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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2017

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 ☒ No ☐

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of June 30, 2017, 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 $2.1 billion, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on June 30, 2017 of $27.89 per share.

As of January 31, 2018, 124,701,944 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 30, 2018 are incorporated by reference into Part III of this report.

ACADIA PHARMACEUTICALS INC.

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For the Year Ended December 31, 2017

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. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "hopes," "may," "will," "plans," "intends," "estimates," "could," "should," "would," "continue," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential" or other similar words (including their use in the negative), or by discussions of future matters such as the benefits to be derived from NUPLAZID® (pimavanserin) and from our drug candidates, the potential market opportunities for pimavanserin and our drug candidates, our strategy for the commercialization of NUPLAZID, our plans for exploring and developing pimavanserin for indications other than Parkinson's disease psychosis, our plans and timing with respect to seeking regulatory approvals, the potential commercialization of any of our drug candidates that receive regulatory approval, the progress, timing, results or implications of clinical trials and other development activities involving NUPLAZID and our drug candidates, our strategy for discovering, developing and, if approved, commercializing drug candidates, our existing and potential future collaborations, our estimates of future payments, revenues and profitability, our estimates regarding our capital requirements, future expenses and need for additional financing, 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, or CNS, disorders. We have a portfolio of product opportunities led by our novel drug, NUPLAZID (pimavanserin), which was approved by the U.S. Food and Drug Administration, or FDA, on April 29, 2016 for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis, or PD Psychosis, and is the only 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 demonstrated significant efficacy in reducing the hallucinations and delusions associated with PD Psychosis in our Phase 3 pivotal trial and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA in the treatment of PD Psychosis. We hold worldwide commercialization rights to pimavanserin. We launched NUPLAZID in the United States in May 2016.

We believe that pimavanserin has the potential to address important unmet medical needs in neurological and psychiatric disorders in addition to PD Psychosis and we plan to continue to study the use of pimavanserin in multiple disease states.

For example, we believe dementia-related psychosis represents one of our most important opportunities for further exploration. In December 2016, we announced positive top-line results from our Phase 2 study exploring the utility of pimavanserin for the treatment of Alzheimer's disease psychosis, or AD Psychosis, a disorder for which no drug is currently approved by the FDA. Following our End-of-Phase 2 Meeting with the FDA and agreement with the agency on our clinical development plan, we initiated

our Phase 3 HARMONY relapse prevention study in October 2017, which allows us to evaluate pimavanserin for a broader indication than AD Psychosis alone. More specifically, HARMONY will evaluate pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis, which includes psychosis in patients with Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia, and frontotemporal dementia. Furthermore, in October 2017, the FDA granted Breakthrough Therapy Designation to pimavanserin for dementia-related psychosis.

As a result of potential overlap of clinical sites and study participants between the HARMONY study and our Phase 2 study evaluating pimavanserin for the treatment of Alzheimer's disease agitation and aggression, which we refer to as SERENE, we decided to discontinue enrollment of new patients in that study. Patients already enrolled in SERENE will complete the study as planned.

We also believe schizophrenia represents a disease with multiple unmet or ill-served needs and we are currently exploring the utility of pimavanserin in this area. Despite a large number of FDA-approved therapies for schizophrenia, current drugs do not adequately address some very important symptoms of schizophrenia, such as the inadequate response to current antipsychotic treatment of psychotic symptoms and negative symptoms. In the fourth quarter of 2016, we initiated two studies evaluating the adjunctive use of pimavanserin in patients with schizophrenia. ENHANCE-1 is a Phase 3 study evaluating pimavanserin for adjunctive treatment of schizophrenia in patients with an inadequate response to their current antipsychotic therapy. ADVANCE is a Phase 2 study evaluating pimavanserin for adjunctive treatment in patients with negative symptoms of schizophrenia.

Depression is another disorder with a high unmet need that we believe represents an attractive development opportunity for pimavanserin. Preclinical and clinical studies have shown that patients with depression often do not receive adequate relief from an antidepressant medication, and, due to side effects of currently available therapies, many patients discontinue their medication, significantly increasing their chance of relapse. Preclinical and clinical evidence suggests 5-HT_{2A} antagonism may be an effective adjunctive therapy to currently prescribed antidepressants. In the fourth quarter of 2016, we initiated CLARITY, a Phase 2 study evaluating pimavanserin for adjunctive treatment in patients with major depressive disorder, or MDD, who have an inadequate response to standard antidepressant therapy. We expect to report top-line results from the CLARITY study in the second half of 2018.

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.

Our Strategy

Our strategy is to discover, develop and commercialize innovative small molecule drugs that address unmet medical needs in CNS 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 PD Psychosis, Alzheimer's disease, schizophrenia, depression, and other CNS disorders. Key elements of our strategy are to:

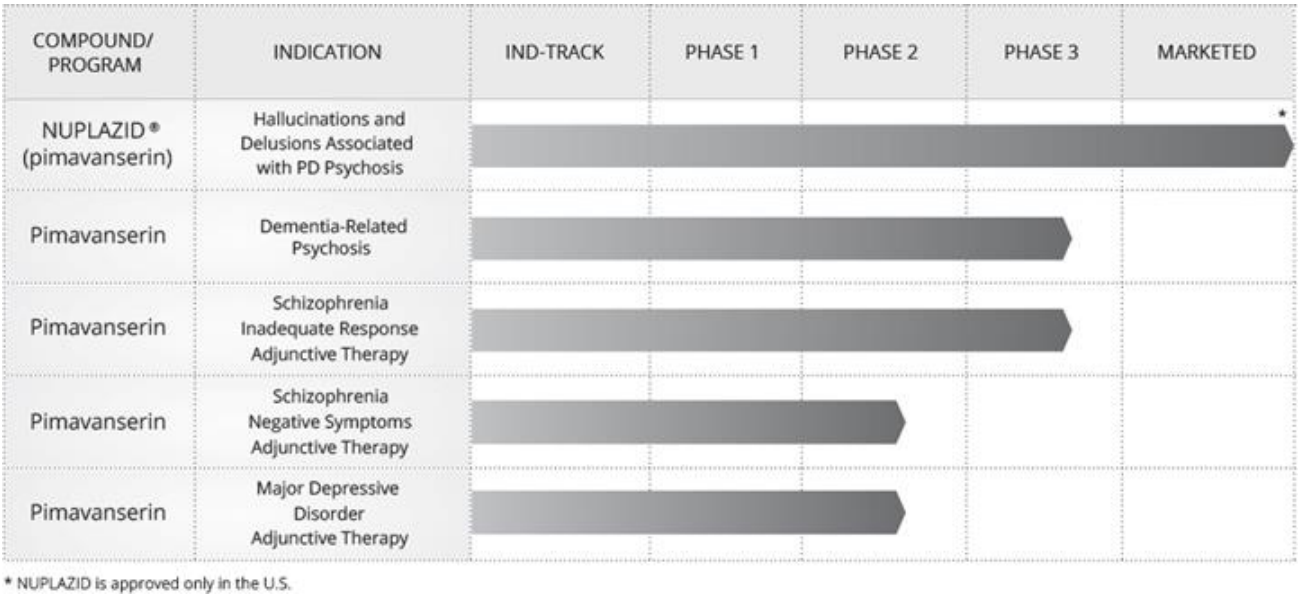
- ***Successfully commercialize NUPLAZID for PD Psychosis in the United States.*** NUPLAZID was approved by the FDA on April 29, 2016 for the treatment of hallucinations and delusions associated with PD Psychosis, and is the only drug approved in the United States for this condition. We launched NUPLAZID in the United States in May 2016 and an important objective is to establish NUPLAZID as the first choice, best choice for PD Psychosis. We employ approximately 150 U.S. sales specialists who are focused on promoting NUPLAZID to physicians who treat PD Psychosis patients, including neurologists, psychiatrists and long-term care physicians.
- ***Leverage the commercial potential of pimavanserin by expanding to additional neurological and psychiatric disorders.*** We intend to continue pursuing the development and commercialization of pimavanserin in additional neurological and psychiatric indications that are underserved by currently available antipsychotics and antidepressants and represent large unmet medical needs. For example, in October 2017, we initiated our Phase 3 HARMONY relapse prevention study to evaluate pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis, which

includes psychosis in patients with Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia and frontotemporal dementia. We are also testing pimavanserin as an adjunctive therapy in schizophrenia for negative symptoms, schizophrenia inadequate response, and depression. In addition to the ongoing development of pimavanserin in these areas, we may also consider additional indications that are a good strategic fit and which have large unmet medical needs.

- ***In-license or acquire complementary products or product candidates.*** Although NUPLAZID (pimavanserin) emanates from internal discoveries, in the future we plan to in-license or acquire assets, which could include clinical-stage product candidates or commercial-stage products, to leverage our U.S. specialty sales force.

Our Pipeline

NUPLAZID (pimavanserin) was approved by the FDA on April 29, 2016 for the treatment of hallucinations and delusions associated with PD Psychosis. In addition to PD Psychosis, our pipeline includes multiple product opportunities being explored in clinical development across several CNS disorders with high unmet medical needs. 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 was approved by the FDA on April 29, 2016 for the treatment of hallucinations and delusions associated with PD Psychosis and is the only drug approved in the United States for this condition and is called NUPLAZID commercially. NUPLAZID is an SSIA preferentially targeting the 5-HT_{2A} receptor, a key serotonin receptor that plays an important role in psychosis. Through this novel mechanism, NUPLAZID demonstrated significant efficacy in reducing the hallucinations and delusions associated with PD Psychosis in our Phase 3 pivotal trial and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA in the treatment of PD Psychosis. We hold worldwide commercialization rights to NUPLAZID for all indications and have established a broad patent portfolio, which includes numerous issued patents in the United States, Europe, and several additional countries. The recommended dosing of NUPLAZID is 34 mg once a day taken as two 17 mg tablets.

NUPLAZID as a Treatment for PD Psychosis

Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease. According to the Parkinson's Disease Foundation, about one million people in the United States and more than 10 million people globally suffer from this disease. More than 50 percent of Parkinson's patients will experience psychosis over the course of their 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.

PD 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. PD Psychosis is associated with a diminished quality of life, nursing home placement, and increased caregiver stress and burden.

As the first and only drug approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis, NUPLAZID provides an innovative and non-dopaminergic approach to the treatment of PD Psychosis without compromising motor control and potentially avoiding many of the debilitating side effects of existing antipsychotics.

In connection with the FDA approval of NUPLAZID, we have committed to conduct post-marketing studies, including a randomized, placebo-controlled withdrawal study in PD Psychosis patients treated with NUPLAZID and randomized, placebo-controlled eight-week studies in predominantly frail and elderly patients that would add to the NUPLAZID safety database by exposing an aggregate of at least 500 patients to NUPLAZID. Through our open-label safety extension study for our Phase 3 studies in PD Psychosis, together with a similar extension study from our earlier Phase 2 PD Psychosis trial, we generated a considerable amount of long-term safety data on NUPLAZID. A total of over 275 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 11 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 Dementia-Related Psychosis

Around 8 million people in the United States are living with dementia and approximately half are diagnosed with the disease. While the primary symptoms of dementia involve cognitive decline, patients with dementia frequently have behavioral symptoms as well. In addition to agitation and aggressive symptoms, they commonly have psychotic symptoms. Studies suggest that approximately 30 percent of patients with dementia have psychosis, commonly consisting of hallucinations and delusions. Patients with dementia-related psychosis share many characteristics and often exhibit similar psychiatric symptoms irrespective of their underlying neurodegenerative disease.

According to the American Psychiatric Association (APA) guidelines "an overwhelming majority" of older adults with dementia will develop psychosis or agitation during the course of their illness. Symptoms are often persistent and occur with increasing frequency as cognition becomes more impaired. Serious consequences have been associated with persistent or severe psychosis in persons with dementia such as repeated hospital admissions, earlier progression to nursing home care, severe dementia, and death. There is currently no approved treatment for dementia-related psychosis. Off-label use of atypical antipsychotics is associated with modest and often equivocal efficacy in these patients. More importantly, use of currently available antipsychotics is associated with a significant acceleration in cognitive decline in patients with dementia as well as numerous off-target toxicities, thus negatively impacting their primary illness. Cognitive effects of treatment with an atypical antipsychotic were evaluated in the National Institute of Mental Health Clinical Antipsychotic Trials of Intervention Effectiveness–Alzheimer's Disease (CATIE-AD) study. In this study, patients on any atypical antipsychotic had significantly greater rates of decline in cognitive function compared to patients on placebo. This pronounced negative impact of currently used antipsychotics on cognitive function is believed to be associated with the common pharmacologic property of these drugs, namely blocking of dopamine receptors. Moreover, anticholinergic activity, which is also present in atypical antipsychotics, is well-known to be associated with cognitive dulling. The lack of selectivity of atypical antipsychotics with respect to receptor activity also results in a number of dose-limiting side effects, such as extrapyramidal symptoms, orthostatic hypotension, hematologic abnormalities, and metabolic, gastrointestinal and sedative effects. These off-target toxicities result in increased risk for falls, infection, aspiration pneumonia, and other serious complications in this vulnerable patient population. With no approved therapies for the treatment of patients with dementia-related psychosis and current off-label use of atypical antipsychotics carrying significant morbidity risks including worsening in cognitive decline and other off target toxicities, we believe that dementia-related psychosis represents an area of high unmet need.

In October 2017, we initiated our HARMONY relapse prevention study, a Phase 3, randomized, double-blind, placebo-controlled study, evaluating the efficacy and safety of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis. The objective of the study is to evaluate the ability of pimavanserin to prevent relapse of psychotic symptoms in a broad population of patients with the most common subtypes of dementia: Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia and frontotemporal dementia. In October 2017, the FDA granted Breakthrough Therapy Designation to pimavanserin for dementia-related psychosis.

The HARMONY study includes a 12-week open-label stabilization period during which patients with dementia-related psychosis will be treated with pimavanserin 34 mg once daily. Dose reduction to 20 mg once daily will be allowed if clinically justified. Following the 12-week stabilization period, patients who meet pre-specified criteria for treatment response will then be randomized into the double-blind period of the study to continue their pimavanserin dose (34 mg or 20 mg per day) or be switched to

placebo and followed for up to 26 weeks or until a relapse of psychosis occurs. The primary endpoint in the study is time to relapse in the double-blind period. The study will be conducted globally and is expected to enroll approximately 360 patients.

This Phase 3 development plan is supported by data from two completed clinical studies. In December 2016 we announced positive top-line results from our Phase 2 study, referred to as the -019 Study, examining the safety and efficacy of pimavanserin as a treatment for patients with AD Psychosis, which is a subset of the dementia-related psychosis population. The -019 Study was a double-blind, placebo-controlled exploratory trial designed to evaluate the efficacy and safety of pimavanserin as a treatment for patients with AD Psychosis. A total of 181 patients were enrolled in the study in the United Kingdom. Following a screening period that included brief psycho-social therapy, patients were randomized on a one-to-one basis to receive either 34 mg of pimavanserin or placebo once-daily. The primary endpoint of the study was antipsychotic efficacy as measured by the mean change in the Neuropsychiatric Inventory—Nursing Home, or NPI-NH, Psychosis score (combined hallucinations and delusions domains) from baseline to week six of dosing. The study also assessed additional secondary endpoints, including the cognitive status of patients and the durability of response to pimavanserin, through week 12 of dosing.

Pimavanserin demonstrated efficacy on the primary endpoint of the -019 Study with a 3.76 point improvement in psychosis at week six compared to a 1.93 point improvement for placebo, representing a statistically significant treatment improvement in the NPI-NH Psychosis score ($p=0.0451$). Baseline mean scores for the pimavanserin and placebo treated groups were 9.52 and 10.00, respectively. Pimavanserin was generally well tolerated and the safety profile was consistent with what has been observed in previous studies. Based on a preliminary analysis of safety data, the most common adverse events reported were falls, urinary tract infection and agitation. The mortality rate was the same in the pimavanserin and placebo treatment groups. Over the course of 12 weeks of treatment, pimavanserin did not impair cognition as measured by the Mini-Mental State Examination, or MMSE, score and was similar to placebo. On the secondary endpoint of mean change in NPI-NH Psychosis score at week 12, pimavanserin maintained the improvement on psychosis observed at the week six primary endpoint, but did not statistically separate from placebo. The mean age of patients in the study was 86 years. Because it has been shown that common symptoms of psychosis in different dementia subtypes need not be etiologically related to respond to pharmacologic treatment, we believe that the results of the -019 Study in patients with AD Psychosis and observations of demented patients in our -020 Study in patients with PD Psychosis indicate that pimavanserin may be an effective treatment for the other subgroups of dementia-related psychosis. Results from this Phase 2 study in AD psychosis were presented at the 10th Clinical Trials on Alzheimer's Disease (CTAD) Meeting on November 3, 2017 in Boston.

Additional clinical evidence for efficacy of pimavanserin in dementia-related psychosis was observed in our Phase 3 -020 Study in patients with Parkinson's disease psychosis. Approximately a quarter of the patients enrolled in the -020 Study also suffered from mild dementia. In a pre-specified subgroup analysis of these patients, those treated with pimavanserin observed a significant improvement in psychosis compared to placebo. This effect was larger than the overall average effect observed in the study.

Pimavanserin as an Adjunctive Treatment for Schizophrenia

Schizophrenia is a severe chronic mental illness that involves disturbances in cognition, perception, emotion, and other aspects of behavior. These disturbances may include positive symptoms, such as hallucinations and delusions, and a range of negative symptoms, including 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, or NIMH, approximately one percent of the U.S. population suffers from schizophrenia.

Most patients with schizophrenia 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. Despite their commercial success, current antipsychotic drugs have substantial limitations, including inadequate efficacy and severe side effects. The side effects induced by the atypical agents may include weight gain, non-insulin dependent (type 2) 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 NIMH, 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.

As an SSIA, pimavanserin is a new class of antipsychotic medication with a distinct mechanism of action targeting serotonergic 5-HT_{2A} receptors while avoiding activity at dopamine and other receptors commonly targeted by other antipsychotics which, we

believe, may enable pimavanserin to be used in certain treatment approaches to improve the therapy for patients with schizophrenia. We initiated the following studies during the fourth quarter of 2016 to evaluate pimavanserin for adjunctive treatment of schizophrenia in patients with an inadequate response to current antipsychotic therapy and for adjunctive treatment in patients with negative symptoms of schizophrenia:

ENHANCE-1

In November 2016, we announced that we initiated ENHANCE-1, a Phase 3 study to evaluate pimavanserin for adjunctive treatment of schizophrenia in patients with an inadequate response to current antipsychotic therapy. According to the American Psychiatric Association, about 30 percent of patients with schizophrenia have inadequate response to antipsychotic medications, meaning that they exhibit improvement, but continue to have residual hallucinations or delusions. As a result, about 25 to 50 percent of schizophrenia patients are treated with two or more antipsychotics. This polypharmacy has led to increased dose-related side effects and complicated dosing regimens that can further contribute to poor treatment compliance and subsequent relapse in these patients. We believe pimavanserin, through its highly selective mechanism of action, could provide an important new option for adjunctive treatment of schizophrenia and improve clinical outcomes by both augmenting the efficacy of currently used antipsychotics and lessening the undesirable side effects associated with polypharmacy.

ENHANCE-1 is a Phase 3, six-week, randomized, double-blind, placebo-controlled, multi-center, outpatient study designed to examine the efficacy and safety of adjunctive use of pimavanserin in patients with schizophrenia who have not achieved an adequate response to their current antipsychotic treatment. Approximately 380 patients will be randomized to receive pimavanserin, or placebo, orally, once daily, in addition to their ongoing antipsychotic in a flexible dosing regimen. The starting daily dose of 20 mg of pimavanserin at baseline may be adjusted to 34 mg or 10 mg during the first three weeks of treatment. The primary endpoint of the study is the change from baseline to week six on the Positive and Negative Syndrome Scale, or PANSS, total score. Following participation in ENHANCE-1, patients will be eligible to enroll in a 52-week open-label extension study.

ADVANCE

In November 2016, we announced that we initiated ADVANCE, a Phase 2 study to evaluate pimavanserin for adjunctive treatment in patients with negative symptoms of schizophrenia. Studies show that about 40 to 50 percent of schizophrenia patients suffer from prominent negative symptoms. While currently available antipsychotic treatments for schizophrenia target positive symptoms, most patients remain functionally impaired because of negative symptoms, cognitive deficits and limited social function. There is currently no drug approved by the FDA for the treatment of the negative symptoms of schizophrenia.

ADVANCE is a Phase 2, 26-week, randomized, double-blind, placebo-controlled, multi-center study designed to examine the efficacy and safety of adjunctive use of pimavanserin in patients with schizophrenia who have predominant negative symptoms. Approximately 380 patients will be randomized to receive either pimavanserin or placebo, orally, once daily, in addition to their ongoing antipsychotic in a flexible dosing regimen. The starting daily dose of 20 mg of pimavanserin at baseline may be adjusted to 34 mg or 10 mg during the first eight weeks of treatment. The primary endpoint of the study is the change from baseline to week 26 on the Negative Symptom Assessment-16, or NSA-16, total score. Following participation in ADVANCE, patients will be eligible to enroll in a 52-week open-label extension study.

Pimavanserin as an Adjunctive Treatment for Major Depressive Disorder

Major depressive disorder is a condition characterized by depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities for more than two weeks, as well as impaired social, occupational or other important functioning. Studies have shown that the majority of people who suffer from MDD do not respond to initial antidepressant therapy. Also, due to side effects of current therapies, many patients discontinue their medication, significantly increasing their chance of relapse. According to the NIMH, MDD affects approximately 16 million adults in the United States and is the leading cause of disability for ages 15-44.

Preclinical and clinical evidence suggests that the blockade of 5-HT_{2A} receptors improves the clinical effects of selective serotonin reuptake inhibitors, or SSRIs. As an SSIA preferentially targeting 5-HT_{2A} receptors, we believe use of pimavanserin as an adjunctive treatment for MDD may improve outcomes for patients with MDD.

