference between the rent expense and the rent paid is recorded as deferred rent. Rent expense under the Company s facility and equipment leases was $2.9 million, $1.2 million, and $594,000, for the years ended December 31, 2015, 2014, and 2013, respectively.

In 2015, the Company entered into a master lease agreement giving the Company the ability to lease vehicles under operating leases with initial terms of 36 months from the date of delivery. In connection with this lease agreement, the Company established a letter of credit for $375,000, which has automatic annual extensions and is fully secured by restricted cash.

The Company also enters into certain other long-term commitments for goods and services that are outstanding for periods greater than one year. To the extent these long-term commitments are noncancelable, they are reflected in the table below.

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Estimated annual future minimum payments related to the Company s operating leases and other long-term contractual obligations were as follows at December 31, 2015 (in thousands):

2016	$ 3,144
2017	2,669
2018	2,419
2019	354
2020	
Thereafter	
	$ 8,586

The Company also enters into short-term agreements with various vendors and suppliers of goods and services in the normal course of operations through purchase orders or other documentation, or that are undocumented except for an invoice. Such short-term agreements are generally outstanding for periods less than a year and are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be stopped on short notice. In such event, the Company would not be liable for the full amount of the agreement and are therefore not reflected in the above table.

Contingent Regulatory Milestone Payment

In connection with the Company s 2006 license agreement with the Ipsen Group, pursuant to which the Company licensed certain intellectual property rights that complement its patent portfolio for its serotonin platform, including NUPLAZID, the Company made a one-time milestone payment of $2.5 million in the fourth quarter of 2015, adjusted for credits for prior payments made by the Company to Ipsen, upon the U.S. Food and Drug Administration s (FDA) acceptance for filing of the Company s New Drug Application (NDA) for NUPLAZID. This milestone payment of $2.5 million was recognized as license fees in the Company s statement of operations for the year ended December 31, 2015. The Company may be obligated in a future period to make an additional one-time regulatory milestone payment of $8.0 million payable upon obtaining the first regulatory approval from the FDA. The Company would also be required to make royalty payments of up to two percent on net product sales, if any.

Legal Proceedings

In March 2015, following the Company s announcement of the update to the timing of its planned NDA submission to the FDA for NUPLAZID for the treatment of Parkinson s disease psychosis (PDP) and the subsequent decline of the price of its common stock, two putative securities class action complaints (captioned *Rihn v. ACADIA Pharmaceuticals Inc.*, Case No. 15-cv-0575-BTM-DHB, and *Wright v. ACADIA Pharmaceuticals Inc.*, Case No. 15-cv-0593- BTM-DHB) were filed in the U.S. District Court for the Southern District of California (the Court) against the Company and certain of its current and former officers. The complaints generally alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding the timing of the Company s planned NDA submission to the FDA for NUPLAZID, thereby artificially inflating the price of its common stock. The complaints sought unspecified monetary damages and other relief. On April 10 and June 1, 2015, the Court entered orders deferring the defendants response to the Rihn and Wright complaints until after the Court appointed a lead plaintiff and assigned lead counsel. On May 12, 2015, several putative stockholders filed separate motions to consolidate the two actions and be appointed lead plaintiff. On September 8, 2015, the Court issued an order consolidating the two actions, appointing lead plaintiff, and assigning lead counsel. On November 16, 2015, lead plaintiff filed a consolidated complaint with the Court which, like the prior complaints,

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

accuses the defendants of making materially false and misleading statements regarding the anticipated timing of the Company s planned NDA submission to the FDA for NUPLAZID. On January 15, 2016, the defendants filed a motion to dismiss the consolidated complaint. Subject to court approval, the parties stipulated that plaintiffs shall file their opposition to defendants motion to dismiss on March 22, 2016 and that defendants shall file their reply to plaintiffs opposition on April 21, 2016. The hearing on the defendants motion to dismiss is scheduled for May 20, 2016. The Company has assessed such legal proceedings, and given the unpredictability inherent in litigation, the Company cannot predict the outcome of these matters. At this time, the Company is unable to estimate possible losses or ranges of losses that may result from such legal proceedings, and it has not accrued any amounts in connection with such legal proceedings other than ongoing attorneys fees.