In December 2016, we announced that we initiated CLARITY, a Phase 2, 10-week, randomized, double-blind, placebo-controlled, multi-center study designed to examine the efficacy and safety of adjunctive use of pimavanserin in patients with MDD who have an inadequate response to standard antidepressant therapy with either an SSRI or a serotonin norepinephrine reuptake inhibitor, or SNRI. Approximately 188 patients will be randomized to receive either 34 mg of pimavanserin or placebo, orally, once daily, in addition to their ongoing antidepressant for 10 weeks. The primary endpoint of the study is the change from baseline on the Hamilton Depression Rating Scale, or HAM-D, total score.

Pimavanserin Study in Patients with AD Agitation and/or Aggression

In October 2016, we announced that we initiated SERENE, a randomized, double-blind, placebo-controlled, multi-center outpatient Phase 2 study designed to examine the efficacy and safety of pimavanserin in AD Agitation. At that time, the study was designed to randomize approximately 430 patients with Alzheimer's disease who have agitation and/or aggression symptoms to receive once daily oral doses of 34 mg pimavanserin, 20 mg pimavanserin or placebo for 12 weeks. The primary endpoint in the study is a reduction in total score on the Cohen-Mansfield Agitation Inventory, or CMAI. Following participation in SERENE, patients would be eligible to enroll in an open-label safety extension study. In October 2017, we announced that due to the potential overlap of clinical sites and study participants between the Phase 3 HARMONY dementia-related psychosis study and the SERENE study, that we had discontinued enrollment of new patients in the SERENE study. Patients already enrolled will complete the study as planned.

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.

For example, the use of NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis competes with off-label use of antipsychotic drugs, including generic drugs quetiapine, clozapine, olanzapine, risperidone and aripiprazole.

If approved, pimavanserin for the treatment of dementia-related 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 plc.

Pimavanserin for the adjunctive treatment of schizophrenia, if approved for that indication, would compete with Rexulti, marketed by Otsuka Pharmaceutical Co., Ltd., Latuda, marketed by Sunovion Pharmaceuticals Inc., and generic drugs, including olanzapine, risperidone, aripiprazole and clozapine.

Pimavanserin for the adjunctive treatment of MDD, if approved for that indication, would compete with Rexulti and generic adjunctive atypical antipsychotics, including aripiprazole, quetiapine and risperidone.

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 for the applicable disorder. 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;
- obtaining FDA and other regulatory approvals; and
- commercializing pharmaceutical products.

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;
- sales and marketing; and
- production facilities.

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 32 issued U.S. patents and 191 issued foreign patents. All of these patents originated from inventions made by us. In addition, we have 19 provisional and utility U.S. patent applications and 23 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 chemical synthetic or manufacturing methods, novel drug targets and novel compounds, and compositions or methods of treatment identified using our technology.

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 that complement the intellectual property portfolio for our serotonin platform, including pimavanserin. We are required to pay to the Ipsen Group royalties of up to two percent of net product sales of NUPLAZID 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-seven U.S. patents have been issued to us that relate to pimavanserin and NUPLAZID, including three that cover the compound generically and 19 that specifically cover pimavanserin, salts or polymorphs thereof, the use thereof for treating PD Psychosis, AD Psychosis, Alzheimer’s disease indications, schizophrenia, bipolar disorder, Lewy body dementia, sleep disorders, hallucinations, delusions and other methods of treatment. These patents also provide protection for certain methods of producing pimavanserin. The pimavanserin-specific patent is currently set to expire in June 2027. The patent that covers polymorphs of pimavanserin is currently set to expire in June 2028. The patents that cover pimavanserin generically expire in 2021. In the United States, we are permitted to extend the term of one U.S. patent for the pimavanserin product. 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 any given patent term extension or any terminal disclaimer that reduces patent term. We note that the U.S. patent laws are always changing and thus any modifications or new interpretations of the law may impact our patent terms. We have 75 issued foreign patents that specifically cover pimavanserin and polymorphs thereof, including patents in 34 European countries, Australia, Canada, China, Hong Kong, India, Japan, Mexico, New Zealand, Russia, Singapore and South Africa, which provide patent protection until 2024 and 2025, respectively. We continue to prosecute and file patent applications directed to pimavanserin and to methods of treating various diseases using pimavanserin, either alone or in combination with other agents, worldwide.

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 and commercialization of 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.

Government Regulation

Our business activities, including the manufacturing and marketing of NUPLAZID and 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. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. Moreover, government coverage and reimbursement policies will both directly and indirectly impact our ability to successfully commercialize NUPLAZID and any future approved products, and such coverage and reimbursement policies will be impacted by enacted and any applicable future healthcare reform and drug pricing 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 1 trials involve the initial introduction of the product candidate into healthy human volunteers. The emphasis of Phase 1 trials is on testing for safety or adverse effects, dosage, tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase 2 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 2 evaluations, Phase 3 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 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, which must be accompanied by payment of a significant user fee unless a waiver or exemption applies. 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. 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, or Phase 4, 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 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 and market acceptance, 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.

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 and must maintain ongoing compliance for commercial product manufacture. 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 a 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.

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.

Coverage and Reimbursement

Sales of NUPLAZID and of our product candidates, if approved, depend and 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 or a decision by a third-party payor to not cover NUPLAZID or any future approved products could reduce physician usage of our products, and have a material adverse effect on our sales, results of operations and financial condition.

In the United States, the Medicare Part D program provides a voluntary outpatient drug benefit to Medicare beneficiaries for certain products. NUPLAZID is available for coverage under Medicare Part D, but the individual Part D plans offer coverage subject to various factors such as those described above. In addition, while Medicare Part D plans have historically included "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, has in the past proposed, but not adopted, changes to this policy. 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, including coverage of NUPLAZID. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own coverage policies.

Healthcare Laws and Regulations

We are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. 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. In addition, the European Union, or EU, has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC, or the Data Protection Directive. The Data Protection Directive will be replaced starting in May 2018 with the recently adopted European General Data Protection Regulation, or GDPR, which contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We currently conduct clinical trials in the EU and will need to be compliant with these requirements. We anticipate that over time we may expand our business operations to include additional operations in the EU. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.
- 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 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 NUPLAZID and our product 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 percent and 13.0 percent 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 percent of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50 percent (and 70 percent commencing January 1, 2019) 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 requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a 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 certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the ACA, and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent under current law to 70 percent. Congress also could consider additional legislation to repeal or repeal and replace other elements of the ACA. At this time, the full effect that the ACA will have on our business in the future remains unclear.

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 percent per fiscal year, which went into effect in April 2013 and, following passage of the BBA, 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. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. The Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that we receive for NUPLAZID and any future approved products. We cannot predict what healthcare reform initiatives may be adopted in the future.

Research and Development Expenses

Our research and development expenses were $149.2 million, $99.3 million, and $73.9 million in 2017, 2016, and 2015, respectively.

Manufacturing and Distribution

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

During 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. ACADIA Pharmaceuticals GmbH manages the worldwide supply chain of pimavanserin API.

ACADIA Pharmaceuticals GmbH has contracted with Siegfried AG, or Siegfried, to manufacture the API to be used in the manufacture of NUPLAZID for commercial use. Under the manufacturing agreement, ACADIA Pharmaceuticals GmbH has agreed to purchase from Siegfried specified percentages of our commercial requirements of API for the United States and Europe. The parties may also agree in the future on additional services under the manufacturing agreement with respect to non-commercial supply or development activities. The term of the manufacturing agreement ends in December 2021 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 earlier pursuant to its terms. Either party may terminate the manufacturing agreement prior to expiration upon an uncured material breach by the other party, upon the dissolution or liquidation of the other party, the commencement of insolvency procedures that are not dismissed within a certain period of time, the appointment of any receiver, trustee or assignee to take possession of the properties of the other party or the cessation of all or substantially all of the other party's business operations, upon certain continuing patent infringement, regulatory litigation or other legal proceedings involving the manufacture of API, upon a continuing force majeure affecting the other party, or if no services are currently being provided under the manufacturing agreement. Additionally, if the parties agree on development services under the manufacturing agreement, the parties may terminate such services by mutual agreement if reasonable efforts to achieve the goals of such services fail. ACADIA Pharmaceuticals GmbH also may terminate any services under the manufacturing agreement for any reason on 90 days' prior notice to Siegfried, subject to the requirements of the manufacturing agreement.

We have contracted with Patheon Pharmaceuticals Inc., or Patheon, to manufacture NUPLAZID drug product tablets for commercial use in the United States. 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 ends in December 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 continuing to commercialize 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 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 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 also contracted with Catalent Pharma Solutions, LLC, or Catalent, to manufacture NUPLAZID drug product capsules for commercial use in the United States. Under the supply agreement, Catalent has agreed to manufacture and supply NUPLAZID 34 mg capsule drug product, referred to as NUPLAZID capsules, for our commercial use in the United States, Canada and Europe, and we have agreed to purchase from Catalent a specified percentage of our commercial requirements of NUPLAZID capsules for such territory, subject to a minimum annual purchase commitment of NUPLAZID capsules. Catalent will manufacture NUPLAZID capsules using API supplied by another third-party manufacturer. Under the supply agreement, Catalent will also perform specified validation services and assist us in obtaining regulatory approvals for Catalent’s manufacture of the NUPLAZID capsules. The term of the supply agreement extends for five years from the date that Catalent is first approved by a regulatory authority in the United States, Canada or Europe to produce NUPLAZID capsules, and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the supply agreement is terminated early pursuant to its terms. Either we or Catalent may terminate the supply agreement prior to expiration upon the bankruptcy or insolvency of the other party or upon an uncured material breach by the other party. We may terminate the supply agreement, subject to certain limitations, if any regulatory authority takes any enforcement or other action against Catalent’s facility which affects Catalent’s ability to manufacture NUPLAZID capsules, or takes any action or raises any objection that prevents us from manufacturing, importing, exporting, purchasing or selling NUPLAZID capsules, if we do not obtain regulatory approval of NUPLAZID capsules in the United States, if we determine not to launch or to discontinue commercialization of NUPLAZID capsules in the United States for safety or efficacy reasons, or if Catalent uses any debarred person in performing its service obligations under the supply agreement. We submitted an NDA to the FDA for the 34 mg capsule.

We sell NUPLAZID to a limited number of specialty pharmacies, or SPs, and specialty distributors, or SDs, which we collectively refer to as our customers. SPs subsequently dispense NUPLAZID to patients based on the fulfillment of a prescription and SDs subsequently sell NUPLAZID to government facilities, long-term care pharmacies, and in-patient hospital pharmacies. Four customers, each based in the United States, accounted for approximately 89 percent of our total revenue for the year ended December 31, 2017. 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 a U.S. sales force of approximately 150 sales specialists who are focused on promoting NUPLAZID to physicians who treat PD Psychosis patients, including neurologists, psychiatrists and long-term care physicians. This sales force is supported by an experienced sales leadership team of regional sales managers and account managers, and our experienced commercial team comprised of experienced professionals in marketing, access and reimbursement, managed markets, marketing research, commercial operations, and sales force planning and management. In addition, our commercial infrastructure includes capabilities in manufacturing, medical affairs, quality control, and compliance.

We launched NUPLAZID in May 2016, and our focus is to continue to establish NUPLAZID as the first choice, best choice for patients with PD Psychosis. In order to help us achieve this goal, we are continuing to increase awareness of NUPLAZID and PD Psychosis with a prescriber and patient education campaign consisting of key opinion leader speaker programs, attendance at medical meetings, multimedia campaigns, and direct-to-patient programs.

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 tangible long-lived assets, comprised of property plant and equipment totaled $2.7 million, $3.1 million, and $2.2 million as of December 31, 2017, 2016 and 2015, respectively. All of our tangible long-lived assets are located in the United States.

Employees

At December 31, 2017, we had approximately 425 employees. Of this workforce, approximately 135 employees were engaged in research and development activities, 85 were engaged in administrative activities such as finance, legal, and information technology, and 205 were engaged in sales, 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.

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 successful commercialization of NUPLAZID, which received approval in April 2016 from the U.S. Food and Drug Administration, or FDA, as a treatment for hallucinations and delusions associated with Parkinson's disease psychosis, and became available for prescription in the United States in May 2016. To the extent 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.

NUPLAZID is our only drug that has been approved for sale and it has only been approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis, or PD Psychosis, in the United States. We are focusing a significant portion of our activities and resources on NUPLAZID, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize NUPLAZID in the United States.

Successful commercialization of NUPLAZID is subject to many risks. Prior to NUPLAZID, we had never, as an organization, launched or commercialized any product, and there is no guarantee that we will be able to successfully commercialize NUPLAZID for its approved indication. There are numerous examples of failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us. While we have established our commercial team and have hired our U.S. sales force, we will need to refine and further develop the team in order to successfully commercialize NUPLAZID. Even if we are successful in developing our commercial team, there are many factors that could cause the commercialization of NUPLAZID to be unsuccessful, including a number of factors that are outside our control. Because no drug has previously been approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis, it is especially difficult to estimate NUPLAZID's market potential. The commercial success of NUPLAZID depends on the extent to which patients and physicians recognize and diagnose PD Psychosis and accept and adopt NUPLAZID as a treatment for hallucinations and delusions

associated with PD Psychosis, and we do not know whether our or others' estimates in this regard will be accurate. For example, if the patient population suffering from hallucinations and delusions associated with PD Psychosis is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to take NUPLAZID due to its "boxed" warning or for other reasons, the commercial potential of NUPLAZID will be limited. We have limited information about how physicians, patients and payors have responded and will respond to the pricing of NUPLAZID, including because as part of our initial launch strategy we provided free product as samples and through a 30-day free supply period of NUPLAZID, and do not know whether patients that initially use NUPLAZID will continue to do so after the sample or free supply period ends. Additionally, we have changed, and may continue to change, the price of NUPLAZID from time to time and, since April 2017, we have been providing free product for a 14-day period rather than a 30-day period, and we have limited information about how physicians, patients and payors have responded or will respond to these changes. Physicians may not prescribe NUPLAZID and patients may be unwilling to use NUPLAZID if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for NUPLAZID in our post-marketing commitments, in clinical development in additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of NUPLAZID. Thus, significant uncertainty remains regarding the commercial potential of NUPLAZID.

If the commercialization of NUPLAZID is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our company could be harmed.

If we do not obtain regulatory approval of NUPLAZID for other indications in the United States, or for any indication in foreign jurisdictions, we will not be able to market NUPLAZID for other indications or in other jurisdictions, which will limit our commercial revenues.

While NUPLAZID (pimavanserin) has been approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis, it has not been approved by the FDA for any other indications, and it has not been approved in any other jurisdiction for this indication or for any other indication. In order to market NUPLAZID for other indications or in other jurisdictions, we must obtain regulatory approval for each of those indications and in each of the applicable jurisdictions, and we may never be able to obtain such approval. Approval of NUPLAZID by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis does not ensure that foreign jurisdictions will also approve NUPLAZID for that indication, nor does it ensure that NUPLAZID will be approved by the FDA for any other indication. In the fourth quarter of 2016, we announced top-line results from a Phase 2 study with pimavanserin in Alzheimer's disease psychosis, or AD Psychosis, as well as the initiation of clinical studies of pimavanserin in several other indications. In addition, in October 2017, we initiated a Phase 3 study of pimavanserin in dementia-related psychosis, an indication for which no drug has been approved. There is no guarantee that any of these studies will be successful, or that the FDA or any regulatory authority in foreign jurisdictions will approve NUPLAZID for any of those indications. The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country. 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 for other indications or in other jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support our NDA submission in PD Psychosis. In addition, strategic considerations need to be taken into account when determining whether and when to submit NUPLAZID for approval in other jurisdictions. For example, in the fourth quarter of 2016, the European Medicines Agency, or EMA, approved our proposed pediatric investigation plan related to our planned submission of a marketing authorization application, or MAA, for NUPLAZID in Europe. However, in light of our continuing clinical development of pimavanserin in indications other than in PD Psychosis, and the time-limited data exclusivity currently granted by the EMA that commences on first approval of a product in Europe, we deferred submission of the MAA and we do not yet have a revised estimate of when we will make that filing. If we do not receive marketing approval for NUPLAZID for any other indication or from any regulatory agency outside of the United States, we will never be able to commercialize NUPLAZID for any other indication in the United States or for any indication in any other jurisdiction. Even if we do receive additional regulatory approvals, we may not be successful in commercializing those opportunities.

If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to NUPLAZID do not meet our or others' expectations, the market price of our common stock could decline significantly.

Even though the FDA has granted approval of NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis, the terms of the approval may limit its commercial potential. Additionally, NUPLAZID is still subject to substantial, ongoing regulatory requirements.

Even though the FDA has granted approval of NUPLAZID, the scope and terms of the approval may limit our ability to commercialize NUPLAZID and, therefore, our ability to generate substantial sales revenues. The FDA has approved NUPLAZID only for the treatment of hallucinations and delusions associated with PD Psychosis. The label for NUPLAZID also contains a "boxed" warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with PD Psychosis.

Additionally, NUPLAZID is approved only for the treatment of hallucinations and delusions associated with PD Psychosis, rather than for the treatment of PD Psychosis and/or other symptoms of PD Psychosis, which may cause confusion for prescribing physicians. This confusion could result in physicians not prescribing NUPLAZID for patients diagnosed with PD Psychosis. In addition, the "boxed" warning may discourage physicians from prescribing NUPLAZID to patients diagnosed with PD Psychosis, including those with dementia.

In connection with the FDA approval, we committed to conduct the following post-marketing studies: (i) a randomized, placebo-controlled withdrawal study in PD Psychosis patients treated with NUPLAZID, (ii) studies to collect additional data to add to the NUPLAZID safety database from an aggregate of at least 500 predominantly frail and elderly subjects on NUPLAZID in one or more randomized, placebo-controlled studies of eight or more weeks duration, (iii) a drug-drug interaction study with NUPLAZID and a strong CYP3A4 inducer, and (iv) re-analysis of tissue samples from certain previously conducted pre-clinical studies. If we fail to comply with our post-marketing commitments, or if the results of the post-marketing studies, or any other ongoing or planned clinical studies of NUPLAZID, are negative, the FDA could decide to withdraw approval, add warnings or narrow the approved indication in the product label.

The manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for NUPLAZID will also continue to 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 council for harmonization guidelines and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our nonclinical and clinical development and for any clinical trials that we conduct post-approval.

Discovery of any issues post-approval, including any safety concerns, such as unexpected side effects or drug-drug interaction problems, adverse events of unanticipated severity or frequency, or concerns over misuse or abuse of the product, problems with the facilities where the product is manufactured, packaged or distributed, or failure to comply with regulatory requirements, may result in, among other things, restrictions on NUPLAZID or on us, including:

- withdrawal of approval, addition of warnings or narrowing of the approved indication in the product label;
- requirement of a Risk Evaluation and Mitigation Strategy to mitigate the risk of off-label use in populations where the FDA may believe that the potential risks of use may outweigh its benefits;
- voluntary or mandatory recalls;
- warning letters;
- suspension of any ongoing clinical studies;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- restrictions on operations, including restrictions on the marketing or manufacturing of the product or the imposition of costly new manufacturing requirements; or
- seizure or detention, or refusal to permit the import or export of products.

If any of these actions were to occur, we may have to discontinue the commercialization of NUPLAZID, limit our sales and marketing efforts, conduct further post-approval studies, and/or discontinue or change any other ongoing or planned clinical studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

NUPLAZID has only been studied in a limited number of patients and in limited populations. As we continue to commercialize NUPLAZID, it is becoming available to a much larger number of patients and in broader populations, and we do not know whether the results of NUPLAZID use in such larger number of patients and broader populations will be consistent with the results from our clinical studies.

Prior to commencing our commercial launch of NUPLAZID in May 2016, NUPLAZID was administered only to a limited number of patients and in limited populations in clinical studies, including our successful pivotal -020 Phase 3 trial with NUPLAZID for the treatment of PD Psychosis, or the -020 Study. While the FDA granted approval of NUPLAZID based on the data included in the NDA, including data from the -020 Study, we do not know whether the results when a large number of patients and broader populations are exposed to NUPLAZID, including results related to safety and efficacy, will be consistent with the results from earlier clinical studies of NUPLAZID that served as the basis for the approval of NUPLAZID. New data relating to NUPLAZID, including from adverse event reports and post-marketing studies in the United States, and from other ongoing clinical studies, may result in changes to the product label and may adversely affect sales, or result in withdrawal of NUPLAZID from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing NUPLAZID marketing applications for indications other than in PD Psychosis and/or in other jurisdictions, or impose additional post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

We currently have very limited experience as a company in marketing and distributing pharmaceutical products and rely on a limited network of third-party distributors and pharmacies to distribute NUPLAZID. If we are unable to effectively commercialize NUPLAZID, we may not be able to generate adequate product revenues.

NUPLAZID is our only drug that has been approved for sale by any regulatory body, and it became available for prescription in the United States on May 31, 2016. As such, we currently have limited experience commercializing pharmaceutical products as an organization. In order to successfully market NUPLAZID, we must continue to develop our sales, marketing, managerial, compliance, and related capabilities or make arrangements with third parties to perform these services. If we are unable to maintain and develop adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to appropriately commercialize NUPLAZID and may not become profitable.

We employ our own internal specialty sales force to commercialize NUPLAZID for the treatment of PD Psychosis as part of our commercialization strategy in the United States. We will need to refine and further develop our sales force as we continue our commercialization efforts, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully refine and further develop our sales force.

Additionally, our strategy in the United States includes distributing NUPLAZID solely through a limited network of third-party specialty distributors and specialty pharmacies. While we have entered into agreements with each of these distributors and pharmacies to distribute NUPLAZID in the United States, they may not perform as agreed or they may terminate their agreements with us. Also, we may need to enter into agreements with additional distributors or pharmacies, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. If we are unable to maintain and, if needed, expand, our network of specialty distributors and specialty pharmacies, we would be exposed to substantial distribution risk.

In the event we are unable to effectively develop and maintain our commercial team, including our U.S. sales force, or maintain and, if needed, expand, our network of specialty distributors and specialty pharmacies, our ability to effectively commercialize NUPLAZID and generate product revenues would be limited.

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

Prior to its launch in May 2016, none of the members of our sales force had ever promoted NUPLAZID. In addition, NUPLAZID is the first drug approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis. As a result, we are and will continue to 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 hallucinations and delusions associated with PD Psychosis to neurologists, select psychiatrists, and pharmacists and physicians in long-term care facilities. In addition, we must ensure that consistent and appropriate messages about NUPLAZID are being delivered to our potential customers by our sales force. 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.

The degree of market acceptance by physicians, healthcare professionals and third-party payors of NUPLAZID, and any other product for which we obtain regulatory approval, and our profitability and growth, will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- the scope of the approved indication(s) for the product;
- the inclusion of any warnings or contraindications in the product label;
- the relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- the 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 will not generate sufficient revenues to achieve or maintain profitability.

With respect to NUPLAZID specifically, 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 is available to treat hallucinations and delusions associated with PD Psychosis, an indication for which no other FDA-approved pharmaceutical treatment exists. Because of this, it is particularly difficult to estimate NUPLAZID's market potential and how physicians, payors and patients will respond to changes in the price of NUPLAZID. 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 PD Psychosis, the rate of diagnosis of PD Psychosis, the prevalence and rate of hallucinations and delusions in patients diagnosed with PD Psychosis, the rate of physician adoption of NUPLAZID, the potential impact of payor restrictions regarding 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 PD Psychosis 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 PD Psychosis. For these reasons, even if PD Psychosis occurs in high rates among patients with Parkinson's disease, it may be underdiagnosed. Even if PD Psychosis is diagnosed, physicians may not prescribe treatment for hallucinations and delusions associated with PD Psychosis, and if they do prescribe treatment, they may prescribe other drugs, even though they are not approved in PD Psychosis, instead of NUPLAZID. Additionally, NUPLAZID is approved only for the treatment of hallucinations and delusions associated with PD Psychosis, rather than for the treatment of PD Psychosis and/or other symptoms of PD Psychosis, which may cause confusion for prescribing physicians. This confusion could result in physicians not prescribing NUPLAZID for patients diagnosed with PD Psychosis. The label for NUPLAZID also contains a "boxed" warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with PD Psychosis. This warning may discourage physicians from prescribing NUPLAZID to patients diagnosed with PD Psychosis, including those with dementia. In addition, even if NUPLAZID is prescribed for the treatment of hallucinations and delusions associated with PD Psychosis, issues may arise with respect to patient adherence and compliance rates. For example, the recommended dosing of NUPLAZID is 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. Although we are currently developing and have submitted an NDA to the FDA for a 34 mg capsule for NUPLAZID to, among other things, try to mitigate this risk, it is not anticipated to be commercially available until the second half of 2018. We have also submitted a supplemental NDA, or sNDA, to the FDA for a 10 mg tablet

Thus, 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 prescribing behaviors and market adoption.

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 product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor drug products when lower cost therapeutic alternatives are already available or subsequently become available. Even with 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 its cost.

In addition, the market for NUPLAZID depends 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 alternative is available, even if not approved for the indication for which NUPLAZID is approved.

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. We have changed, and may continue to change, the price of NUPLAZID from time to time, however, we do not know if the price we have selected, or may select in the future, for NUPLAZID is or will be the optimized price. Additionally, we do not know whether and to what extent third-party payors will react to any possible future changes in the price of NUPLAZID. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for NUPLAZID may 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 NUPLAZID 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 to change the healthcare system in ways that could impact our ability to sell NUPLAZID, and any other potential products, 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, additional reporting requirements and/or oversight, and the curtailment or 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 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 NUPLAZID, and any other products we may market, 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. With respect to pharmaceutical products, the ACA, among other things, expanded and increased

industry rebates for drugs covered by Medicaid and made changes to the coverage requirements under Medicare Part D, Medicare's prescription drug benefits program There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the ACA, and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent under current law to 70 percent. Given that the current patient population for NUPLAZID is primarily Medicare beneficiaries, accelerating the closure of the coverage gap and the increase in the discount that must be paid, could have a significant impact on the Company's business in 2019 and beyond. Congress also could consider additional legislation to repeal or repeal and replace other elements of the ACA. At this time, the full effect that the ACA will have on our business in the future remains unclear.

An expansion in the government's role in the U.S. healthcare industry may increase existing congressional or governmental agency scrutiny on price increases, such as the ones we have implemented for NUPLAZID, cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using NUPLAZID or any other product for which we obtain regulatory approval, reduce product utilization and adversely affect our business and results of operations. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. For example, the Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. cost control measures legislation has been enacted at the state level. 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 NUPLAZID or any other products for which we may receive regulatory approval.

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, as noted above. 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 are subject, directly and 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.

Our operations are directly, and 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 sales, marketing, grants, charitable donations, and education programs and constrain the business or financial arrangements with healthcare providers, physicians, charitable foundations that support Parkinson's disease patients generally, and other parties that have the ability to directly or indirectly influence the prescribing, ordering, marketing, or distribution of our products for which we obtain marketing approval. In addition, we are 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 rebates),

directly or indirectly, overtly or covertly, in cash or in kind, to 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, including 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 or 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 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. and the European General Data Protection Regulation, or GDPR, which will become effective May 2018 and contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation, including companies like us that conduct clinical trials in the EU; we anticipate that over time we may expand our business operations to include additional operations in the EU and with such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.

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. For example, contributions to third-party charitable foundations are a current area of significant governmental and congressional scrutiny, and we could face action if a federal or state governmental authority were to conclude that our charitable contributions to foundations that support Parkinson's disease patients generally are not compliant. 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, additional reporting requirements and/or oversight, 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, for NUPLAZID, and any other product candidates that may be approved, 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 NUPLAZID, or any other product candidates that may be approved, outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price, or AMP, and best price, or BP, for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in a civil monetary penalty of $18,107 per day for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

The FDA granted marketing approval of NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis, and we could face liability if a regulatory authority determines that we are promoting NUPLAZID for any "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. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of NUPLAZID, and any other products we may market, 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 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, 2017, we had an accumulated deficit of approximately $1.2 billion. We expect to incur net losses over the next few years as we invest in the commercialization of NUPLAZID and advance our development programs.

Even though we began commercializing NUPLAZID in the United States in May 2016, we still expect to incur significant expenses and net losses for at least the next few years as we continue our commercialization efforts for NUPLAZID and pursue the further development of NUPLAZID and our product candidates. Substantially all of our revenues since May 2016 were from net product sales of NUPLAZID.

We expect that our near-term revenues will be substantially dependent on our ability to generate net product sales of NUPLAZID. To the extent that we cannot generate significant revenues from the sale of NUPLAZID to cover our expenses, including the significant expenses associated with commercializing NUPLAZID and continuing to develop pimavanserin in additional indications, we may never achieve profitability and/or may have to reduce our commercialization and/or research and development activities to become profitable, which would harm our future growth prospects. Additionally, to obtain revenues from product candidates other than NUPLAZID, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, manufacturing and marketing compounds with significant market potential. We may never succeed in these activities and may never generate revenues from our commercialization of NUPLAZID, or from other product candidates that may be approved, 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 continue the development and commercialization of NUPLAZID or successfully develop and commercialize our product candidates.

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents, and investment securities totaled $341.3 million at December 31, 2017. 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, post-marketing studies for NUPLAZID to be conducted over the next several years, ongoing and planned commercial activities for NUPLAZID, and other research and development programs;
- the costs of maintaining and developing our sales and marketing capabilities for NUPLAZID;
- the costs of establishing, or contracting for, sales and marketing capabilities for other product candidates;
- the amount of U.S. product sales from NUPLAZID;

- the costs of preparing applications for regulatory approvals for NUPLAZID in jurisdictions other than the United States, and potentially in additional indications other than in PD Psychosis, and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID for commercial use in the United States;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, NUPLAZID in jurisdictions other than the United States or in additional indications other than in PD Psychosis, or from 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 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 maintaining or securing manufacturing arrangements and supply for clinical or commercial production of pimavanserin or other product candidates; and
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to NUPLAZID.

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.

The pivotal Phase 3 study with NUPLAZID for PD Psychosis, the results of which were announced in November 2012, was our first successful pivotal Phase 3 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 the -020 Study. Additionally, in December 2016, we announced positive top-line results from our Phase 2 exploratory study of pimavanserin in patients with AD Psychosis. Even though we successfully completed this Phase 2 exploratory study, or the -019 Study, and the -020 Study, those results are not predictive of the results of any additional studies that we are currently undertaking or may undertake in the future with pimavanserin, including the post-marketing studies we committed to conduct in connection with FDA approval of NUPLAZID and the ongoing studies of pimavanserin in various indications. We believe that pimavanserin also may have utility in indications other than in PD Psychosis, such as in dementia-related psychosis, schizophrenia, and depression. However, prior to the efficacy study that we initiated in October 2017, we had never tested pimavanserin in clinical studies where the primary outcome was for the broad indication of dementia-related psychosis, and prior to the study in major depressive disorder that we initiated in the fourth quarter of 2016, we had never tested pimavanserin in clinical studies in depression. Additionally, prior to the studies in schizophrenia that we initiated in the fourth quarter of 2016, we had only conducted a Phase 2 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 have the same level of success with pimavanserin in dementia-related psychosis or in other indications that we had with the -019 Study. Further, there is no guarantee that we will be successful at all in ongoing or future studies for additional indications or in our post-marketing studies, or that future results of studies of NUPLAZID for treatment in PD Psychosis or for other indications, including dementia-related psychosis, will be consistent with those from the -019 Study or -020 Study.

If we do not successfully complete additional development of NUPLAZID, we will be unable to market and sell NUPLAZID or products derived from it for indications other than the treatment of hallucinations and delusions associated with PD Psychosis, or to generate related product revenues.

We do not have a partner for the development of pimavanserin, and are solely responsible for the advancement of this program and 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 in PD Psychosis, in the future we would need to add resources and raise additional funds in order to take this product candidate to market for indications other than in PD Psychosis or in jurisdictions outside the United States, and to conduct the necessary sales and marketing activities, and to conduct further development activities, if we do not secure a partner. Our current strategy is to commercialize NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis in the United States using our specialty sales force focused primarily on neurologists, a small group of psychiatrists, and pharmacists and physicians in long-term care facilities who treat PD Psychosis patients. In addition, if we are approved to commercialize NUPLAZID in 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 conducted, and continue to revisit, our life-cycle planning project for pimavanserin that was initiated in 2015 and through which we have formulated a multi-year plan to develop pimavanserin in additional indications other than in PD Psychosis, including in dementia-related psychosis, schizophrenia and depression, as described above. Given the unique profile of pimavanserin, together with the list of potential indications we could pursue, this has been a substantial and 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 though NUPLAZID is approved for the treatment of hallucinations and delusions associated with PD Psychosis, a failure in a subsequent study for another indication, including our ongoing studies in dementia-related psychosis, schizophrenia and depression, or a failure in our post-marketing studies could harm our ability to successfully market NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis 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.

Pimavanserin is currently in development for several additional indications other than in PD Psychosis, and development is a long, expensive and unpredictable process with 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 had an unsuccessful Phase 3 trial with NUPLAZID in 2009. An unfavorable outcome in any of our ongoing or future development efforts or in the post-marketing studies for NUPLAZID could be a major set-back for the program and for us, generally. In particular, an unfavorable outcome in our NUPLAZID program or in the post-marketing studies 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 October 2017, we initiated a Phase 3 study of pimavanserin in patients with dementia-related psychosis, and in the fourth quarter of 2016 we initiated both a Phase 2 and a Phase 3 study of pimavanserin as an adjunctive treatment in patients with schizophrenia as well as a Phase 2 study of pimavanserin as an adjunctive treatment in patients with major depressive disorder. We may plan and conduct additional studies in other indications in the future.

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;
- 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:

- competition for internal and external resources, including clinical sites and study patients, that we may choose to allocate to other programs;
- 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 previously have depended, and in the future may 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.

in the past, we have selectively entered into collaboration agreements with third parties. We relied on our collaborators for financial resources and for development, regulatory, and commercialization expertise for selected product candidates, and we had limited control over the amount and timing of resources that our collaborators devoted to our product candidates. We may choose to rely on collaborations in the future for certain portions of our pimavanserin program, or other product candidates, or for the commercialization of NUPLAZID in certain territories outside of the United States.

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.

We also face competition in our search for new collaborators, if we seek a new partner for our pimavanserin program or other programs. 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.

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 past 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. Any collaborations we establish in the future may have the effect of limiting the areas of research that we may pursue, either alone or with others. Conversely, the terms of any collaboration we may establish in the future might not restrict our collaborators from developing, 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 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. 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 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 in the future will continue to depend, on third parties to manufacture NUPLAZID and our 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 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, NUPLAZID and our product candidates.

We have contracted with Patheon Pharmaceuticals Inc. and Catalent Pharma Solutions, LLC to manufacture NUPLAZID drug product for commercial use in the United States. Additionally, we have contracted with Siegfried AG 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 face delays or increased costs in our supply chain that could jeopardize the commercialization of NUPLAZID. Additionally, if any of our product candidates in addition to NUPLAZID are approved by the FDA or other regulatory agencies for commercial sale, or if NUPLAZID is approved for commercial sale in jurisdictions outside the United States, we will need to contract with a third party to manufacture such products for commercial sale in the United States and/or in such other jurisdictions.

Even though we have agreements with Patheon and Catalent 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 for each form of drug product (tablet and capsule) 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, maintain or

obtain, as applicable, regulatory approval for or market NUPLAZID or any of our product candidates. While we believe that there will be alternative sources available to manufacture NUPLAZID and our product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts.

The manufacturers of NUPLAZID and our product candidates, including Catalent, Patheon and Siegfried, are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs, and we have limited 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 NUPLAZID and 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 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, or result in issues maintaining regulatory approval of NUPLAZID and any other product candidate that receives regulatory approval, negatively impact our commercialization of NUPLAZID, or lead to significant delays in the launch and commercialization of any other products we may have in the future. 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. 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 NUPLAZID or our product candidates 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 NUPLAZID and any other approved 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 NUPLAZID or our 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 commercialize our products, including NUPLAZID, or develop our product candidates, including pimavanserin for indications beyond PD Psychosis.

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. We are currently hiring, and in the future we expect to need to continue to hire, additional personnel as we expand our research and development efforts for pimavanserin and commercial activities for NUPLAZID. 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 our commercialization efforts for NUPLAZID and the achievement of our research and development objectives.

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, 2017, we employed approximately 425 employees. Although we have already added several capabilities, we will need to add additional qualified personnel and resources. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. 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 NUPLAZID and any other product candidates that receive regulatory approval and to compete effectively will depend, in part, on our ability to manage any future growth effectively. In particular, as we commercialize NUPLAZID, we will need to support the training and ongoing activities of our sales force 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;
- develop our 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 as 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 capabilities for the ongoing commercialization of NUPLAZID, we have implemented, and will continue to evaluate and may implement additional, changes to our organization that may be appropriate in order to properly manage and direct our growth as 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, during 2015 and 2016, five long-standing board members either resigned from the board or did not stand for re-election, and during approximately the same timeframe our board elected three new board members. We hired a new head of Regulatory Affairs in February 2017 and, in March 2017, we hired a new Chief Commercial Officer following the retirement of our prior chief commercial officer. In addition, in February 2018, our General Counsel announced that he would be leaving ACADIA. We 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 we are unable to add additional commercial products to our portfolio, we may not be able to successfully leverage our commercial organization that we have assembled for the marketing and sale of NUPLAZID.

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 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 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:

- the success of our commercialization of NUPLAZID in the United States for the treatment of hallucinations and delusions associated with PD Psychosis;
- the status and cost of our post-marketing commitments for NUPLAZID;
- the variation in our gross-to-net adjustments from quarter to quarter, primarily because of the fluctuation in our share of the donut hole for Medicare Part D patients;
- the status and cost of development and commercialization of pimavanserin for indications other than in PD Psychosis and in jurisdictions other than the United States;
- the status and cost of development and commercialization of our 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 any product liability claims that may be brought against us related to NUPLAZID; and
- general and industry-specific economic conditions.

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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended, or the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 percent to a flat rate of 21 percent, limitation of the tax deduction for interest expense to 30 percent of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80 percent of current-year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2017, we had federal, state and foreign net operating loss carryforwards of $407.1 million, $340.0 million and $647.4 million, respectively. The majority of our net operating loss carryforwards will begin to expire, if not utilized, beginning in 2023. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Code and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percent change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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

During 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. For example, we have been evaluating the impact of the December 2017 U.S. tax law changes on our current structure and future plans and may decide to make changes based on that evaluation.

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 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. With the exception of NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis, we have never successfully completed clinical development of any of our product candidates, and, except for NUPLAZID, 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 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.

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. 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.

Changes or modifications in financial accounting standards, including those related to revenue recognition, may harm our results of operations.

From time to time, the Financial Accounting Standards Board, or FASB, either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial position, results of operations or reported cash flows. In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASU 2014-09, which supersedes nearly all existing revenue recognition guidance under generally accepted accounting principles. ASU 2014-09 is a comprehensive new revenue recognition model that requires an entity 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. ASU 2014-09 also requires additional disclosures about the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts. We adopted this new standard for the year beginning January 1, 2018 and have elected to apply the new standard using the modified retrospective approach with the cumulative effect of initial application recognized as of January 1, 2018. We do not believe there will be a material impact on our results of operations from the adoption of this standard however, any difficulties in implementing this standard, or in adopting or implementing any other new accounting standard, and to update or modify our internal controls as needed on a timely basis, could result in our failure to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. Finally, if we were to change our critical accounting estimates, including those related to the recognition of product or collaboration revenue, our operating results could be significantly affected.

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 products and 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;
- 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 Leahy-Smith America Invents Act, or the America Invents Act, 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 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 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 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. 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.

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 are subject to stringent regulation in connection with the marketing of NUPLAZID and any other products derived from our product candidates, which could delay the development and commercialization of our products.

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product, 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 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, the FDA and other regulatory agencies 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 NUPLAZID or our product candidates, they may reduce or eliminate our commercial opportunity. update with marketing

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 hallucinations and delusions associated with PD Psychosis competes with off-label use of antipsychotic drugs, including the generic drugs quetiapine and clozapine. If approved, pimavanserin for the treatment of dementia-related psychosis would compete with off-label use of antipsychotic drugs, including the generic drugs 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 adjunctive treatment of schizophrenia, if approved for that indication, would compete with Rexulti, marketed by Otsuka Pharmaceutical Co., Ltd., Latuda, marketed by Sunovion Pharmaceuticals Inc., and generic drugs, including olanzapine, risperidone, aripiprazole and clozapine. Pimavanserin for the adjunctive treatment of major depressive disorder, if approved for that indication, would compete with Rexulti, off-label use of antipsychotic drugs and the 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.

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;
- obtaining FDA and other regulatory approvals; and
- commercializing pharmaceutical products.

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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of NUPLAZID or any other product for which we obtain regulatory approval, or development or commercialization of our product candidates.

We face an inherent risk of product liability as a result of the commercial sales of NUPLAZID in the United States and the clinical testing of our product candidates, and will face an even greater risk following commercial launch of NUPLAZID in additional jurisdictions, if approved, or if we engage in the clinical testing of new product candidates or commercialize any additional products.

For example, we may be sued if NUPLAZID or any other product we develop allegedly causes injury or is found to be otherwise unsuitable for administration in humans. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates; and
- a decline in our stock price.

Although we currently have product liability insurance that covers our clinical trials and the commercialization of NUPLAZID, we may need to increase and expand this coverage, including if we commence larger scale trials and if other 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. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products. Product liability claims could have a material adverse effect on our business and results of operations.

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.

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 success of our commercialization of NUPLAZID in the United States for the treatment of hallucinations and delusions associated with PD Psychosis;
- the status and cost of our post-marketing commitments for NUPLAZID;
- the status and cost of development and commercialization of pimavanserin for indications other than in PD Psychosis and in jurisdictions other than the United States;
- the status and cost of development and commercialization of our 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;
- any other communications or guidance from the FDA or other regulatory authorities that pertain to NUPLAZID or our product candidates;
- 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 PD Psychosis 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 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 parties agreed to a settlement in that case, which was approved by the court in January 2018. However, if we are not successful in defense of other future claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such future 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. 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. Under the registration rights agreement we have agreed that, if at any time and from time to time, 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. On April 1, 2016, we filed a registration statement covering the sale of up to 26,179,806 shares of our common stock, which includes 500,000 shares of our common stock issuable upon the exercise of warrants that were owned by the Baker Entities as of December 31, 2017, and which represent approximately 21 percent of our outstanding shares. Our registration obligations under this registration rights agreement cover all shares now held or later acquired by the Baker Entities (including approximately $43.0 million of shares that the Baker Entities purchased at the public offering price in our August 2016 public offering), 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 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 may elect to sell an indeterminate number of shares on our own behalf pursuant to a 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;
- 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, 2017, our primary facility consists of approximately 78,000 square feet of leased office space located in San Diego, California, the majority of which is leased through February 2019 with the remainder leased through May 2020. We also lease a facility in Princeton, New Jersey that covers approximately 15,000 square feet of office space. We believe that any additional space we may require to accommodate our growing organization will be available on commercially reasonable terms.

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 PD Psychosis 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 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 plaintiffs, and assigning lead counsel. On November 16, 2015, lead plaintiffs filed a consolidated complaint with the Court which, like the prior complaints, accused 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, the defendants filed a motion to dismiss the consolidated complaint. On September 19, 2016, the Court issued an order denying the motion to dismiss the consolidated complaint. On March 13, 2017, the parties signed a Stipulation of Settlement setting forth the terms of the proposed settlement. On June 9, 2017, the Court preliminarily approved the settlement, or the Preliminary Approval Order. Among other things, the Preliminary Approval Order set an opt-out deadline of August 29, 2017; an objection deadline of September 13, 2017; and a final approval hearing for October 3, 2017. . On August 29, 2017, lead plaintiffs filed a motion for final approval of the settlement and a motion for attorneys' fees and expenses. On October 3, 2017, the Court continued the hearing so that, among other things, lead plaintiffs could submit additional documents in support of final approval. On January 22, 2018, the Court issued an order granting the final approval motions and entered final judgment in the consolidated action.

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

This item is not applicable.

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.