11. Subsequent Event

In January 2016, the Company raised net proceeds of approximately $281.6 million from the sale of 10,344,827 shares of its common stock in a follow-on public offering. The common stock issued in this financing is not included in basic or diluted common shares outstanding as of December 31, 2015. In connection with the January 2016 offering, the Company entered into a registration rights agreement (the Registration Rights Agreement) with 667, L.P., Baker Brothers Life Sciences, L.P. and 14159, L.P. (the Baker Entities), all of which are existing stockholders of the Company and are affiliated with two of its directors, Julian C. Baker and Dr. Stephen R. Biggar. Under the Registration Rights Agreement, the Company agreed that, if at any time and from time to time after April 5, 2016, the Baker Entities demand that the Company register their shares of its common stock, par value $0.0001 per share, for resale under the Securities Act of 1933, as amended (the Securities Act), the Company would be obligated to effect such registration. The Company s registration obligations under the Registration Rights Agreement cover all shares of its common stock now held or later acquired by the Baker Entities (including approximately $75.0 million of shares that the Baker Entities purchased at the public offering price in the January 2016 offering), will continue in effect for up to 10 years, and include the Company s obligation to facilitate certain underwritten public offerings of its common stock by the Baker Entities in the future. The Company has agreed to bear all expenses incurred by it in effecting any registration pursuant to the Registration Rights Agreement as well as the legal expenses of the Baker Entities of up to $50,000 per underwritten public offering effected pursuant to the Registration Rights Agreement.

12. Selected Quarterly Financial Data (Unaudited)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for the years ended December 31, 2015 and 2014 are as follows (in thousands, except per share data):

	Fiscal Year 2015 Quarters				
	1st	2nd	3rd	4th	Total
Revenues	$ 4	$ 1	$ 39	$ 17	$ 61
Net loss	$ (40,375)	$ (39,378)	$ (38,906)	$ (45,784)	$ (164,443)
Basic and diluted net loss per share(1)	$ (0.40)	$ (0.39)	$ (0.39)	$ (0.45)	$ (1.63)

	Fiscal Year 2014 Quarters				
	1st	2nd	3rd	4th	Total
Revenues	$ 30	$ 28	$ 15	$ 47	$ 120
Net loss	$ (17,828)	$ (21,495)	$ (24,786)	$ (28,366)	$ (92,475)
Basic and diluted net loss per share(1)	$ (0.19)	$ (0.22)	$ (0.25)	$ (0.28)	$ (0.95)

(1) Net loss per common share, basic and diluted, are computed independently for each quarter and the full year based upon respective average shares outstanding. Therefore, the sum of the quarterly net loss per common share amounts may not equal the annual amounts reported.

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INDEX TO EXHIBITS

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as Amended (incorporated by reference to Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q, filed August 6, 2015).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed September 12, 2013).
4.1	Form of common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to Registration Statement No. 333-52492).
4.2	Form of Warrant to Purchase Common Stock issued to purchasers in a private placement on January 12, 2011 (incorporated by reference to Exhibit 4.5 to Registration Statement No. 333-171722).
4.3	Form of Warrant to Purchase Common Stock issued to certain purchasers in a private placement on December 17, 2012 (incorporated by reference to Exhibit 4.4 to Registration Statement No. 333-185639).
10.1[a]	Form of Indemnity Agreement for directors and officers (incorporated by reference to Exhibit 10.1 to Registration Statement No. 333-113137).
10.2[a]	2004 Equity Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.3 to Registration Statement No. 333-113137).
10.3[a]	2010 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed June 19, 2015).
10.4[a]	Forms of agreement under the 2010 Equity Incentive Plan.
10.5[a]	2004 Employee Stock Purchase Plan and initial offering thereunder (incorporated by reference to Exhibit 10.4 to Registration Statement No. 333-113137).
10.6[a]	Employment Letter Agreement, dated December 21, 1998, between the Registrant and Uli Hacksell, Ph.D. (incorporated by reference to Exhibit 10.7 to Registration Statement No. 333-52492).
10.7[a]	Employment Offer Letter, dated May 26, 2006, between the Registrant and Roger Mills (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed April 2, 2007).
10.6[a]	Employment Agreement, dated March 16, 2010, between the Registrant and Glenn F. Baity (incorporated by reference to Exhibit 10.13 to the Registrant s Annual Report on Form 10-K, filed March 10, 2011).
10.7[a]	Employment Agreement, dated August 19, 2013, between the Registrant and Terrence Moore (incorporated by reference to Exhibit 10.13 to the Registrant s Annual Report on Form 10-K, filed February 27, 2014).
10.8[a]	Employment Agreement, dated September 1, 2015, between the Registrant and Stephen Davis (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed September 3, 2015).
10.9[a]	Retention Bonus Agreement, dated March 20, 2015, between the Registrant and Stephen Davis (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q, filed May 7, 2015).
10.10[a]	Employment Offer Letter, dated October 28, 2015, between the Registrant and Srdjan Stankovic.
10.11[a]	Executive Employment Transition Agreement, dated March 11, 2015, between the Registrant and Uli Hacksell, Ph.D. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q, filed May 7, 2015).