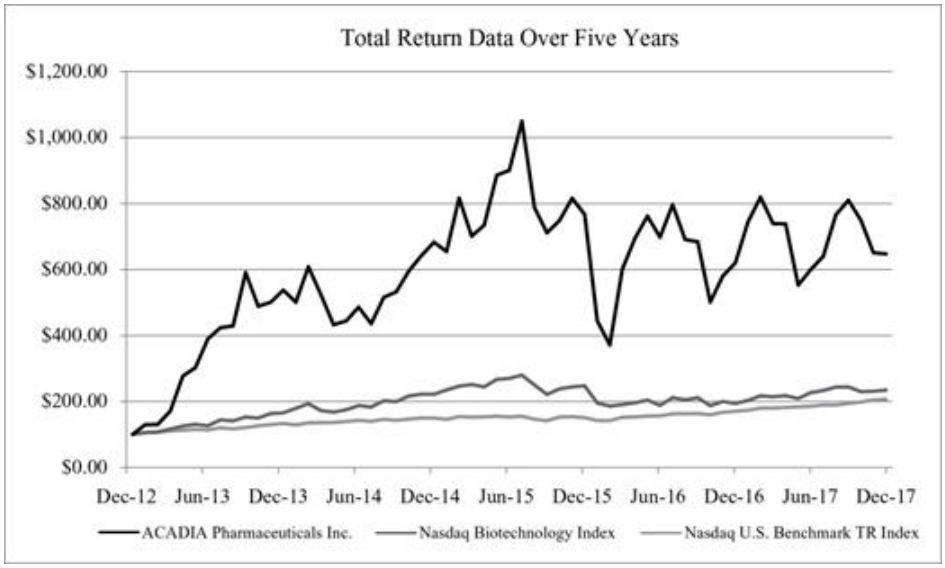
2017	High	Low
First Quarter	$ 40.83	$ 28.53
Second Quarter	$ 36.20	$ 25.06
Third Quarter	$ 38.54	$ 26.41
Fourth Quarter	$ 41.20	$ 26.01

2016	High	Low
First Quarter	$ 35.20	$ 16.64
Second Quarter	$ 42.49	$ 26.50
Third Quarter	$ 38.08	$ 30.50
Fourth Quarter	$ 31.70	$ 20.68

As of January 31, 2018, there were 124,701,944 shares of common stock outstanding held by approximately 30 stockholders of record. Many stockholders hold their shares in street name and we believe that there are approximately 44,000 beneficial owners of our common stock.

Performance Graph

The following graph shows a comparison of the total cumulative returns of an investment of $100 in cash from December 31, 2012 through December 31, 2017 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).



Dividend Policy

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.

Recent Sales of Unregistered Securities

In October and November 2017, we issued an aggregate of 1,408,570 shares of our common stock pursuant to the exercise of warrants issued by us to investors in our January 2011 private placement of common stock and warrants. The warrants were exercisable for up to 1,465,968 shares of our common stock at an exercise price of $1.38 per share. The investors exercised the warrants in full on a cashless basis, resulting in us withholding 57,398 shares of our common stock as payment for the exercise price. The shares were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

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

The following data has been derived from our audited financial statements, including the consolidated balance sheets at December 31, 2017 and 2016 and the related consolidated statements of operations for each of the three years ended December 31, 2017 and related notes appearing elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2014 and 2013 and the consolidated balance sheet data as of December 31, 2015, 2014 and 2013 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,				
	2017	2016	2015	2014	2013
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Revenues:					
Product sales, net	$ 124,901	$ 17,327	$ —	$ —	$ —
Collaborative revenue	—	4	61	120	1,145
Total revenues	124,901	17,331	61	120	1,145
Operating expenses:					
Cost of product sales	9,077	3,075	—	—	—
License fees and royalties	3,983	1,331	2,500	—	—
Research and development	149,189	99,284	73,869	60,602	26,722
Selling, general and administrative	255,062	186,456	88,304	32,748	12,720
Total operating expenses	417,311	290,146	164,673	93,350	39,442
Loss from operations	(292,410)	(272,815)	(164,612)	(93,230)	(38,297)
Interest income, net	4,126	2,763	499	755	349
Loss before income taxes	(288,284)	(270,052)	(164,113)	(92,475)	(37,948)
Income tax expense	1,119	1,341	330	—	—
Net loss	$ (289,403)	$ (271,393)	$ (164,443)	$ (92,475)	$ (37,948)
Net loss per common share, basic and diluted	$ (2.36)	$ (2.34)	$ (1.63)	$ (0.95)	$ (0.44)
Weighted average common shares outstanding, basic and diluted	122,600	115,858	100,630	97,248	85,715

	At December 31,				
	2017	2016	2015	2014	2013
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investment securities	$ 341,342	$ 529,036	$ 215,132	$ 322,486	$ 185,790
Working capital	324,447	505,312	197,087	308,784	181,381
Total assets	384,506	561,153	221,896	325,458	189,118
Total stockholders' equity	335,285	518,411	199,762	309,489	182,131

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 the benefits to be derived from NUPLAZID® (pimavanserin) and from our drug candidates, the potential market opportunities for pimavanserin and our drug candidates, our strategy for the commercialization of NUPLAZID, our plans for exploring and developing pimavanserin for indications other than Parkinson's disease psychosis, our plans and timing with respect to seeking regulatory approvals, the potential commercialization of any of our drug candidates that receive regulatory approval, the progress, timing, results or implications of clinical trials and other development activities involving NUPLAZID and our drug candidates, our strategy for discovering, developing and, if approved, commercializing drug candidates, our existing and potential future collaborations, our estimates of future payments, revenues and profitability, our estimates regarding our capital requirements, future expenses and need for additional financing, possible changes in legislation, 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," "continues," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential" or similar words. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain. 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, NUPLAZID (pimavanserin), which was approved by the U.S. Food and Drug Administration, or FDA, on April 29, 2016 for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis, or PD Psychosis, and is the only 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 demonstrated significant efficacy in reducing the hallucinations and delusions associated with PD 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 by the FDA in the treatment of PD Psychosis. We hold worldwide commercialization rights to pimavanserin. We launched NUPLAZID in the United States in May 2016.

We believe that pimavanserin has the potential to address important unmet medical needs in neurological and psychiatric disorders in addition to PD Psychosis and we plan to continue to study the use of pimavanserin in multiple disease states.

For example, we believe Alzheimer's disease represents one of our most important opportunities for further exploration. In December 2016, we announced positive top-line results from our Phase II study exploring the utility of pimavanserin for the treatment of Alzheimer's disease psychosis, or AD Psychosis, a disorder for which no drug is currently approved by the FDA. Following our End-of-Phase II Meeting with the FDA and agreement with the agency on our clinical development plan, we initiated our Phase III HARMONY relapse prevention study in October 2017, which allows us to evaluate pimavanserin for a broader indication than AD Psychosis alone. More specifically, HARMONY will evaluate pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis, which includes psychosis in patients with Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia and frontotemporal dementia. Furthermore, in October 2017, the FDA granted Breakthrough Therapy Designation to pimavanserin for this dementia-related psychosis indication.

As a result of potential overlap of clinical sites and study participants between the HARMONY study and our SERENE study, which is our Phase II study evaluating pimavanserin for the treatment of Alzheimer's disease agitation and aggression, we decided to discontinue enrollment of new patients in that study. Patients already enrolled in SERENE will complete the study as planned.

We also believe schizophrenia represents a disease with multiple unmet or ill-served needs and we are currently exploring the utility of pimavanserin in this area. Despite a large number of FDA-approved therapies for schizophrenia, current drugs do not adequately address some very important symptoms of schizophrenia, such as the inadequate response to current antipsychotic treatment of psychotic symptoms and negative symptoms. In the fourth quarter of 2016, we initiated two studies evaluating the adjunctive use of pimavanserin in patients with schizophrenia. ENHANCE-1 is a Phase III study evaluating pimavanserin for adjunctive treatment of schizophrenia in patients with an inadequate response to their current antipsychotic therapy. ADVANCE is a Phase II study evaluating pimavanserin for adjunctive treatment in patients with negative symptoms of schizophrenia.

Depression is another disorder with a high unmet need that we believe represents an attractive development opportunity for pimavanserin. Preclinical and clinical studies have shown that patients with depression often do not receive adequate relief from an antidepressant medication, and, due to side effects of currently available therapies, many patients discontinue their medication, significantly increasing their chance of relapse. Preclinical and clinical evidence suggests 5-HT_{2A} antagonism may be an effective adjunctive therapy to first-line antidepressants. In the fourth quarter of 2016, we initiated CLARITY, a Phase II study evaluating pimavanserin for adjunctive treatment in patients with major depressive disorder, or MDD, who have an inadequate response to standard antidepressant therapy. We expect to report top-line results from the CLARITY study in the second half of 2018.

During 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. ACADIA Pharmaceuticals GmbH manages 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. Our selling, general and administrative expenses have also increased significantly in connection with the preparation for, and support of, the launch of our first product, NUPLAZID. As of December 31, 2017, we had an accumulated deficit of $1.2 billion. 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.

Financial Operations Overview

Product and Collaborative Revenues

Net product sales consist of sales of NUPLAZID, our first and only commercial product to date. The FDA approved NUPLAZID in April 2016 and we launched the product in the United States in May 2016. Prior to the generation of revenue from NUPLAZID, our revenues had been generated substantially from payments under our collaboration agreements.

Cost of Product Sales

Cost of product sales consists of third-party manufacturing costs, freight, and indirect overhead costs associated with sales of NUPLAZID. Cost of product sales may also include period costs related to certain inventory manufacturing services, excess or obsolete inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances.

License Fees and Royalties

License fees and royalties consist of milestone payments expensed or capitalized and subsequently amortized under our 2006 license agreement with the Ipsen Group. License fees and royalties also include royalties of two percent due to the Ipsen Group based upon net sales of NUPLAZID.

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 incurred related to pre-commercial product candidates. We charge all research and development expenses to operations as incurred. Our research and development activities have primarily focused on NUPLAZID (pimavanserin) which was approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis in April 2016. We currently are responsible for all costs incurred in the ongoing development of pimavanserin and we expect to continue to make substantial investments in clinical studies of pimavanserin for indications other than PD Psychosis, including dementia-related psychosis, schizophrenia and depression. Additionally, in connection with the FDA approval of NUPLAZID, we committed to conduct post-marketing studies, including a randomized, placebo-controlled withdrawal study in PD

Psychosis patients treated with NUPLAZID and randomized, placebo-controlled eight-week studies in predominantly frail and elderly patients that would add to the NUPLAZID safety database by exposing an aggregate of at least 500 patients to NUPLAZID. We will be responsible for all costs incurred for these post-marketing studies.

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, 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, 2017, 2016, and 2015 (in thousands):

	Years Ended December 31,		
	2017	2016	2015
Costs of external service providers:			
NUPLAZID (pimavanserin)	$ 83,402	$ 53,622	$ 40,506
Other programs	505	518	890
Subtotal	83,907	54,140	41,396
Internal costs	38,797	27,094	20,302
Stock-based compensation	26,485	18,050	12,171
Total research and development	$ 149,189	$ 99,284	$ 73,869

Although NUPLAZID was approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis, at this time, due to the risks inherent in clinical development, we are unable to estimate with certainty the costs we will incur for the ongoing development of pimavanserin in additional indications, including those within dementia-related psychosis, schizophrenia and depression. 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 development efforts are primarily focused on advancing the development of pimavanserin in additional indications other than PD Psychosis, 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. Similarly, we are unable to estimate with certainty the costs we will incur for post-marketing studies that we committed to conduct in connection with FDA approval of NUPLAZID.

We expect our research and development expenses to increase and continue to be substantial as we conduct studies pursuant to our post-marketing commitments and pursue the development of pimavanserin in additional indications other than PD Psychosis, including our studies within dementia-related psychosis, schizophrenia and depression 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.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist of salaries and other related costs, including stock-based compensation expense, for our commercial personnel, including our specialty sales force, our medical education professionals, and our personnel serving in executive, finance, business development, and business operations functions. Also included in selling, general and administrative expenses are fees paid to external service providers to support our commercial activities associated with NUPLAZID, professional fees associated with legal and accounting services, costs associated with patents and patent applications for our intellectual property and charitable donations to independent charitable foundations that support Parkinson’s disease patients generally. We expect our selling, general and administrative expenses to increase in future periods to support commercial activities associated with NUPLAZID and our further development of pimavanserin in additional indications other than PD 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.

Revenue Recognition

Product Sales, Net

Our net product sales consist of U.S. sales of NUPLAZID and are recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title to the product and associated risk of loss has passed to the customer, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. NUPLAZID was approved by the FDA on April 29, 2016 and we commenced shipments of NUPLAZID to specialty pharmacies, or SPs, and specialty distributors, or SDs, in May 2016. Prior to April 1, 2017, we utilized the "sell-through" revenue recognition model with respect to sales of NUPLAZID, meaning that we deferred the recognition of revenue from sales of NUPLAZID until product was dispensed to patients by SPs or sold to government facilities and long-term care and in-patient hospital pharmacies by SDs. In the second quarter of 2017, we determined we had sufficient volume of activity to reasonably estimate our allowances for rebates and chargebacks, and began recognizing NUPLAZID revenue using the "sell-in" revenue recognition model pursuant to which we recognize NUPLAZID revenue at the point of sale to the SPs and SDs. Product shipping and handling costs are included in cost of product sales.

We recognize revenue from product sales net of the following allowances and reflect each of these as either a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

Distribution Fees: Distribution fees include distribution service fees paid to our SPs and SDs based on a contractually fixed percentage of the wholesale acquisition cost, or WAC, fees for data, and prompt payment discounts. Distribution fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. Our estimates for expected utilization of rebates is based on historical data received from the SPs and SDs since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs at a discounted price. The SDs charge back to us the difference between the price initially paid by the SDs and the discounted price paid to the SDs by these entities. We also incur group purchasing organization fees for transactions through certain purchasing organizations. We estimate sales with these entities and accrue for anticipated chargebacks and organization fees, based on the applicable contractual terms. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Co-Payment Assistance: We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued for based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Returns: Consistent with industry practice, we offer the SPs and SDs limited product return rights for damages, shipment errors, and expiring product; provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. We do not allow product returns for product that has been dispensed to a patient. As we receive inventory reports from the SPs and SDs and have the ability to control the amount of product that is sold to the SPs and SDs, we are able to make a reasonable estimate of future potential product returns based on this on-hand channel inventory data and sell-through data obtained from the SPs and SDs. In arriving at our estimate, we also consider historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

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 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 progress and timing of expenditures related to our commercial activities associated with NUPLAZID and the extent to which we generate revenue from product sales, our development of pimavanserin in additional indications other than PD Psychosis, the progress and timing of expenditures related to studies pursuant to our post-marketing commitments, and the timing and amount of payments received pursuant to collaborations. Further, we expect our sales allowances to vary from quarter to quarter due to fluctuations in our Medicare Part D Coverage Gap liability and the volume of purchases eligible for government mandated discounts and rebates, as well as changes in discount percentages that may be impacted by potential future price increases and other factors. 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, 2017 and 2016

Product Sales, Net

Net product sales, comprised of NUPLAZID, which we launched in May 2016, were $124.9 million and $17.3 million in 2017 and 2016, respectively. Net product sales for the year ended 2017 increased as compared to the year ended 2016 due to continued growth in sales of NUPLAZID since its launch in mid-2016 and a higher average sales price for NUPLAZID in 2017 as compared to 2016.

The following table provides a summary of activity with respect to our sales allowances and accruals for the year ended December 31, 2017 (in thousands):

	Distribution Fees, Discounts & Chargebacks	Rebates, Co-Pay Assistance & Returns	Total
Balance at December 31, 2016	$ 201	$ 1,798	$ 1,999
Provision related to current period sales	12,837	10,905	23,742
Credits/payments for current period sales	(12,591)	(7,560)	(20,151)
Credits/payments for prior period sales	(201)	(1,798)	(1,999)
Balance at December 31, 2017	$ 246	$ 3,345	$ 3,591

Cost of Product Sales

Cost of product sales was $9.1 million and $3.1 million in 2017 and 2016, respectively, or approximately 7% and 18% of net product sales. Costs of sales increased for the year ended December 31, 2017 as compared to 2016 due to lower manufacturing levels, resulting in lower inventory cost absorption, and greater sales volume. Additionally, with the launch of NUPLAZID in mid-2016, costs of sales were not incurred for the entire fiscal year in 2016. The cost of product sales as a percentage of net sales decreased during 2017 as compared to 2016 due primarily to the increased sales volume in 2017, partially offset by a charge of $0.7 million in 2017 to reduce certain finished goods inventory to its net realizable value. Product sold during 2017 and 2016 was manufactured with raw material that was previously charged to research and development expense prior to FDA approval of NUPLAZID. This zero cost raw material did not materially impact our cost of product sales and related product gross margins in 2017 and 2016.

License Fees and Royalties

License fees and royalties were $4.0 million and $1.3 million in 2017 and 2016, respectively, and include amortization related to the milestone paid to the Ipsen Group upon FDA approval of NUPLAZID in 2016 and royalties due to the Ipsen Group of two percent of net sales of NUPLAZID. The increase in license fees and royalties was due to the increase in sales volume during 2017.

Research and Development Expenses

Research and development expenses increased to $149.2 million in 2017, including $26.5 million in stock-based compensation, from $99.3 million in 2016, including $18.1 million in stock-based compensation. The increase in research and development expense was due to an increase of $29.8 million in external service costs and an increase of $20.1 million in personnel and related costs, including stock compensation expense, associated with our expanded research and development organization. The increase in external service costs was primarily due to increased clinical costs associated with the development of pimavanserin in indications other than PD Psychosis, including Alzheimer's disease, dementia-related psychosis, schizophrenia, and depression.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $255.1 million in 2017, including $45.3 million in stock-based compensation, from $186.5 million in 2016, including $36.0 million in stock-based compensation. The increase in selling, general and administrative expenses was due to an increase of $36.4 million in external service costs and an increase of $32.2 million in personnel and related costs, including stock compensation expense. The increase in external service costs was primarily due to additional charitable contributions to independent charitable foundations that support Parkinson's disease patients generally made during the year ended December 31, 2017 compared to the year ended December 31, 2016, as well as an increase in advertising expense related to our direct-to-consumer advertising program. The increase in personnel and related costs was largely due to costs associated with our specialty sales force that we hired in the second quarter of 2016 and further expanded in the first half of 2017.

Comparison of the Years Ended December 31, 2016 and 2015

Product Sales, Net

Net product sales were $17.3 million in 2016 and were comprised of sales of NUPLAZID which was approved by the FDA on April 29, 2016 and launched in May 2016. No similar net product sales were recognized in 2015.

During the initial launch period, we deferred the recognition of revenue from sales of NUPLAZID until product was dispensed to patients by the SPs or sold to government facilities and long-term care and in-patient hospital pharmacies by the SDs. At December 31, 2016, deferred product revenue of $2.6 million was recorded as a liability on our consolidated balance sheet, net of distribution fees.

The following table provides a summary of activity with respect to our sales allowances and accruals for the year ended December 31, 2016 (in thousands):

	Distribution Fees, Discounts & Chargebacks	Rebates, Co-Pay Assistance & Returns	Total
Balance at December 31, 2015	$ —	$ —	$ —
Provision related to current period sales	2,163	2,703	4,866
Credits/payments made	(1,962)	(905)	(2,867)
Balance at December 31, 2016	$ 201	$ 1,798	$ 1,999

Cost of Product Sales

Cost of product sales was $3.1 million for the year ended December 31, 2016, or approximately 18% of net product sales. Product sold during 2016 was manufactured with raw material that was previously charged to research and development expense prior to FDA approval of NUPLAZID. This zero cost raw material did not materially impact our cost of product sales and related product gross margins in 2016. No similar cost of product sales was recognized in 2015.

License Fees and Royalties

License fees and royalties decreased to $1.3 million in 2016 compared to $2.5 million in 2015. The decrease in license fees and royalties was due to a license fee of $2.5 million incurred in 2015 in connection with the FDA's acceptance for filing of our NDA for NUPLAZID pursuant to our 2006 license agreement with the Ipsen Group. For the year ended December 31, 2016, license fees and royalties included the amortization of the $8.0 million milestone paid to the Ipsen Group upon the FDA approval of NUPLAZID. The $8.0 million milestone was recorded as an intangible asset and is being amortized over the estimated useful life of the asset through the second half of 2021. Also included in 2016 were royalties due to the Ipsen Group of two percent of net sales of NUPLAZID. No similar royalty expense was recorded in 2015.

Research and Development Expenses

Research and development expenses increased to $99.3 million in 2016, including $18.1 million in stock-based compensation, from $73.9 million in 2015, including $12.2 million in stock-based compensation. The increase in research and development expense was due to an increase of $12.7 million in personnel and related costs, including stock compensation expense, associated with our expanded research and development organization and an increase of $12.7 million in external service costs. The increase in external service costs was due to increased clinical costs related to the development of pimavanserin in indications other than PD Psychosis as well as costs associated with the FDA's Psychopharmacologic Drugs Advisory Committee meeting that occurred in the first quarter of 2016. These increases were partially offset by a decrease in manufacturing development costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $186.5 million in 2016, including $36.0 million in stock-based compensation, from $88.3 million in 2015, including $28.0 million in stock-based compensation. The increase in selling, general and administrative expenses was due to an increase of $53.8 million in external service costs and an increase of $44.4 million in personnel and related costs, inlcuding stock compensation expense. The increase in external service costs was primarily due to preparations for, and support of, the launch of NUPLAZID and related commercial activities, as well as additional medical education programs. The increase in personnel and related costs was primarily driven by costs associated with the hiring of our specialty sales force in April 2016. These increases were partially offset by a one-time expense of $9.6 million incurred in 2015 in connection with the transition agreement with our former Chief Executive Officer entered into upon his retirement in March 2015. Included in this compensation expense of $9.6 million was $9.0 million in stock-based compensation expense.

Liquidity and Capital Resources

We have funded our operations primarily through sales of our equity securities, payments received under our collaboration agreements, debt financings, interest income, and, since 2016, with revenues from sales of NUPLAZID. In January and August 2016, we raised total net proceeds of approximately $497.5 million in follow-on public offerings, and in 2014 we raised net proceeds of $196.8 million in a public offering 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 ongoing and planned commercial activities for NUPLAZID, our ongoing and planned development activities for pimavanserin in additional indications other than PD Psychosis, and studies to be conducted pursuant to our post-marketing commitments. 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, post-marketing studies for NUPLAZID to be conducted over the next several years, ongoing and planned commercial activities for NUPLAZID, and other research and development programs;
- the costs of maintaining and developing our sales and marketing capabilities for NUPLAZID;
- the costs of establishing, or contracting for, sales and marketing capabilities for other product candidates;

- the amount of U.S. product sales from NUPLAZID;
- the costs of preparing applications for regulatory approvals for NUPLAZID in jurisdictions other than the United States, and potentially in additional indications other than PD Psychosis and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, NUPLAZID in jurisdictions other than the United States or in additional indications other than PD Psychosis, or from 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;
- our ability to enter into new 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 any product liability claims that may be brought against us related to NUPLAZID.

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, public or private sales of our securities, debt financings, strategic collaborations, 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, 2017, we had $341.3 million in cash, cash equivalents, and investment securities, compared to $529.0 million at December 31, 2016. This $187.7 million decrease in cash, cash equivalents, and investment securities during 2017 was primarily due to our cash used in operations partially offset by proceeds from stock option exercises. Net cash used in operating activities increased to $217.9 million in 2017 compared to $210.4 million in 2016 and $121.8 million in 2015. The increase in net cash used in operating activities in 2017 relative to 2016 was primarily due to the expansion of our research and development activities and additional costs to support the commercialization of NUPLAZID in 2017 as compared to 2016 and 2015.

Net cash provided by investing activities totaled $92.5 million in 2017 compared to net cash used in investing activities of $261.9 million in 2016 and net cash provided by investing activities of $147.6 million in 2015. Net cash provided by investing activities in 2017 compared to the net cash used in investing activities in 2016 was primarily due to a decrease in purchases of investment securities attributable to cash used to fund operations. Net cash used in investing activities in 2016 compared to the net cash provided by investing activities in 2015 was primarily due to an increase in purchases of investment securities attributable to the January and August 2016 follow-on public offerings that contributed approximately $497.5 million in total net proceeds available for investment.

Net cash provided by financing activities decreased to $31.2 million in 2017 compared to $533.8 million in 2016 and increased compared to $14.5 million in 2015. The decrease in net cash provided by financing activities in 2017 relative to 2016 was primarily attributable to the January and August 2016 follow-on public offerings that contributed approximately $497.5 million in total net proceeds in 2016, with no comparable offerings in 2017. The increase in net cash provided by financing activities in 2016 relative to 2015 was primarily attributable to the January and August 2016 follow-on public offerings that contributed approximately $497.5 million in total net proceeds. Also contributing to the increase in net cash provided by financing activities in 2016 relative to 2015 was an increase of $6.6 million in proceeds from stock option exercises and purchases under our employee stock purchase plan, and $14.3 million received pursuant to a settlement agreement with prior 10% stockholders who sold shares of our stock in 2013, as described in Item 15 of Part IV, “Notes to Consolidated Financial Statements — Note 6 — Stockholders’ Equity”.

Contractual Obligations

The following is a summary of our long-term contractual obligations as of December 31, 2017 (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases	$ 3,868	$ 2,529	$ 1,339	$ —	$ —
Other long-term contractual obligations	1,862	1,312	550	—	—
Total	$ 5,730	$ 3,841	$ 1,889	$ —	$ —

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, pursuant to the terms of our 2006 license agreement with the Ipsen Group, we are required to make royalty payments based upon net sales of NUPLAZID of two percent. Royalty payments are contingent upon net product sales and accordingly these amounts are not included in the above table.

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

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

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

Interest Rate Risk

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in a money market fund, U.S. Treasury notes, and high quality marketable debt instruments of corporations and government sponsored enterprises with contractual maturity dates of generally less than two years. All investment securities have a credit rating of at least 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, 2017, 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 Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial officer, respectively), 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, 2017, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2017.

Management's Report on Internal Control Over Financial Reporting

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

As of December 31, 2017, 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). Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, concluded that, as of December 31, 2017, 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, 2017 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 and our Chief Financial 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.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
ACADIA Pharmaceuticals Inc.

Opinion on Internal Control over Financial Reporting

We have audited ACADIA Pharmaceuticals Inc.'s internal control over financial reporting as of December 31, 2017, 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). In our opinion, ACADIA Pharmaceuticals Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of ACADIA Pharmaceuticals Inc. as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and the financial statement schedule listed in the Index at Item 15a(2) of the Company and our report dated February 27, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

The Company'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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

Definition and Limitations of Internal Control Over Financial Reporting

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.

/s/ Ernst & Young LLP

San Diego, California
February 27, 2018

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

On February 22, 2018, Glenn F. Baity, our Executive Vice President, General Counsel and Secretary, informed us that, following a transition period, he will be leaving ACADIA to enter the next phase of his career and pursuing other business interests and challenges. ACADIA is commencing a search for Mr. Baity's replacement as General Counsel and Mr. Baity will be an integral part of that process and in assisting with the transition. No definitive departure date for Mr. Baity is known at this time.

On February 22, 2018, we entered into a commercial supply agreement with Catalent Pharma Solutions, LLC, or Catalent, for the manufacture of NUPLAZID drug product capsules for commercial use in the United States. Under the supply agreement, Catalent has agreed to manufacture and supply NUPLAZID 34 mg capsule drug product, referred to as NUPLAZID capsules, for our commercial use in the United States, Canada and Europe, and we have agreed to purchase from Catalent a specified percentage of our commercial requirements of NUPLAZID capsules for such territory, subject to a minimum annual purchase commitment of NUPLAZID capsules. Catalent will manufacture NUPLAZID capsules using API supplied by another third-party manufacturer. Under the supply agreement, Catalent will also perform specified validation services and assist us in obtaining regulatory approvals for Catalent's manufacture of the NUPLAZID capsules. The term of the supply agreement extends for five years from the date that Catalent is first approved by a regulatory authority in the United States, Canada or Europe to produce NUPLAZID capsules, and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the supply agreement is terminated early pursuant to its terms. Either we or Catalent may terminate the supply agreement prior to expiration upon the bankruptcy or insolvency of the other party or upon an uncured material breach by the other party. We may terminate the supply agreement, subject to certain limitations, if any regulatory authority takes any enforcement or other action against Catalent's facility which affects Catalent's ability to manufacture NUPLAZID capsules, or takes any action or raises any objection that prevents us from manufacturing, importing, exporting, purchasing or selling NUPLAZID capsules, if we do not obtain regulatory approval of NUPLAZID capsules in the United States, if we determine not to launch or to discontinue commercialization of NUPLAZID capsules in the United States for safety or efficacy reasons, or if Catalent uses any debarred person in performing its service obligations under the supply agreement.

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 2018 Annual Meeting of Stockholders to be filed with the SEC by April 30, 2018 (our "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 compliance department 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.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this report.

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

2. List of financial statement schedules:

Schedule II – Valuation and Qualifying Accounts

Schedules not listed above have been 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.

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 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 15, 2017).
10.4[a]	Forms of agreement under the 2010 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, filed February 29, 2016).
10.5[a]	2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed June 10, 2016).
10.6[a]	Offerings under the 2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K, filed February 28, 2017).
10.7[a]	Employment Offer Letter, dated July 25, 2016, between the Registrant and Todd S. Young (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed November 7, 2016).
10.8[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).

Exhibit Number	Description
10.9[a]	Employment Offer Letter, dated February 24, 2017, between the Registrant and Michael J. Yang (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed May 9, 2017).
10.10[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).
10.11[a]	Employment Offer Letter, dated October 28, 2015, between the Registrant and Srdjan Stankovic (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K, filed February 29, 2016).
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 18, 2016).
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 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 8, 2017).
10.16[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).
10.17[b]	First Amendment to Product Agreement, dated April 25, 2016, 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 August 4, 2016).
10.18[b]	Second Amendment to Product Agreement, dated October 6, 2016, 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 7, 2016).
10.19[b]	Third Amendment to Product Agreement, dated December 11, 2017, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.20[b]	Master Services Agreement, dated December 15, 2016, by and between ACADIA Pharmaceuticals GmbH and Siegfried AG and its affiliates, and Attachment #1, Attachment #2 and Attachment #3 (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K, filed February 28, 2017).
10.21[b]	Change Order #1 to Master Services Agreement Attachment #1, dated January 3, 2017, by and between ACADIA Pharmaceuticals GmbH and Siegfried AG (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K, filed February 28, 2017).
10.22[b]	Attachment #4, Attachment #5 and Attachment #6, each dated May 12, 2017, to the Master Services Agreement, dated December 15, 2016, by and between ACADIA Pharmaceuticals GmbH and Siegfried AG and its affiliates (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed August 8, 2017).
10.23[b]	Commercial Supply Agreement, dated February 22, 2018, by and between the Registrant and Catalent Pharma Solutions, LLC.
10.24	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).
10.25[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).
10.26	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).
10.27[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.
24.1	Power of Attorney (see signature page hereto).

Exhibit Number	Description
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.
31.2	Certification of Todd Young, Chief Financial Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of 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.
32.2	Certification of Todd Young, Chief Financial 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.

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 DAVIS

Stephen Davis
President and Chief Executive Officer
(on behalf of the registrant and as the registrant's Principal Executive Officer)

Date: February 27, 2018

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Stephen Davis, his true and lawful attorney-in-fact and agent with full power of substitution, for him and in his or her 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 or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her 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 DAVIS **Stephen Davis**	Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2018
/s/ TODD YOUNG **Todd Young**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2018
/s/ STEPHEN BIGGAR **Stephen Biggar**	Chairman of the Board	February 27, 2018
/s/ JULIAN BAKER **Julian Baker**	Director	February 27, 2018
/s/ LAURA BREGE **Laura Brege**	Director	February 27, 2018
/s/ JAMES DALY **James Daly**	Director	February 27, 2018
/s/ EDMUND HARRIGAN **Edmund Harrigan**	Director	February 27, 2018
/s/ DANIEL SOLAND **Daniel Soland**	Director	February 27, 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
ACADIA Pharmaceuticals Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ACADIA Pharmaceuticals Inc. (the Company) as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and the financial statement schedule listed in the Index at Item15(a)2 (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31 2017, 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) (PCAOB), the Company’s internal control over financial reporting as of December 31, 2017, 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 27, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2015.

San Diego, California
February 27, 2018

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2017	2016
Assets		
Cash and cash equivalents	$ 69,418	$ 163,620
Investment securities, available-for-sale	271,924	365,416
Accounts receivable, net	17,343	5,903
Interest and other receivables	1,087	1,237
Inventory	5,248	4,175
Prepaid expenses	8,457	7,546
Total current assets	373,477	547,897
Property and equipment, net	2,662	3,081
Intangible assets, net	5,538	7,015
Restricted cash	2,475	2,375
Other assets	354	785
Total assets	$ 384,506	$ 561,153
Liabilities and stockholders' equity		
Accounts payable	$ 8,786	$ 3,912
Accrued liabilities	40,244	36,029
Deferred revenue	—	2,644
Total current liabilities	49,030	42,585
Long-term liabilities	191	157
Total liabilities	49,221	42,742
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at December 31, 2017 and 2016; no shares issued and outstanding at December 31, 2017 and 2016	—	—
Common stock, $0.0001 par value; 225,000,000 shares authorized at December 31, 2017 and December 31, 2016; 124,410,552 shares and 121,367,169 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	12	12
Additional paid-in capital	1,559,343	1,452,272
Accumulated deficit	(1,223,671)	(933,979)
Accumulated other comprehensive (loss) income	(399)	106
Total stockholders' equity	335,285	518,411
Total liabilities and stockholders' equity	$ 384,506	$ 561,153

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

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

	Years Ended December 31,		
	2017	2016	2015
Revenues			
Product sales, net	$ 124,901	$ 17,327	$ —
Collaborative revenue	—	4	61
Total revenues	124,901	17,331	61
Operating expenses			
Cost of product sales	9,077	3,075	—
License fees and royalties	3,983	1,331	2,500
Research and development	149,189	99,284	73,869
Selling, general and administrative	255,062	186,456	88,304
Total operating expenses	417,311	290,146	164,673
Loss from operations	(292,410)	(272,815)	(164,612)
Interest income, net	4,126	2,763	499
Loss before income taxes	(288,284)	(270,052)	(164,113)
Income tax expense	1,119	1,341	330
Net loss	$ (289,403)	$ (271,393)	$ (164,443)
Net loss per common share, basic and diluted	$ (2.36)	$ (2.34)	$ (1.63)
Weighted average common shares outstanding, basic and diluted	122,600	115,858	100,630

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

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Years Ended December 31,		
	2017	2016	2015
Net loss	$ (289,403)	$ (271,393)	$ (164,443)
Other comprehensive gain (loss):			
Unrealized (loss) gain on investment securities	(499)	94	13
Foreign currency translation adjustments	(6)	1	7
Comprehensive loss	$ (289,908)	$ (271,298)	$ (164,423)

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

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

	Years Ended December 31,		
	2017	2016	2015
Cash flows from operating activities			
Net loss	$ (289,403)	$ (271,393)	$ (164,443)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	75,532	55,265	40,194
Amortization of premiums and accretion of discounts on investment securities	(291)	89	(2,060)
Amortization of intangible assets	1,477	985	—
Depreciation	1,236	843	647
Income tax benefit from exercise of stock options	—	(596)	(247)
Loss on disposal of assets	4	5	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(11,440)	(5,903)	—
Interest and other receivables	150	401	(674)
Inventory	(1,012)	(3,305)	—
Prepaid expenses and other current assets	(911)	(4,731)	(804)
Restricted cash	(100)	(2,000)	(375)
Other assets	431	(456)	(42)
Accounts payable	4,874	2,240	(344)
Accrued liabilities	4,206	15,579	6,256
Deferred revenue	(2,644)	2,644	—
Long-term liabilities	34	(75)	97
Net cash used in operating activities	(217,857)	(210,408)	(121,795)
Cash flows from investing activities			
Purchases of investment securities	(478,818)	(683,355)	(269,486)
Maturities of investment securities	572,103	430,937	419,197
Intangible assets	—	(8,000)	—
Purchases of property and equipment	(812)	(1,506)	(2,141)
Net cash provided by (used in) investing activities	92,473	(261,924)	147,570
Cash flows from financing activities			
Proceeds from issuance of common stock, net of issuance costs	31,188	518,896	14,547
Proceeds from settlement agreement	—	14,320	—
Deferred offering costs	—	—	(292)
Income tax benefit from exercise of stock options	—	596	247
Net cash provided by financing activities	31,188	533,812	14,502
Effect of exchange rate changes on cash	(6)	2	7
Net (decrease) increase in cash and cash equivalents	(94,202)	61,482	40,284
Cash and cash equivalents at beginning of period	163,620	102,138	61,854
Cash and cash equivalents at end of period	$ 69,418	$ 163,620	$ 102,138
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 1,367	$ 365	$ 415
Supplemental disclosure of noncash information:			
Property and equipment purchases in accounts payable and accrued liabilities	$ 9	$ 220	$ 156
Stock-based compensation capitalized in inventory	$ (61)	$ 870	$ —

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

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, 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
Issuance of common stock in public offering, net of issuance costs	17,314,523	2	497,763	—	—	497,765
Issuance of common stock from exercise of stock options	1,977,661	—	18,000	—	—	18,000
Issuance of common stock pursuant to employee stock purchase plan	136,283	—	3,131	—	—	3,131
Income tax benefit from exercise of stock options	—	—	596	—	—	596
Proceeds from settlement agreement	—	—	14,320	—	—	14,320
Net loss	—	—	—	(271,393)	—	(271,393)
Stock-based compensation	—	—	56,135	—	—	56,135
Other comprehensive income	—	—	—	—	95	95
Balances at December 31, 2016	121,367,169	$ 12	$ 1,452,272	$ (933,979)	$ 106	$ 518,411
Issuance of common stock from exercise of stock options	1,442,411	—	26,665	—	—	26,665
Issuance of common stock pursuant to employee stock purchase plan	192,402	—	4,522	—	—	4,522
Issuance of common stock from exercise of warrants on a net issuance basis	1,408,570	—	—	—	—	—
Net loss	—	—	—	(289,403)	—	(289,403)
Cumulative effect adjustment from adoption of ASU 2016-09	—	—	—	(289)	—	(289)
Stock-based compensation	—	—	75,884	—	—	75,884
Other comprehensive loss	—	—	—	—	(505)	(505)
Balances at December 31, 2017	124,410,552	$ 12	$ 1,559,343	$ (1,223,671)	$ (399)	$ 335,285

The accompanying notes are an integral part of these 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.

On April 29, 2016, the U.S. Food and Drug Administration ("FDA") approved the Company's first drug, NUPLAZID® (pimavanserin), for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis ("PD Psychosis"). NUPLAZID became available for prescription in the United States on May 31, 2016. Accordingly, the Company's financial statements for 2017 and 2016 include product revenue and other transactions related to the commercialization of NUPLAZID that did not exist in prior years.

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, trade receivables, 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.

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.

Accounts Receivable

Accounts receivable are recorded net of customer allowances for distribution fees, prompt payment discounts, chargebacks, and doubtful accounts. Allowances for distribution fees, prompt payment discounts and chargebacks are based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. At December 31, 2017, the Company determined that an allowance for doubtful accounts was not required. No accounts were written off during the periods presented.

Inventory

Inventory, consisting of raw material and finished goods, is stated at the lower of cost or estimated net realizable value. The Company uses a combination of standard and actual costing methodologies to determine the cost basis for its inventories which approximates actual costs. Inventory is valued on a first-in, first-out basis and includes third-party manufacturing costs, freight, and indirect overhead costs. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. Prior to FDA approval of NUPLAZID, all costs related to the manufacturing of NUPLAZID were charged to research and development expense in the period incurred. At December 31, 2017 the Company had an immaterial amount of zero-cost raw material that was available for use in the manufacturing of commercial product. The Company reduces its inventory to net realizable value for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. During 2017, the Company recorded a charge of $0.7 million to reduce certain finished goods inventory to its net realizable value. No such charges were recorded in 2016 or 2015.

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. Through December 31, 2017, no such impairment losses have been recorded by the Company.

License Fees and Royalties

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.

In connection with the FDA approval of NUPLAZID in April 2016, the Company made a one-time milestone payment of $8.0 million pursuant to its 2006 license agreement with the Ipsen Group in which the Company licensed certain intellectual property rights that complement its patent portfolio for its serotonin platform, including NUPLAZID. The Company capitalized the $8.0 million payment as an intangible asset and is amortizing the asset on a straight-line basis over the estimated useful life of the licensed patents through the second half of 2021. The Company recorded amortization expense related to its intangible asset of $1.5 million and $1.0 million for the years ended December 31, 2017 and 2016, respectively. No such amortization was incurred during the year ended December 31, 2015. As of December 31, 2017, estimated future amortization expense related to the Company's intangible asset was $1.5 million for each of 2018, 2019 and 2020, and $1.0 million for 2021.

Royalties incurred in connection with the Company's license agreement with the Ipsen Group, as disclosed in Note 9, are expensed to license fees and royalties as revenue from product sales is recognized.

Advertising Expense

In connection with the FDA approval and commercial launch of NUPLAZID in 2016, the Company began to incur advertising costs. Advertising costs are expensed when services are performed or goods are delivered. The Company incurred $15.6 million and $1.6 million in advertising costs in 2017 and 2016, respectively, related to its marketed product, NUPLAZID. No advertising costs were capitalized as prepaid expenses at December 31, 2017 or 2016.

Revenue Recognition

Product Sales, Net

The Company's net product sales consist of U.S. sales of NUPLAZID and are recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title to the product and associated risk of loss has passed to the customer, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured.

NUPLAZID was approved by the FDA on April 29, 2016 and the Company commenced shipments of NUPLAZID to specialty pharmacies ("SPs") and specialty distributors ("SDs") in late May 2016. Prior to April 1, 2017, the Company deferred sales of NUPLAZID and recognized revenue when an SP dispensed product to a patient based on the fulfillment of a prescription and when an SD sold product to a government facility, long-term care pharmacy, or in-patient hospital pharmacy. In the second quarter of 2017 the Company determined that it had sufficient volume of activity to reasonably estimate its allowances for rebates and chargebacks and began recognizing NUPLAZID revenue, net of estimated allowances for rebates, price adjustments, returns, chargebacks, and prompt payment discounts, at the point of sale to the SPs and SDs which is commonly referred to as the "sell-in" revenue recognition model. As a result, the Company recorded a one-time adjustment during the three months ended June 30, 2017, to recognize deferred revenue on previously shipped product.

The effect on income from operations and on net income is that the Company is able to recognize revenue earlier on this sell-in method, net of a provision for estimated allowances, since the Company can record revenue once sold to the SP or SD rather than waiting until the product is sold to the end user on a sell-through basis, which it had done for periods prior to April 1, 2017.

Product shipping and handling costs are included in cost of product sales.

The Company recognizes revenue from product sales net of the following allowances and reflects each of these as either a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

Distribution Fees: Distribution fees include distribution service fees paid to the SPs and SDs based on a contractually fixed percentage of the wholesale acquisition cost ("WAC"), fees for data, and prompt payment discounts. Distribution fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. The Company's estimates for expected utilization of rebates is based on historical data received from the SPs and SDs since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates. If actual future rebates vary from estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs at a discounted price. The SDs charge back to the Company the difference between the price initially paid by the SDs and the discounted price paid to the SDs by these entities. The Company also incurs group purchasing organization fees for transactions through certain purchasing organizations. The Company estimates sales with these entities and accrues for anticipated chargebacks and organization fees, based on the applicable contractual terms. If actual future chargebacks vary from these estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued for based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Returns: Consistent with industry practice, the Company offers the SPs and SDs limited product return rights for damages, shipment errors, and expiring product; provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SPs and SDs and has the ability to control the amount of product that is sold to the SPs and SDs, it is able to make a reasonable estimate of future potential product returns based on this on-hand channel inventory data and sell-through data obtained from the SPs and SDs. In arriving at its estimate, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

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 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 accordingly.

Concentration Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, investment securities, accounts receivable, and restricted cash. 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. Further, the Company specifies credit quality standards for its customers that are designed to limit the Company's credit exposure to any single party.

The Company does not currently have any of its own manufacturing facilities, and therefore it depends on an outsourced manufacturing strategy for the production of NUPLAZID for commercial use and for the production of its product candidates for clinical trials. The Company has contracts in place with two third-party manufacturers of drug product, one that is approved for the commercial production of NUPLAZID tablets and one that still requires approval for commercial production of capsules, and one third-party manufacturer of drug substance that is approved for the production of NUPLAZID active pharmaceutical ingredient ("API"). 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.