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Exhibit Number	Description
10.12[a]	Description of Executive Officer Annual Incentive Cash Compensation Program (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed March 11, 2014).
10.13[a]	Management Severance Benefit Plan (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed December 15, 2015).
10.14[a]	Amended and Restated Change in Control Severance Benefit Plan (incorporated by reference to Exhibit 99.2 to the Registrant s Current Report on Form 8-K, filed December 15, 2015).
10.15[a]	Description of Outside Director Compensation Program (incorporated by reference to Exhibit 10.13 to the Registrant s Annual Report on Form 10-K, filed March 12, 2013).
10.16[b]	Collaborative Research, Development and License Agreement, dated September 24, 1997, by and among the Registrant, Allergan, Inc. and Vision Pharmaceuticals L.P. (now Allergan Sales, Inc.) (incorporated by reference to Exhibit 10.12 to Registration Statement No. 333-113137).
10.17[b]	Amendment to Collaborative Research, Development and License Agreement, dated March 27, 2003, by and among the Registrant, Allergan Sales LLC (as successor in interest of Vision Pharmaceuticals L.P.) and Allergan, Inc. (incorporated by reference to Exhibit 10.13 to Registration Statement No. 333-113137).
10.18[b]	Second Amendment to Collaborative Research, Development and License Agreement, dated February 28, 2006, by and among the Registrant, Allergan Sales LLC (as successor in interest of Vision Pharmaceuticals L.P.) and Allergan, Inc. (incorporated by reference to Exhibit 10.25 to the Registrant s Annual Report on Form 10-K, filed March 15, 2006).
10.19[b]	Third Amendment to Collaborative Research, Development and License Agreement, dated March 3, 2008, by and among the Registrant, Allergan Sales LLC (as successor in interest of Vision Pharmaceuticals L.P.) and Allergan, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q, filed May 5, 2008).
10.20[b]	Fourth Amendment to Collaborative Research, Development and License Agreement, dated April 22, 2009, by and among the Registrant, Allergan Sales LLC (as successor in interest of Vision Pharmaceuticals L.P.) and Allergan, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q, filed August 5, 2009).
10.21[b]	Fifth Amendment to Collaborative Research, Development and License Agreement, dated March 23, 2010, by and among the Registrant, Allergan Sales LLC (as successor in interest of Vision Pharmaceuticals L.P.) and Allergan, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q, filed May 10, 2010).
10.22[b]	Sixth Amendment to Collaborative Research, Development and License Agreement, dated March 28, 2011, by and among the Registrant, Allergan Sales LLC (as successor in interest of Vision Pharmaceuticals L.P.) and Allergan, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q, filed May 9, 2011).
10.23[b]	Seventh Amendment to Collaborative Research, Development and License Agreement, dated February 29, 2012, by and among the Registrant, Allergan Sales LLC (as successor in interest of Vision Pharmaceuticals L.P.) and Allergan, Inc. (incorporated by reference to Exhibit 10.23 to the Registrant s Annual Report on Form 10-K, filed March 6, 2012).
10.24[b]	Master Manufacturing Services Agreement and Product Agreement, dated August 3, 2015, by and between the Registrant and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q, filed November 5, 2015).

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Exhibit Number	Description
10.25[b]	Co-Operation Agreement and Product Schedule, dated August 17, 2015, by and between ACADIA Pharmaceuticals GmbH and BASF Pharma (Evionnaz) SA (now Siegfried Evionnaz SA) (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q, filed November 5, 2015).
10.26	Registration Rights Agreement, dated January 6, 2016, between the Registrant and the investors listed on Schedule A thereto (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K, filed January 7, 2016).
10.27	Lease Agreement for 11085 Torreyana Road, dated June 5, 2013, between the Registrant and HCP Torreyana, LLC (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed June 7, 2013).
10.28	First Amendment to Lease Agreement for 11085 Torreyana Road, dated August 28, 2013, between the Registrant and HCP Torreyana, LLC (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q, filed November 6, 2013).
10.29[b]	Sublease Agreement, effective November 13, 2014, between the Registrant and Trion Worlds, Inc. (incorporated by reference to Exhibit 10.28 to the Registrant s Annual Report on Form 10-K, filed February 26, 2015).
10.30	Assignment of Brann Intellectual Property Rights, dated January 29, 1997, by Mark R. Brann in favor of the Registrant (incorporated by reference to Exhibit 10.17 to Registration Statement No. 333-52492).
10.31[b]	License Agreement, dated November 30, 2006, by and between the Registrant and Société de Conseils, de Recherches et d Applications Scientifiques SAS, a French corporation member of the Ipsen Group (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed December 4, 2006).
21.1	List of subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page hereto).
31.1	Certification of Stephen Davis, Chief Executive Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Stephen Davis, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial statements from this Annual Report, formatted in XBRL (Extensible Business Reporting Language), are filed herewith: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Cash Flows, (v) Consolidated Statements of Stockholders Equity, and (vi) Notes to Consolidated Financial Statements.

[a] Indicates management contract or compensatory plan or arrangement.

[b] We have requested or received confidential treatment of certain portions of this agreement, which have been omitted and filed separately with the SEC pursuant to Rule 406 under the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.