The Company has entered into distribution agreements with a limited number of SPs and SDs, and all of the Company's product sales are to these customers. For the year ended December 31, 2017, the Company's four largest customers represented approximately 89% of the Company's product revenue and 87% of the Company's accounts receivable balance at December 31, 2017. For the year ended December 31, 2016, the Company's four largest customers represented approximately 93% of the Company's product revenue and 91% of the Company's accounts receivable balance at December 31, 2016.

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 is then expensed over the requisite service period, which is generally the vesting period. The following weighted-average assumptions were used during these periods:

	Years Ended December 31,		
	2017	2016	2015
Stock Options:			
Expected volatility	68%	78%	89%
Risk-free interest rate	2%	1-2%	1-2%
Expected dividend yield	0%	0%	0%
Expected life of options in years	5.8	5.7	5.7

	Years Ended December 31,		
	2017	2016	2015
Employee Stock Purchase Plan:			
Expected volatility	44%-62%	60%-77%	51%-59%
Risk-free interest rate	1.0%-1.7%	0.4%-1.0%	0.1%-0.9%
Expected dividend yield	0%	0%	0%
Expected life in years	0.5-2.0	0.5-2.0	0.5-2.0

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.

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 obtained.

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,		
	2017	2016	2015
Cost of product sales	$ 3,690	$ 1,218	$ —
Research and development	26,485	18,050	12,171
Sales, general and administrative	45,357	35,997	28,023
	$ 75,532	$ 55,265	$ 40,194

Stock-based compensation expense for the year ended December 31, 2015 included a one-time $9.0 million charge related to the transition agreement with the Company's former Chief Executive Officer entered into in connection with his retirement from the Company in March 2015.

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 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, employee stock purchase rights, 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, 2017, 2016 and 2015, options, employee stock purchase rights, and warrants totaling approximately 18,526,000 shares, 14,739,000 shares and 11,525,000 shares, respectively, were excluded from the calculation of diluted net loss per share 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, 2017, 2016 and 2015 were generated in the United States.

Recently Issued Accounting Standards

In November 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-18, *Statement of Cash Flows: Restricted Cash*, which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The Company has adopted this standard effective January 1, 2018. The adoption of this ASU will modify the Company's current classification within the consolidated statement of cash flows but will not materially impact the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*, which changes the impairment model for most financial assets and certain other instruments. For trade receivables and other instruments, entities will be required to use a new forward-looking expected loss model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than as reductions in the amortized cost of the securities. This guidance is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those years, with early adoption permitted only as of annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the timing and impact of the adoption of this guidance on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation-Stock Compensation: Improvements to Employee Share-Based Payment Accounting*, which is intended to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows, and accounting for forfeitures. This guidance was effective for annual reporting periods beginning after December 15, 2016, including interim periods within those years. The Company adopted this guidance in the first quarter of 2017 using the modified retrospective transition method. Accordingly, the Company increased its deferred tax assets by $36.8 million, with a corresponding increase to its valuation allowance, to record previously unrecognized excess tax benefits. Additionally, the Company elected to make an accounting policy change to recognize forfeitures as they occur. As a result, the Company recorded an increase to additional paid-in capital and a corresponding increase to accumulated deficit of $0.3 million, respectively, to reflect the incremental stock-based compensation expense that would have been recognized in prior years pursuant to the modified guidance. Additionally, the Company increased its deferred tax assets by $0.1 million, with a corresponding increase to its valuation allowance, to record the excess tax benefit from the change.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which requires a lessee to recognize a lease liability and a right-of-use asset for all leases with lease terms of more than 12 months. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those years, and early adoption is permitted. Companies are required to adopt this guidance using a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. As disclosed in Note 9, *Commitments and Contingencies*, the Company leases facilities under operating leases. While the Company is still evaluating the timing and impact of the adoption of this guidance on its consolidated financial statements, it anticipates that the adoption could result in an increase in the assets and liabilities recorded on its consolidated balance sheet.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes nearly all existing revenue recognition guidance under generally accepted accounting principles. This ASU, as amended, is a comprehensive new revenue recognition model that requires an entity 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. This ASU also requires additional disclosure about the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts. 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. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance.

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Topic 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

The Company has adopted this standard effective January 1, 2018 using the modified-retrospective approach. Under this method the Company will apply the new standard to all new contracts initiated after the effective date, and, for contracts which have remaining obligations as of the effective date, will record an adjustment to the beginning balance of retained earnings. To date, the Company has assessed the effect of adoption of this standard as it relates to the Company’s one source of revenue: the sale of NUPLAZID to its customers. Based on the Company’s evaluation of the customer contracts governing these sales, the Company currently estimates that recognition of the Company’s revenue under the new standard will be materially consistent with the Company’s current revenue recognition policy, which uses the sell-in method. The Company also estimates there will not be a material impact to the beginning balance of retained earnings.

3. Investment Securities

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

	December 31, 2017			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 32,976	$ —	$ (12)	$ 32,964
Government sponsored enterprise securities	10,082	—	(10)	10,072
Corporate debt securities	138,650	1	(321)	138,330
Commercial paper	90,623	—	(65)	90,558
	$ 272,331	$ 1	$ (408)	$ 271,924

	December 31, 2016			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 82,484	$ 6	$ (3)	$ 82,487
Government sponsored enterprise securities	73,789	1	(5)	73,785
Corporate debt securities	79,190	—	(72)	79,118
Commercial paper	129,861	165	—	130,026
	$ 365,324	$ 172	$ (80)	$ 365,416

At each reporting date, the Company performs an evaluation of impairment to determine if any 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, 2017 and 2016.

The Company has classified all of its available-for-sale investment securities, including those with maturities beyond one year, as current assets on its consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations. As of December 31, 2017, the Company held $48.7 million of available-for-sale investment securities with contractual maturity dates more than one year and less than two years. No securities with similar maturity dates were held as of December 31, 2016.

4. Fair Value Measurements

The Company's investments include cash equivalents and available-for-sale investment securities consisting of a money market fund, U.S. Treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises 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, 2017 and 2016, respectively.

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 classification levels.

The recurring fair value measurements of the Company's cash equivalents and available-for-sale investment securities at December 31, 2017 and 2016 consisted of the following (in thousands):

	December 31, 2017	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$ 38,057	$ 38,057	$ —	$ —
U.S. Treasury notes	32,964	32,964	—	—
Government sponsored enterprise securities	10,072	—	10,072	—
Corporate debt securities	154,396	—	154,396	—
Commercial paper	98,052	—	98,052	—
	$ 333,541	$ 71,021	$ 262,520	$ —

	December 31, 2016	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$ 129,292	$ 129,292	$ —	$ —
U.S. Treasury notes	82,487	82,487	—	—
Government sponsored enterprise securities	88,773	—	88,773	—
Corporate debt securities	82,857	—	82,857	—
Commercial paper	140,024	—	140,024	—
	$ 523,433	$ 211,779	$ 311,654	$ —

5. Balance Sheet Details

Inventory consisted of the following (in thousands):

	December 31,	
	2017	2016
Finished goods	$ 1,164	$ 2,355
Raw material	4,084	1,820
	$ 5,248	$ 4,175

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

	December 31,	
	2017	2016
Machinery and equipment	$ 1,076	$ 1,087
Computers and software	2,868	2,718
Leasehold improvements	1,642	1,317
Furniture and fixtures	1,305	1,141
Construction-in-process	—	226
	6,891	6,489
Accumulated depreciation	(4,229)	(3,408)
	$ 2,662	$ 3,081

Depreciation of property and equipment was $1.2 million, $0.8 million, and $0.6 million for the years ended December 31, 2017, 2016, and 2015, respectively. During 2017, 2016 and 2015, the Company retired $0.4 million, $0.2 million, and $0.1 million, respectively, of fully depreciated property and equipment.

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2017	2016
Accrued compensation and benefits	$ 15,260	$ 14,382
Accrued consulting and professional fees	9,395	9,488
Accrued research and development services	9,487	8,551
Accrued sales allowances	3,591	1,999
Other	2,511	1,609
	$ 40,244	$ 36,029

6. Stockholders' Equity

Public Offerings

In August 2016, the Company raised net proceeds of approximately $215.9 million from the sale of 6,969,696 shares of its common stock in a follow-on public offering, including 909,090 shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares.

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. 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 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 and $43.0 million of shares that the Baker Entities purchased at the public offering price in the January 2016 and August 2016 offerings, respectively), 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. On April 1, 2016, pursuant to the Registration Rights Agreement, the Company filed a registration statement covering all shares owned by the Baker Entities as of March 31, 2016.

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 and no dividend yield. These warrants were recorded as a component of stockholders' equity within additional paid-in capital. Per their terms, the warrants to purchase 500,000 shares of common stock, all of which remained outstanding at December 31, 2017, may not be exercised if the holder's ownership of the Company's common stock would exceed 19.99 percent following such exercise.

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 had an exercise price of $1.38 per share and an expiration date of 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, 2017,

warrants to purchase 1,465,968 shares of common stock were exercised on a net issuance basis, resulting in the issuance of 1,408,570 shares of common stock. 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, 2017, no warrants to purchase shares of common stock remained outstanding.

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, June 2016, and June 2017, the Company's stockholders approved amendments 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, 3,000,000 shares, and 5,500,000 shares respectively, and at December 31, 2017, there were 25,997,247 shares of common stock authorized for issuance, of which 8,053,811 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.

Stock option transactions during the year ended December 31, 2017 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, 2016	12,743,877	$ 26.41		
Granted	7,867,683	$ 34.73		
Exercised	(1,442,411)	$ 18.49		
Cancelled/forfeited	(1,225,713)	$ 30.48		
Outstanding at December 31, 2017	17,943,436	$ 30.42	8.1	$ 55,794
Vested and expected to vest at December 31, 2017	17,943,436	$ 30.42	8.1	$ 55,794
Exercisable at December 31, 2017	6,464,292	$ 26.07	6.6	$ 41,449

The aggregate intrinsic value of options exercisable as of December 31, 2017 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 $30.11 per share. The aggregate intrinsic value of options exercised during the years ended December 31, 2017, 2016, and 2015 was approximately $24.4 million, $43.2 million, and $55.9 million, respectively, determined as of the date of exercise. The Company received $26.7 million in cash from options exercised during the year ended December 31, 2017.

The weighted average per share fair value of options granted during the years ended December 31, 2017, 2016, and 2015 was approximately $21.11, $17.65, and $25.80, respectively. As of December 31, 2017, total unrecognized compensation cost related to stock options and purchase rights was approximately $206.5 million, and the weighted average period over which this cost is expected to be recognized is approximately 3.19 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. In June 2016, the Company's stockholders approved an amendment to the

Purchase Plan to, among other things, increase the aggregate number of shares of common stock authorized for issuance under the plan by 400,000 shares, and at December 31, 2017, a total of 1,925,000 shares of common stock had been reserved for issuance under the Purchase Plan. At December 31, 2017, 388,011 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, 2017, 2016, and 2015, a total of 192,402, 136,283, and 68,793 shares of common stock were issued under the Purchase Plan at average per share prices of $23.50, $22.97, and $22.62, respectively. The weighted average per share fair value of purchase rights granted during the years ended December 31, 2017, 2016, and 2015 was $11.44, $12.34, and $14.31, respectively. During the years ended December 31, 2017, 2016, and 2015, the Company recorded cash received from the exercise of purchase rights of $4.5 million, $3.1 million, and $1.6 million, respectively.

Settlement Agreement Proceeds

In April 2016, the Company received a payment of $14.3 million pursuant to a settlement agreement with prior 10% stockholders who sold shares of the Company's stock in 2013 that may have resulted in short-swing profits by the stockholders pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended. The Company recognized these proceeds as a capital contribution from stockholders and reflected a corresponding increase to additional paid-in capital.

7. 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 $3.3 million, $2.1 million, and $1.0 million for the years ended December 31, 2017, 2016, and 2015, respectively.

8. Income Taxes

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

	Years Ended December 31,		
	2017	2016	2015
Domestic	(45,249)	$ (18,419)	$ 25,854
Foreign	(243,035)	(251,633)	(189,967)
	(288,284)	$ (270,052)	$ (164,113)

At December 31, 2017, the Company had federal, state, and foreign net operating loss ("NOL") carryforwards of approximately $407.1 million, $340.0 million, and $647.4 million, respectively. The Company recognized state income tax provisions of $1.1 million, $1.3 million and $0.3 million for the years ended December 31, 2017, 2016 and 2015, respectively. These tax liabilities were 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. 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, 2017 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 less than $0.1 million will expire in 2018, respectively, unless utilized. The remaining federal and state NOL carryforwards will begin to expire in 2023. At December 31, 2017, the Company had $19.8 million of federal R&D credit carryforwards of which $0.1 million will expire in 2018 unless utilized, and the remaining federal R&D credit carryforwards will begin to expire in 2019. At December 31, 2017, the Company had state R&D credit carryforwards of approximately $0.2 million that will begin to expire in 2023 and $10.0 million that have no expiration date. At December 31, 2017, the Company had foreign NOL carryforwards of approximately $643.9 million that will expire in 2022 and $3.6 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.

Prior to the issuance of ASU No. 2016-09, entities were required to recognize excess tax benefit or deficiency as additional paid-in capital. To simplify the presentation of stock compensation, the amendments in this ASU require that the excess tax benefit or deficiency is recognized as expense. For public business entities, the amendments in this ASU are effective for financial statements issued for annual periods beginning after December 15, 2016 and interim periods within those annual periods. The Company adopted the update as of January 1, 2017. Given the Company's full valuation position there is no quantitative impact to the financial statements.

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

	December 31,	
	2017	2016
NOL carryforwards	$ 163,059	$ 168,753
R&D credit carryforwards	27,862	21,016
Capitalized R&D	5,606	3,977
Stock-based compensation	30,986	27,576
Other	10,110	6,102
	237,623	227,424
Valuation allowance	(237,623)	(227,424)
	$ —	$ —

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 $10.2 million in 2017 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 2017 and the remeasurement of our deferred tax balance for changes in future tax rates.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act") was signed into legislation. At December 31, 2017, the Company has not yet completed its accounting assessment for the tax effects of the enactment of the Act; however, as described below, the Company has made a reasonable estimate of the effects on the existing deferred tax balances.

As a result of the lower enacted corporate tax rate, the Company has remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The provisional amount recorded related to the remeasurement of the Company's deferred tax balance was $68.9 million, that is fully offset by a corresponding decrease to the valuation allowance.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of US GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In accordance with SAB 118, the Company has provisionally determined that there is no deferred tax benefit or expense with respect to the remeasurement of certain deferred tax assets and liabilities due to the full valuation allowance against net deferred tax assets. The Company is still analyzing certain aspects of the Act and refining its calculations, which could potentially affect the measurement of these balances or potentially give rise to new deferred tax amounts. Additional analysis of the law and the impact to the Company will be performed and any impact will be recorded in the respective quarter in 2018.

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

	Years Ended December 31,		
	2017	2016	2015
Amounts computed at statutory federal rate	$ (98,016)	$ (91,818)	$ (55,799)
Stock-based compensation and other permanent differences	1,341	3,065	1,752
R&D credits	(5,573)	(3,390)	(3,782)
Change in valuation allowance	(28,230)	27,583	4,580
State taxes	(26)	272	742
Contingencies	360	361	2,247
Foreign rate differential	61,480	64,065	48,456
Tax Cuts and Jobs Act	68,889	—	—
Other	894	1,203	2,134
Income tax expense	$ 1,119	$ 1,341	$ 330

The tax years 1998-2016 remain open to examination by the major taxing jurisdictions to which the Company is subject.

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. The Company recorded an uncertain tax position reserve of $0.4 million, $0.4 million and $2.3 million for the years ended December 31, 2017, 2016 and 2015, respectively. In addition, due to the Tax Cuts and Jobs Act a provisional adjustment of $1.1 million was made to remeasure the uncertain tax position reserve at December 31, 2017. Due to the valuation allowance recorded against the Company's deferred tax assets, an immaterial amount of the total unrecognized tax benefits as of December 31, 2017 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, 2017 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, 2017 or 2016, respectively. Further, the Company did not recognize any interest and/or penalties in the statement of operations for the years ended December 31, 2017, 2016 and 2015, respectively, related to uncertain tax positions.

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

	Years Ended December 31,		
	2017	2016	2015
Balance at beginning of period	$ 2,664	$ 2,301	$ —
Additions related to current period tax positions	361	363	2,301
Provisional impact of Tax Cuts and Jobs Act	(1,092)	—	—
Balance at end of period	$ 1,933	$ 2,664	$ 2,301

9. 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 May 2020. 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 $3.8 million, $2.8 million, and $2.9 million, for the years ended December 31, 2017, 2016, and 2015, 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 has established a letter of credit for $0.5 million, 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.

Estimated annual future minimum payments related to the Company's operating leases were as follows at December 31, 2017 (in thousands):

2018	$ 2,529
2019	1,019
2020	320
2021	—
2022	—
Thereafter	—
	$ 3,868

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.

Royalty Payments

Pursuant to the terms of its 2006 license agreement with the Ipsen Group, the Company is required to make royalty payments of two percent of net sales of NUPLAZID.

Corporate Credit Card Program

In connection with the Company's credit card program, the Company established a letter of credit in 2016 for $2.0 million, which has automatic annual extensions and is fully secured by restricted cash.

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 PD Psychosis 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 plaintiffs, and assigning lead counsel. On November 16, 2015, lead plaintiffs 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 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. On September 19, 2016, the Court issued an order denying the motion to dismiss the consolidated complaint. On December 6, 2016, the parties had a mediation and agreed in principle to settle the action. On March 13, 2017, the parties signed a Stipulation of Settlement setting forth the terms of the proposed settlement. On June 9, 2017, the Court preliminarily approved the settlement (the "Preliminary Approval Order"). Among other things, the Preliminary Approval Order set an opt-out deadline of August 29, 2017; an objection deadline of September 13, 2017; and a final approval hearing for October 3, 2017. On August 29, 2017, lead plaintiffs filed a motion for final approval of the settlement and a motion for attorneys' fees and expenses (the "Final Approval Motions"). On October 3, 2017, the Court continued the hearing so that, among other things, lead plaintiffs could submit additional documents in support of final approval. On January 22, 2018, the Court issued an order granting the Final Approval Motions and entered final judgment in the consolidated action.

10. 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, 2017 and 2016 are as follows (in thousands, except per share data):

	Fiscal Year 2017 Quarters				
	1st	2nd	3rd	4th	Total
Revenues(1)	$ 15,286	$ 30,475	$ 35,578	$ 43,562	$ 124,901
Gross profit(2)	$ 13,023	$ 28,251	$ 33,443	$ 41,107	$ 115,824
Net loss	$ (87,843)	$ (67,441)	$ (65,248)	$ (68,871)	$ (289,403)
Basic and diluted net loss per share(3)	$ (0.72)	$ (0.55)	$ (0.53)	$ (0.55)	$ (2.36)

	Fiscal Year 2016 Quarters				
	1st	2nd	3rd	4th	Total
Revenues(1)	$ 4	$ 97	$ 5,268	$ 11,962	$ 17,331
Gross profit(2)	$ —	$ (429)	$ 4,423	$ 10,258	$ 14,252
Net loss	$ (49,762)	$ (71,322)	$ (71,613)	$ (78,696)	$ (271,393)
Basic and diluted net loss per share(3)	$ (0.45)	$ (0.63)	$ (0.61)	$ (0.65)	$ (2.34)

(1) The Company commenced commercial sales of NUPLAZID in May 2016. The quarters after March 31, 2016 reflect net product revenue related to NUPLAZID.

(2) Determined by subtracting cost of product sales from product sales, net.

(3) 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.

SCHEDULE II – Valuation and Qualifying Accounts
(in thousands)

	Balance at Beginning of Period	Additions	Deductions		Balance at End of Period
		Provision Related to Current Period Sales	Actual Distribution Fees, Discounts and Chargebacks Related to Current Period Sales	Actual Distribution Fees, Discounts and Chargebacks Related to Prior Period Sales	
Allowance for distribution fees, discounts and chargebacks:					
For the year ended December 31, 2016	$ —	$ 2,163	$ (1,962)	$ —	$ 201
For the year ended December 31, 2017	$ 201	$ 12,837	$ (12,591)	$ (201)	$ 246

Exhibit 10.19

*****Text Omitted and Filed Separately**
with the Securities and Exchange Commission.
Confidential Treatment Requested
Under 17 C.F.R. Sections 200.80(b)(4)
and 240.24b-2.

Third Amendment to Product Agreement
between Patheon Pharmaceuticals Inc. and ACADIA Pharmaceuticals Inc.

This Third Amendment to Product Agreement (this "**Amendment**"), dated December 11, 2017 (the "**Amendment Date**"), is made by and between Patheon Pharmaceuticals Inc. ("**Patheon**") and ACADIA Pharmaceuticals Inc. ("**ACADIA**").

WHEREAS, Patheon and ACADIA have entered into that certain Master Manufacturing Services Agreement, dated August 3, 2015 (the "**MSA**") and that certain Product Agreement under the MSA, dated August 3, 2015, as amended on April 25, 2016 and October 6, 2016 (the "**Product Agreement**"); and

WHEREAS, Patheon and ACADIA now wish to amend Schedules A, B, C, and D to the Product Agreement to add Nuplazid 10 mg tablets as a Product as set forth in this Amendment. All capitalized terms used but not defined in this Amendment will have the respective meanings set forth in the MSA or Product Agreement, as applicable.

NOW THEREFORE in consideration of the premises hereof and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, the parties agree as follows:

1.**Amendment to Schedules A, B, C, and D.**

(a) **Schedule A** is revised to add to the Product List an additional and separate Product as follows: "**Pimavanserin Tablets 10mg Strength**." The language regarding Specifications shall remain as currently drafted, and is applicable to both Products.

(b) **Schedule B** is revised to add information for Pimavanserin Tablets 10mg Strength as set forth in **Exhibit 1**.

(c) **Schedule C** is revised to add information for Pimavanserin Tablets 10mg Strength as set forth in **Exhibit 2**.

(d) **Schedule D, Active Materials Credit Value, and Maximum Credit Value, Product,** are revised to add "**Pimavanserin Tablets 10mg Strength**" in the Product column of each table.

(e) For clarity, the term of the Product Agreement as set forth on the cover page of the Product Agreement shall remain unchanged.

2.Side Letter Agreements. For clarity, the language in Section 2 of the Second Amendment to the Product Agreement, dated April 25, 2016, regarding side letter agreements to document future changes to stability testing and annual adjustments to pricing pursuant to

Section 4.2 of the MSA, shall continue to apply to both Products covered by the Product Agreement.

3.No Other Modifications. Except as specifically modified by this Amendment, the terms and conditions of the Product Agreement including, without limitation, all other terms and conditions included in each of the amended Schedules, and the MSA, remain unchanged.

[signature page to follow]

IN WITNESS WHEREOF, the parties have caused this Amendment to be duly executed by their authorized representatives, effective as of the Amendment Date.

Patheon Pharmaceuticals Inc.	**ACADIA Pharmaceuticals Inc.**
By: /s/ Amanda Bosse	By: /s/ James Nash
Name: Amanda Bosse	Name: James Nash
Title: VP and GM Cincinnati Regional Ops	Title: SVP, Technology Development & Operations

Exhibit 1

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME AND PRICE
(Pimavanserin Tablets 10mg Strength)

Annual Volume Forecast

[…***…]

Pricing Tables

Pricing includes the cost of labor, overhead, raw materials, packaging components and QC testing and such additional items noted as being included in the price as described below. For clarity, both commercial and validation batches of Pimavanserin Tablets 10mg Strength are subject to this Product Agreement as described below.

[…***…]

Costs Included in Unit Price

[…***…]

Costs Not Included in Unit Price

[…***…]

Key Technical Assumptions

The following technical parameters apply to the production of Pimavanserin Tablets 10mg Strength and the materials used therein. […***…]

Manufacturing Assumptions

[…***…]

Packaging Assumptions

- **Packaging Components:**

[…***…]

Testing Assumptions

[…***…]

Supply Chain Assumptions

[…***…]

For clarity, the foregoing shall not amend the Pricing provisions of the MSA that are applicable to all Products and Product Agreements as set forth in the MSA.

Exhibit 2

SCHEDULE C

ANNUAL STABLITY TESTING
(Pimavanserin Tablets 10mg Strength)

ACTIVITY ***PRICE***

[…***…]

Exhibit 10.23

*****Text Omitted and Filed Separately with the Securities and Exchange Commission. Confidential Treatment Requested Under 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2.**

FINAL

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement is made as of this 22nd day of February, 2018 (the "**Effective Date**"), by and between ACADIA Pharmaceuticals Inc., a Delaware corporation, with a place of business at 3611 Valley Centre Drive, Suite 300, San Diego, California 92130 ("**Client**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, having a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA ("**Catalent**").

RECITALS

A. Client develops, markets and sells pharmaceutical products;

B. Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services, for pharmaceutical, biotechnology and consumer healthcare companies;

C. Client desires to have Catalent provide the services set forth in this Agreement (as defined below) in connection with Client's Product (as defined below), and Catalent desires to provide such services, all pursuant to the terms and conditions in this Agreement.

THEREFORE, in consideration of the circumstances described above and the mutual covenants, terms and conditions set forth below, the parties agree as follows:

ARTICLE 1
DEFINITIONS

The following terms have the following meanings in this Agreement:

1.1 "**Acknowledgement**" has the meaning set forth in Section 4.3(B).

1.2 "**Affiliate(s)**" means, with respect to Client or any third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity; and with respect to Catalent, Catalent, Inc. and any corporation, firm, partnership or other entity controlled by it. For the purposes of this definition, "**control**" means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.

1.3 "**Agreement**" means this document, including all its Attachments and other appendices (all of which are incorporated by reference) and any amendment to any of the foregoing made in accordance with Section 18.1.

1.4 "**API**" means the generic compound Pimavanserin as further described in the Specifications.

1.5 "**Applicable Laws**" means, with respect to Client all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in the Territory in which API or Product is produced, marketed, distributed, used or sold; and with respect to Catalent, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, (a) of the jurisdiction in which Catalent Processes Product and (b) with respect to the Processing of Product only under this Agreement (e.g. not with respect to employment or other general business matters), in the Territory, in each case including cGMP.

1.6 "**Batch**" means a defined quantity of Product that has been or is being Processed in accordance with the Specifications.

1.7 "**Catalent**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.8 "[…***…**]**" has the meaning set forth in […***…].

1.9 "**Catalent Indemnitees**" has the meaning set forth in Section 13.2.

1.10 "**Catalent IP**" has the meaning set forth in Article 11.

1.11 "**Catalent Inventions**" has the meaning set forth in Article 11.

1.12 "**cGMP**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to Client and Catalent respectively). In the United States, this includes 21 C.F.R. Parts 210 and 211, as amended; and in the European Union, this includes 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented in the relevant constituent country.

1.13 "**Client**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.14 "**Client Indemnitees**" has the meaning set forth in Section 13.1.

1.15 "**Client Inventions**" has the meaning set forth in Article 11.

1.16 "**Client IP**" has the meaning set forth in Article 11.

1.17 "**Client-supplied Materials**" means any materials to be supplied by or on behalf of Client to Catalent for Processing, as described in Attachment B, which is limited to API and reference standards unless agreed in writing by the parties.

1.18 "**Commencement Date**" means the first date upon which a Regulatory Authority in the Territory approves Catalent as a manufacturer of Product.

1.19 "**Confidential Information**" has the meaning set forth in Section 10.1.

1.20 "**Contract Year**" means the consecutive twelve (12)-month period beginning on the Commencement Date or any anniversary of the Commencement Date during the Term, as applicable.

1.21 "**Defective Product**" has the meaning set forth in Section 5.2.

1.22 "**Discloser**" has the meaning set forth in Section 10.1.

1.23 "**Effective Date**" has the meaning set forth in the introductory paragraph.

1.24 "**EMA**" means the European Medicines Agency, and any successor agency in the European Union.

1.25 "**European Union**" means the European Union and its member states as of the Effective Date, which are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, and each of their constituent parts, territories and possessions and their successors to the extent such successors occupy the same territory, regardless of whether any of such countries ceases to be a member state after the Effective Date.

1.26 "**Exception Notice**" has the meaning set forth in Section 5.2.

1.27 "**Facility**" means Catalent's facility located in Somerset, New Jersey or such other facility as agreed by the parties in writing.

1.28 "**FDA**" means the United States Food and Drug Administration, and any successor agency in the United States.

1.29 "**Firm Commitment**" has the meaning set forth in Section 4.2.

1.30 "**Intellectual Property**" means all patents, patent applications, know-how, trade secrets, copyrights, trademarks, designs, concepts, technical information, manuals, standard operating procedures, instructions, specifications, processes, data, inventions and other forms of intellectual property (whether or not patented or patentable).

1.31 "**Invention**" has the meaning set forth in Article 11.

1.32 "**Latent Defect**" means a defect in a Product that (a) was not discoverable upon reasonable inspection during the Review Period, and (b) Client provides Catalent written notice of within no more than […***…] after delivery of such Product.

1.33 "**Losses**" has the meaning set forth in Section 13.1.

1.34 "**Minimum Commitment**" has the meaning set forth in Section 4.1.

1.35 "**PPI**" has the meaning set forth in Section 7.2.

1.36 "**Process**" or "**Processing**" means the compounding, filling, encapsulating, producing and bulk packaging (but not secondary packaging) of Client-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement.

1.37 "**Processing Date**" means the day on which the first step of physical Processing is scheduled to occur, as identified in an Acknowledgement.

1.38 "**Product**" means the bulk pharmaceutical product comprising the 34 mg capsule containing the API, as more specifically described in the Specifications.

1.39 "**Product Maintenance Services**" has the meaning set forth in Section 2.3.

1.40 "**Purchase Order**" has the meaning set forth in Section 4.3(A).

1.41 "**Quality Agreement**" has the meaning set forth in Section 9.6.

1.42 "**Raw Materials**" means all raw materials, supplies, components and packaging necessary to Process and ship Product in accordance with the Specifications, but excluding Client-supplied Materials.

1.43 "**Recall**" has the meaning set forth in Section 9.5.

1.44 "**Recipient**" has the meaning set forth in Section 10.1.

1.45 "**Regulatory Approval**" means each approval, permit, product and/or establishment license, registration or authorization, including each approval pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of a Regulatory Authority that is necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product in the Territory.

1.46 "**Regulatory Authority**" means an international, federal, state or local governmental or regulatory body, agency, department, bureau, court or other entity in the Territory that is responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally. In the United States, this includes the FDA; and in the European Union, this includes the EMA.

1.47 "**Representatives**" of an entity means such entity's duly authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.48 "**Retained Liability**" has the meaning set forth in Section 14.1(A).

1.49 "**Review Period**" has the meaning set forth in Section 5.2.

1.50 "**Rolling Forecast**" has the meaning set forth in Section 4.2.

1.51 "**Safety Stock**" has the meaning set forth in Section 3.2(A).

1.52 "**Specifications**" means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment B, as modified from time to time in accordance with Article 8.

1.53 "**Term**" has the meaning set forth in Section 16.1.

1.54"**Territory**" means the United States, Canada, the European Union and any other country that the parties agree in writing to add to this definition of Territory in an amendment to this Agreement, but excluding any countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States. Catalent shall not be obliged to Process the Product for sale in any of such countries if it is prevented from doing so, or would be required to obtain or apply for special permission to do so, due to any restriction (such as an embargo) imposed on it by any governmental authority, including those imposed by the U.S. Department of the Treasury's Office of Foreign Assets Control.

1.55 "**Unit**" means one capsule of Product.

1.56 "**United States**" means the United States of America and its territories and possessions.

1.57 "**Unit Pricing**" has the meaning set forth in Section 7.1(B).

1.58 "**Validation Services**" has the meaning set forth in Section 2.1.

1.59 "**Vendor**" has the meaning set forth in Section 3.2(B).

ARTICLE 2
VALIDATION, PROCESSING & RELATED SERVICES

2.1 Validation Services. Catalent shall perform the Product qualification, validation and stability services described in Attachment A (the "**Validation Services**") in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.2 Supply and Purchase of Product. Catalent shall Process Product in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.3 Product Maintenance Services. Catalent shall provide and Client will receive those product maintenance services specified in Attachment D (the "**Product Maintenance Services**") in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.4 Other Related Services. Catalent shall provide Product-related services, other than Validation Services, Processing or Product Maintenance Services, as agreed in writing by the parties from time to time. Such writing shall include the scope and fees for any such service and be appended to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services unless otherwise agreed in writing by the parties.

2.5 Affiliates. Catalent shall have the right to cause any of its Affiliates to perform any of its obligations hereunder, and Client shall accept such performance as if it were performance by

Catalent; provided that Catalent shall notify Client in advance of performance of Catalent's obligations by any of its Affiliates and shall remain directly responsible to Client for the performance of such obligations to the same extent it would if it had performed such obligations itself, and in no event shall such performance occur at a facility other than the Facility unless agreed in advance in writing by Client.

ARTICLE 3
MATERIALS

3.1 Client-supplied Materials.

A. Client shall supply to Catalent for Processing, at Client's cost, Client-supplied Materials in quantities sufficient to meet Client's requirements for Product. Client shall deliver such items and associated certificates of analysis to the Facility no later than […***…] days (but not earlier than […***…] days) before the scheduled delivery date. Client shall be responsible at its expense for securing any necessary DEA, export, import or other governmental clearance, permit or certification required in respect of such supply of Client-supplied Materials. Catalent shall use Client-supplied Materials solely for Processing. Prior to delivery of any Client-supplied Materials, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any governmental certification or authorization that may be required under Applicable Laws relating to the API and Product, and thereafter shall provide promptly any update thereto.

B. Catalent shall inspect all Client-supplied Materials received to verify their identity. Unless otherwise expressly required by the Specifications, Catalent shall have no obligation to test Client-supplied Materials it receives to confirm that they meet the associated specifications, certificate of analysis or otherwise; but in the event that Catalent detects a nonconformity with the Specifications, Catalent shall give Client prompt notice of such nonconformity. Catalent shall not be liable for any defect in Client-supplied Materials, or in Product as a result of defective Client-supplied Materials, unless Catalent did not perform the foregoing obligations in accordance with the Specifications. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client's cost.

C. Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss of any such Client-supplied Materials; provided that Catalent shall be responsible for losses resulting from […***…] subject to the limitations on liability for Client-supplied Materials as set forth in Article 14.

3.2 Raw Materials.

A. Catalent shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed by the parties in writing, and, without limiting the foregoing, shall order and hold sufficient capsules and such other Raw Materials as may be agreed by the parties (collectively, the "**Safety Stock**"). Catalent shall not be liable for any delay in delivery of Product if (i) Catalent is unable to obtain, in a timely manner, a particular Raw Material necessary for Processing and (ii) Catalent placed

orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that

any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the parties will negotiate in good faith an appropriate amendment to this Agreement, including Section 4.2. Client shall bear the risk of loss of such Safety Stock in accordance with Section 3.2(C) as long as Catalent has ordered such Safety Stock in accordance with the Rolling Forecast.

B. If Client requires a specific supplier, manufacturer or vendor ("**Vendor**") to be used for Raw Material, then (i) such Vendor will be identified in the Specifications and (ii) the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of the other Sections of this Agreement. If the cost of the Raw Material from any such Vendor is greater than Catalent's costs for the same raw material of equal quality from other vendors, Catalent shall add the difference between Catalent's cost of the Raw Material and the Vendor's cost of the Raw Material to the Unit Pricing, unless Client directly pays the Vendor the cost thereof. Client will be responsible for all costs associated with qualification of any such Vendor that has not been previously qualified by Catalent.

C. In the event of (i) a Specification change for any reason, (ii) obsolescence of any Raw Material or (iii) termination or expiration of this Agreement, Client shall bear the cost of any Raw Materials (including packaging) unusable for Processing or Product and unused by Catalent for another customer, so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations, and at Client's election, Catalent shall promptly ship such unused Raw Materials to Client at Client's cost.

3.3 Artwork and Labeling. Client shall provide or approve, prior to the procurement of applicable Raw Material, all artwork, advertising and labeling information necessary for Processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder without Client's written consent.

3.4API Yield.

A.Catalent will give Client a quarterly inventory report of the API held by Catalent within […***…] business days of the end of the most recent three-month period in a Contract Year which contains the following information for such period: (a) quantity of API conforming to specifications that is received at the Facility ("Quantity Received"), (b) quantity of API dispensed in Processing Product at the Facility calculated by adding the Quantity Received to the inventory of API that complies with the specifications and is held by Catalent at the beginning of the applicable period, less the inventory of API that complies with the specifications and is held by Catalent at the end of the period ("Quantity Dispensed"), and (c) the total amount of API contained in the Product manufactured with the Quantity Dispensed delivered by Catalent and not rejected, recalled or returned […***…] ("Quantity Converted").

B.Within […***…] days after the end of each Contract Year, Catalent will prepare an annual reconciliation of API that sets out the "Actual Annual Yield" or "AAY" for the Product at the Facility during the Contract Year. AAY is the percentage of the Quantity

Dispensed that

was converted to Product and is calculated as follows: […***…]. The parties agree that the target AAY will be determined as follows:

i. Initial Target Yield - will be the […***…] of Product that is Processed for Client and calculated as follows: […***…] (the "Initial Target Yield"). The Initial Target Yield […***…] as defined below.

ii. Adjusted Target Yield - will be the […***…] and calculated as follows: […***…] (the "Adjusted Target Yield").

iii. Without limiting Client's other rights or remedies, […***…] the Initial or Adjusted Target Yield […***…], then within […***…] after the end of the […***…].

C. Catalent's liability for API calculated in accordance with this Section 3.4 will be subject to the limits on Catalent's liability set forth in Section 14.2.

ARTICLE 4
MINIMUM COMMITMENT, PURCHASE ORDERS & FORECASTS

4.1 Minimum Commitment. During each Contract Year, Client shall spend the minimum amount of […***…] U.S. dollars (US$[…***…]) on the purchase of Product pursuant to this Agreement (the "**Minimum Commitment**"). For purposes of the Minimum Commitment, the amount spent in a Contract Year shall be based on the amount owed under Purchase Orders placed for Product with a requested delivery date in the applicable Contract Year, as long as such requested delivery dates are made pursuant to Sections 4.2 and 4.3 below. The cost of the validation Batches and any Batches that are Processed in preparation for Product launch prior to the Commencement Date shall be included for purposes of the Minimum Commitment in the first Contract Year. If Client does not spend at least the Minimum Commitment on the purchase of Product during any Contract Year, then within […***…] days after the end of such Contract Year, Client shall pay Catalent […***…]. In addition, Client agrees that Catalent shall be the supplier in the Territory for no less than […***…] percent ([…***…]%) of Client's total commercial requirements of Product (expressly

excluding any supplies for clinical or other non-commercial purposes) in the Territory for each Contract Year during the Term. Notwithstanding the foregoing, in the event of a Supply Failure as defined below, the Minimum Commitment shall be adjusted pursuant to Section 5.6 below. For clarity and without limiting Client's other rights or remedies, in the event […***…] under this Agreement, and […***…], the Minimum Commitment for such Contract Year shall be […***…], and the […***…].

4.2 Forecast. On or before the first (1st) day of each calendar month, beginning at least […***…] months prior to the anticipated Commencement Date, Client shall furnish to Catalent a written […***…] month rolling forecast of the quantities of Product that Client intends to order from Catalent during such […***…] month period (the "**Rolling Forecast**"). The first […***…] months of each Rolling Forecast shall constitute a binding order for the quantities of Product specified in such Rolling Forecast (the "**Firm Commitment**") and the following […***…] months of the Rolling Forecast shall be non-binding, good-faith estimates. Client shall purchase and Catalent shall supply to Client all quantities of Product set forth in the Firm Commitment in accordance with this Agreement.

4.3 Purchase Orders.

A. From time to time as provided in this Section 4.3(A), Client shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch (each, a "**Purchase Order**"). Concurrently with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the Firm Commitment. Purchase Orders for quantities of Product in excess of the Firm Commitment shall be submitted by Client at least […***…] days in advance of the delivery date requested in the Purchase Order.

B. Promptly (and in any event within […***…] days) following receipt of a Purchase Order, Catalent shall issue a written acknowledgement (each, an "**Acknowledgement**") that it accepts or rejects such Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date, as agreed in advance with Client. Catalent may reject any Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement.

C. Notwithstanding Section 4.3(B), Catalent shall accept Purchase Orders for quantities specified in the Firm Commitment, and shall use commercially reasonable efforts to supply Client with quantities of Product set forth in a Purchase Order which are up to […***…] percent ([…***…]%) (rounded up to the nearest whole Batch) in excess of the quantities specified in the Firm Commitment subject to Catalent's other supply commitments and manufacturing, packaging and equipment capacity.

D. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

4.4 Catalent's Cancellation of Purchase Orders. Notwithstanding anything in Section 4.3 and Section 4.5 to the contrary, Catalent reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Client, and Catalent shall have no further obligation or liability with respect to such Purchase Order to the extent Client refuses or fails to supply conforming Client-supplied Materials in accordance with Section 3.1 that is necessary in order for Catalent to manufacture a complete Batch of Product for such Purchase Order. Any cancellation of Purchase Orders in accordance with this Section 4.4 shall not constitute a breach of this Agreement by Catalent nor shall it absolve Client of its obligation in respect of the Minimum Commitment.

4.5 Client's Modification or Cancellation of Purchase Orders.

A. Client may modify the delivery date or quantity of Product in a Purchase Order only by submitting a written change order to Catalent at least […***…] days in advance of the earliest delivery date (which period shall be reduced to […***…] days for delivery dates/quantities scheduled for delivery in the first […***…] months after the Commencement Date) covered by such change order, or on such other timeline or other quantity as may be mutually agreed by the Parties. Such change order shall be effective and binding against Catalent only upon the written approval of Catalent, and, notwithstanding any such written approval, Client shall remain responsible for the Firm Commitment.

B. Notwithstanding any amount due to Catalent under Section 4.1, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Client shall pay to Catalent in accordance with Article 7 […***….] Any amounts paid by Client pursuant to this Section 4.5(B) shall be counted toward the Minimum Commitment for the applicable Contract Year.

C. Neither changes to nor postponement of any Batch of Product, nor the payment of the fees described in this Section 4.5, will reduce or in any way affect the Minimum Commitment obligations set forth in Section 4.1.

4.6 Unplanned Delay of Processing. Catalent shall provide Client with as much advance notice as practicable prior to the scheduled date of Processing if Catalent determines that any Processing will be delayed for any reason.

4.7 Observation of Processing. In addition to Client's audit right pursuant to Section 9.4, Client may send up to […***…] Representatives to the Facility to observe Processing for a maximum of […***…] days per Contract Year (unless otherwise agreed by Catalent in writing), upon at least […***…] days' prior notice, at reasonable times during regular business hours. Such Representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance. Client shall indemnify and hold harmless Catalent for any action, omission or other activity of its Representatives while on Catalent's premises. Client's Representatives who are not employees of Client shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility.

ARTICLE 5
TESTING; RELEASE

5.1 Batch Records and Data; Release. Unless otherwise agreed to by the parties in writing, after Catalent completes Processing of a Batch, Catalent shall provide Client with copies of Batch records prepared in accordance with the Specifications; *provided*, that if testing reveals an out-of-Specification result, Catalent shall provide such Batch records promptly following resolution of the out-of-Specification result. After Catalent completes Processing of a Batch, Catalent shall also provide Client or its designee with Catalent's certificate of analysis for such Batch. Issuance of a certificate of conformance/analysis by Catalent constitutes release of the Batch by Catalent to Client. Client shall be responsible for final release of Product (including testing, at its cost) to the market.

5.2 Testing; Rejection. No later than […***…] days after Client's or its designee's receipt of the Batch and the certificate of conformance/analysis ("**Review Period**"), Client shall notify Catalent whether the Batch conforms to the Specifications and meets cGMP (for purposes of this Article 5, "conformity/conform(s) to Specifications"). Upon receipt of notice from Client that a Batch conforms to the Specifications, or upon failure of Client to provide any written notice to Catalent by the end of the Review Period subject to Section 5.2, the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch, except in the case of a Latent Defect that causes a Batch to fail to conform to the Specifications. If Client timely notifies Catalent in writing by the end of the Review Period or the later period set forth in the definition of Latent Defect with respect to any Latent Defect (an "**Exception Notice**") that a Batch does not conform to the Specifications ("**Defective Product**"), and provides a sample of the alleged Defective Product, then Catalent shall promptly conduct an appropriate investigation in its discretion to determine whether Catalent agrees with Client that Product is Defective Product and to determine the cause of any nonconformity. Catalent shall provide written notice to Client as promptly as reasonably possible, but in any event within […***…] days after completing its internal investigation, and in any event no later than […***…] days after date of the Exception Notice, whether Catalent agrees that Product is Defective Product. If Catalent agrees that Product is Defective Product and […***…], or if Catalent fails to timely provide written notice to Client that (a) it disagrees with Client's position that Product is Defective Product or (b) it disagrees with Client's position that […***…], then Section 5.4 shall apply. Catalent will work in good faith with Client to identify the cause of nonconformity in the case that Client provides notice of Defective Product after the Review Period (or after the period in the definition of Latent Defect with respect to any Latent Defect).

5.3 Discrepant Results. If the parties disagree as to whether Product is Defective Product and/or whether […***…], and such disagreement is not resolved within […***…] days of the Exception Notice date, the parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. For avoidance of doubt, […***…]. Unless otherwise agreed by the parties in writing, the costs associated with such

testing and review shall be borne by Catalent, except that […***…] then Client shall bear the costs associated with such testing and review.

5.4 Remedy for Defective Product. Catalent shall, at the option of Client, either (A) […***…], or (B) if […***…] within […***…] days from the later of (i) the date of Client's request or (ii) the date that Client-supplied Materials are made available to Process such replacement Product (if there are not sufficient amounts already available to Catalent), […***…]. For the avoidance of doubt, […***…]. THE OBLIGATION OF CATALENT TO REPLACE DEFECTIVE PRODUCT IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT PAYMENTS MADE BY CLIENT FOR DEFECTIVE PRODUCT AND COSTS OF CLIENT-SUPPLIED MATERIALS AS PROVIDED IN THIS SECTION 5.4, SHALL BE CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR CATALENT CAUSED DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

5.5 Supply of Material for Defective Product. In the event Catalent replaces Defective Product pursuant to Section 5.4, Client shall supply, at Client's cost […***…], Catalent with sufficient quantities of Client-supplied Materials in order for Catalent to complete such replacement.

5.6Repeated Supply Failures. Without limiting Client's other rights or remedies in this Agreement, if Catalent is unable to deliver the quantities of Product ordered in a Purchase Order within […***…] days of the scheduled delivery date, and/or delivers Product that does not conform to the Specifications […***…] (each a "**Supply Failure**"), on […***…] or more separate occasions within a […***…]-month period, the percentage of Client's commercial requirements that it is obligated to purchase from Catalent for the Territory pursuant to Section 4.1 above shall be reduced from […***…] percent ([…***…]%) to […***…] percent ([…***…]%) and the Minimum Commitment shall be reduced from $[…***…] to $[…***…] (pro-rated for any partial Contract Year). In such case, such reduced percentage and Minimum Commitment shall apply until Catalent has no Supply Failures for a […***…]-month period in which case the percentage and Minimum Commitment, respectively, shall revert to the amounts set forth in Section 4.1. Notwithstanding the foregoing, if Catalent has […***…] or more Supply Failures within a […***…]-month period, the parties will meet and agree on and implement a delivery improvement action plan within […***…] business days. If, after the delivery improvement plan is in place, […***…] additional Supply Failures occur within a […***…]-month period, these Supply Failures may be considered a material breach of this Agreement by Client under Section 16.2(B) and Catalent will not be allowed any further opportunity to remedy the material breach. Notwithstanding the foregoing, a Supply Failure for purposes of this Section 5.6 will not include any delay in shipment of Product caused by events outside of Catalent's reasonable control, such as a force majeure event,

a delay in delivery of API or other Client-supplied Materials, or receipt of non-conforming API or Client-supplied Materials.

ARTICLE 6
DELIVERY

6.1 Delivery. Catalent shall deliver Product ExWorks (Incoterms 2010) the Facility promptly following Catalent's release of Product and in accordance with Acknowledgments made in accordance with Section 4.3. Catalent shall segregate and store all Product until tender of delivery. To the extent not already held by Client, title to Product shall transfer to Client upon Catalent's tender of delivery. If Catalent provides storage services, title to such items shall pass to Client upon transfer to storage. Client shall be responsible for coordinating the use of a qualified carrier to ship Product. In the event Catalent arranges shipping or performs similar loading and/or logistics services for Client at Client's request, such services are performed by Catalent as a convenience to Client only and do not alter the terms and limitations set forth in this Section 6.1. Catalent shall not be responsible for Product in transit, including any cost of insurance or transport fee for Product, or any risk associated with transit or customs delays, storage and handling.

6.2 Storage Fees. If Client fails to take delivery of any Product on any scheduled delivery date, Catalent shall store such Product and have the right to invoice Client monthly following such scheduled delivery for reasonable administration and storage fees.

ARTICLE 7
PAYMENTS

7.1 Fees. In consideration for Catalent performing services hereunder:

A. Client shall pay to Catalent the fees for Validation Services (including cost of validation Batches) set forth on Attachment A. Catalent shall submit an invoice to Client for such fees upon the completion of the relevant phase of the Validation Services.

B. Client shall pay Catalent the unit pricing for Product set forth on Attachment C (the "**Unit Pricing**"). Client shall pay the Unit Pricing that is in effect on the date of delivery pursuant to Section 6.1. Catalent shall submit an invoice to Client for such fees upon tender of delivery of Product as provided in Section 6.1.

C. Client shall pay Catalent the annual fees for Product Maintenance Services set forth on Attachment C. Catalent shall submit an invoice to Client for such fees upon the Commencement Date and thereafter, upon the first day of each Contract Year.

D. Other Fees. Client shall pay Catalent for all other fees and expenses of Catalent owing in accordance with the terms of this Agreement, including pursuant to Sections 2.4, 4.1, 6.2 and 16.3, as applicable. Catalent shall submit an invoice to Client for such fees as and when appropriate.

7.2 Unit Pricing Increase. The Unit Pricing shall be adjusted on an annual basis, effective on 1st of each calendar year after the Effective Date beginning on January 1, 2019 for Product in Purchase Orders placed on or after January 1st, upon one hundred and twenty (120) days prior written notice from Catalent to Client, […***…],

not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Labor Statistics, over the most recent twelve (12) month period preceding such adjustment date for which the PPI is available. In addition, price increases for […***…] shall be […***…].

7.3 Intentionally Omitted.

7.4 Payment Terms. Payment of all undisputed portions of Catalent invoices shall be due […***…] days after the date of receipt of invoice. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. If any undisputed payment is not received by Catalent by its due date, then Catalent may, in addition to other remedies available at equity or in law, charge interest on the outstanding sum from the due date (both before and after any judgment) at […***…] percent ([…***…]%) per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws).

7.5 Taxes. All taxes, duties and other amounts (excluding taxes based on net income and franchise taxes) assessed in respect of Client-supplied Materials, services or Product prior to or upon provision or sale pursuant to this Agreement, as the case may be, whether assessed on Catalent or Client, are the responsibility of Client, and either Client shall reimburse Catalent for all such taxes, duties or other amounts paid by Catalent or such sums will be added to invoices directed at Client. If any deduction or withholding in respect of tax or otherwise is required by law to be made from any of the sums payable hereunder, Client shall be obliged to pay to Catalent such greater sum as will leave Catalent, after deduction or withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

7.6 Client and Third-Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, Client shall be responsible for one hundred percent (100%) of its own and all third-party expenses associated with development, Regulatory Approval and commercialization of Product, including regulatory filings and post-approval marketing studies.

7.7 Development Batches. Each Batch produced under this Agreement, including those necessary to support the validation portion of Client's submissions for Regulatory Approvals, will be considered to be a "development batch" unless and until Processing has been validated. Client shall […***…]. Catalent and Client shall cooperate in good faith to resolve any problem causing the out-of-Specification Batch. For clarity, when a validation Batch is ultimately used for commercial purposes, such Batch shall no longer be considered a development batch.

ARTICLE 8
CHANGES TO SPECIFICATIONS

All Specifications, and any change to the Specifications agreed by the parties from time to time, shall be in writing, dated and signed by the parties. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing) and any Regulatory Approvals required by Applicable Laws have been obtained. Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use commercially reasonable, good-faith efforts to agree to the terms of such change in a timely manner. As soon as practicable after a request is made for any change in Specifications, Catalent shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with agreed changes to the Specifications. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. Catalent reserves the right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the required written amendment.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. Catalent shall maintain materially complete and accurate Batch, laboratory data and other technical records relating to Processing in accordance with Catalent standard operating procedures. Such information shall be maintained for a period of at least […***…] years from the relevant finished Product expiration date or longer if required under Applicable Laws or the Quality Agreement.

9.2 Regulatory Compliance. Catalent shall obtain and maintain all permits and licenses with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Catalent Processes Product. Client shall obtain and maintain all other Regulatory Approvals required of Client by Applicable Law with respect to Product or the services provided pursuant to this Agreement, including those necessary for Catalent to commence Processing. Client shall not identify Catalent in any ANDA/NDA application or other such initial regulatory filing or submission without Catalent's prior written consent. Such consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized Representatives of both parties. Upon written request, Client shall provide Catalent with a copy of each Regulatory Approval required to distribute, market or sell Product in the Territory. If Client is unable to provide such information, other than for Product ordered prior to Regulatory Approval in anticipation of launch, Catalent shall have no obligation to deliver Product to Client, notwithstanding anything to the contrary in this Agreement. During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client's request and expense. The parties shall cooperate to allow each party to satisfy their respective obligations under Applicable Laws relating to Processing under this Agreement.

9.3 Government/Regulatory Inspections and Requests. Catalent shall promptly advise Client if any Regulatory Authority (or agent acting on its behalf) notifies Catalent that the Regulatory

Authority intends to or does visit the Facility where at least one purpose relates to Processing.

Upon request, Catalent shall provide Client with a copy of any report provided to Catalent by such Regulatory Authority following such visit, which report may be redacted as appropriate to protect any confidential information of Catalent that is unrelated to Processing or any confidential information of Catalent's other customers; and Client shall provide Catalent with any material correspondence with such Regulatory Authority, including FDA refusal to file, rejection or warning letters. Client acknowledges that it may not direct the manner in which Catalent fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities. Client shall reimburse Catalent for all reasonable and documented costs incurred by Catalent associated with inspections by Regulatory Authorities in connection with Product to the extent such inspection does not directly relate to the gross negligence of Catalent, and pay the applicable fees specified in Attachment D. In connection with such inspection, Catalent shall respond promptly to the inspectors and shall use reasonable efforts to notify Client of such inspection and disclose Confidential Information of Client only to the extent necessary.

9.4 Client Facility Audits. During the Term, Client's Representatives shall be granted access upon at least […***…] days' prior notice, at reasonable times during regular business hours, to (A) the portion of the Facility where Catalent performs Processing, (B) relevant personnel involved in Processing and (C) Processing records described in Section 9.1, in each case solely for the purpose of verifying that Catalent is Processing in accordance with cGMPs, the Specifications and the Product master Batch records. Client may not conduct an audit under this Section 9.4 more than […***…] during any twelve (12) month period; *except* that additional inspections may be conducted in the event there is a material quality or compliance issue concerning Product or Processing. Audits and inspections shall be designed to minimize disruption of operations at the Facility. The obligations of Client and its Representatives in Section 4.7 shall apply to all audits undertaken by Client and its Representatives pursuant to this Section 9.4.

9.5 Recall. If a Regulatory Authority orders or requires the recall of Product supplied pursuant to this Agreement or if either Catalent or Client believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly (within one business days) notify the other party in writing. Catalent shall not initiate a Recall without the express prior written approval of Client, unless required by Applicable Laws. With respect to any Recall, Catalent shall provide all necessary cooperation and assistance to Client. Client shall provide Catalent with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, such copy being provided no less than one (1) business day prior to submission to a Regulatory Authority. Client shall consider in good faith any comments from Catalent relating to such submission. The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for expenses incurred in connection with any Recall, in each case unless such Recall is caused solely by Catalent's breach of its manufacturing obligations under this Agreement or Catalent's violation of Applicable Laws or its negligence or willful misconduct, in which case Catalent shall bear the reasonable, actual and documented administrative costs (*e.g.*, printed materials, postage, cost of shipment of return product) incurred by Client for such Recall and, if applicable, the cost of replacing Product returned to Catalent pursuant to such Recall, both to the extent and as provided in Article 5.

9.6 Quality Agreement. Within one (1) month after the Effective Date, and in any event prior to the first Processing of Product under this Agreement, the parties shall negotiate in good

faith and enter into a quality agreement (the "**Quality Agreement**"). The Quality Agreement shall in

no way determine liability or financial responsibility of the parties for the responsibilities set forth in that agreement. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to any commercial matter, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

9.7 Adverse Events. Catalent shall promptly report to Client all adverse drug events and customer complaints with regard to Product of which Catalent or its Affiliates or its or their employees becomes aware within […***…] of becoming aware of such events or complaints.

9.8 Regulatory Authority Fees. Catalent reserves the right to assess Client for any Regulatory Authority fees that may be established by any Regulatory Authority, which fees result directly from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of Product or Client-supplied Materials.

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term "**Confidential Information**" means all confidential information of the disclosing person of whatever type, including all information furnished by or on behalf of Catalent or Client (as the case may be, "**Discloser**"), its Affiliates or any of its or their respective Representatives, to the other party (as the case may be, "**Recipient**"), its Affiliates or any of its or their respective Representatives, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other Intellectual Property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any Confidential Information furnished by Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence and terms of this Agreement, and each party shall be considered the Discloser and the Recipient with respect thereto.

10.2 Exclusions. Notwithstanding anything in Section 10.1 to the contrary, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by Recipient or its Affiliate at the time of disclosure as evidenced by Recipient's written records, (C) becomes available to Recipient or its Affiliate on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for Recipient or its Affiliate without reference to Discloser's Confidential Information as evidenced by Recipient's written records.

10.3 Mutual Obligation. Recipient (A) will keep confidential all Confidential Information, employing such protections as it would use for its own Confidential Information of a similar type but in no case less than reasonable protections under the circumstances, (B) will not use Discloser's Confidential Information except in connection with the performance of its obligations under this Agreement and (C) will not disclose to any third party, without Discloser's prior written consent, Discloser's Confidential Information, except that Recipient may disclose Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives that (A) need to know such Confidential Information for the purpose of performing obligations or exercising rights under this Agreement, (B) are advised of the contents of this Article and (C) are bound to Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives.

10.4 Permitted Disclosure. Recipient may disclose Discloser's Confidential Information to the extent required by Applicable Laws or pursuant to a valid order of a court or other governmental authority; *provided*, that prior to making any such legally required disclosure, Recipient shall give Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances and shall provide reasonable assistance, at Discloser's request and cost, in obtaining a protective order or confidential treatment preventing or limiting the disclosure or requiring that Confidential Information so disclosed be used only for the purposes required by Applicable Laws or the applicable order. Any such disclosure, however, shall not relieve Recipient of its obligations under this Agreement. The parties will consult with each other on the provisions of this Agreement to be redacted in any public filings made by a party as required by Applicable Laws; provided that each party shall have the right, after good faith review and discussion of the other Party's recommendations regarding such redactions, to make any such filing as it reasonably determines necessary under Applicable Laws. In addition, following such disclosure, either party shall be free to disclose, without the other party's prior written consent, the existence of this Agreement, the identity of the other party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

10.5 No Implied License. Recipient will obtain no right of any kind or license under any of Discloser's Confidential Information, including any patent application or patent, by reason of this Agreement. Discloser's Confidential Information will remain Discloser's sole property, subject to Article 11.

10.6 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information, the parties agree that monetary damages would not be a sufficient remedy for any breach of this Article 10. In addition to all other remedies, a party shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 10.

10.7 Return of Confidential Information. Upon expiration or termination of this Agreement, Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within thirty (30) days either return or destroy (and certify as to such destruction) all of Discloser's Confidential Information, including any copy of such information, except for a single copy, which may be retained under a continuing obligation of

confidentiality for the sole purpose of ensuring compliance with its obligations under this Agreement.

10.8 Survival. The obligations of this Article will terminate five (5) years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under law.

ARTICLE 11
INTELLECTUAL PROPERTY

As used in this Agreement, "**Client IP**" means all Intellectual Property and related embodiments owned by or licensed to Client as of the Effective Date or developed by Client other than in connection with this Agreement; "**Catalent IP**" means all Intellectual Property and related embodiments owned by or licensed to Catalent as of the Effective Date or developed by Catalent other than in connection with this Agreement; "**Invention**" means any Intellectual Property developed by either party or jointly by the parties in connection with this Agreement; "**Client Inventions**" means […***…]; and "**Catalent Inventions**" means […***…]. All Client IP and Client Inventions shall be owned solely by Client and no right therein is granted to Catalent under this Agreement, except that Catalent shall have a non-exclusive, royalty-free license to Client IP and Client Inventions that is necessary for use in Processing Product solely to the extent necessary for Catalent to perform its obligations under this Agreement. […***…]. All Catalent IP and Catalent Inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement. […***…]. The parties shall cooperate to achieve the allocation of rights to Inventions set forth in this Article 11, and each party shall be solely responsible for costs associated with the protection of its Intellectual Property. Each party will cause its employees or contractors who perform activities pursuant to this Agreement to enter into agreements that protect Confidential Information and enable compliance with the foregoing provisions regarding ownership of Inventions.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 Catalent. Catalent represents, warrants and undertakes to Client that:

A. At the time of delivery by Catalent as provided in Section 6.1, Product shall have been Processed in accordance with Applicable Laws and Product shall conform with the Specifications and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided*, that Catalent shall not be liable for defects attributable to Client-supplied Materials (including artwork, advertising and labeling).

B. Neither Catalent nor its Affiliates will in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or

(b)., excluded from a federal healthcare program, debarred from federal contracting or convicted or plead nolo contendere to any felony or to any violation of laws relating to fraud, and Catalent will comply in all material respects with Applicable Laws relating to Catalent's performance under this Agreement. In the event that during the Term Catalent becomes aware of any non-compliance with this Section 12.1(B), Catalent shall notify Client immediately. In either such event, Client will have the right to terminate this Agreement upon written notice to Catalent if such non-compliance is not cured within sixty (60) days.

C. Catalent has all necessary authority to use the Catalent IP as contemplated by this Agreement.

D. To its knowledge, there is (i) no patent owned by a third party related to the Catalent IP used to Process Product that would be infringed or misused by performance under this Agreement, and (ii) no trade secret or other proprietary right of a third party related to the Catalent IP used to Process Product that would be infringed or misused by performance under this Agreement.

E. No transaction or dealing under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom, or United States.

F. Catalent has full power and authority to enter into this Agreement, and this Agreement has been duly authorized by it and this Agreement is binding upon it.

12.2 Client. Client represents, warrants and undertakes to Catalent that:

A. All Client-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement.

B. The content of all artwork provided by or on behalf of Client to Catalent shall comply with all Applicable Laws.

C. All Product delivered to Client by Catalent shall be held, used and disposed of by or on behalf of Client in accordance with Applicable Laws, and Client will otherwise comply with Applicable Laws relating to Client's performance under this Agreement.

D. Client will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Client does not hold all necessary Regulatory Approvals to market and sell the Product.

E. Client has all necessary authority to use and to permit Catalent to use pursuant to and in accordance with this Agreement all Client IP related to Product or Client-supplied Materials (including artwork) or the Processing of either of them, including all applicable copyrights, trademarks, trade secrets, patents, inventions and developments.

F. To its knowledge, there is (i) no patent owned by a third party related to the Client IP used to Process Product that would be infringed or misused by performance under and in

accordance with this Agreement and (ii) no trade secret or other proprietary right of a third party related to the Client IP used to Process Product that would be infringed or misused by performance under and in accordance with this Agreement.

G. To its knowledge, the services to be performed by Catalent under this Agreement if performed in strict accordance with the Specifications will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other Intellectual Property or other right held by any person or entity. Client has all authorizations and permits required to deliver (or have delivered) API to the Facility.

H. No transaction or dealing under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom, or United States.

I. Client has full power and authority to enter into this Agreement, and this Agreement has been duly authorized by it and this Agreement is binding upon it.

12.3 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATION, WARRANTY OR GUARANTEE OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by Catalent. Catalent shall indemnify, defend and hold harmless Client, its Affiliates, and their respective directors, officers, employees and agents (collectively, "**Client Indemnitees**"), from and against any and all losses, liabilities, damages, costs and expenses (including reasonable attorneys' fees and expenses and reasonable investigative costs) in connection with any claim, demand, suit, demand or action by any third party ("**Losses**") arising out of, relating to or resulting from (A) any breach of representations, warranties or obligations of Catalent set forth in this Agreement, (B) any actual or alleged infringement or violation of any third party Intellectual Property to the extent resulting exclusively from practice or use of Catalent IP or Catalent Inventions, or (C) any negligence or willful misconduct by Catalent or any of its Affiliates, in each case, except to the extent of any Losses that arise out of, relate to or result from any negligence or willful misconduct by any Client Indemnitee or breach of representations, warranties or obligations of Client set forth in this Agreement.

13.2 Indemnification by Client. Client shall indemnify, defend and hold harmless Catalent, its Affiliates, and their respective directors, officers, employees and agents (collectively, "**Catalent Indemnitees**"), from and against any and all Losses arising out of, relating to or resulting from (A) any breach of representations, warranties or obligations of Client set forth in this Agreement, (B) any manufacture (other than by Catalent), packaging, sale, promotion, distribution or use of or exposure to Product or Client-supplied Materials, including product liability or strict liability, (C) Client's exercise of control over the Processing, to the extent that Client's instructions or directions violate Applicable Laws, (D) the conduct of any clinical trial utilizing Product or API, (E) any

actual or alleged infringement or violation of any third party Intellectual Property to the extent resulting exclusively from the practice or use of Client IP, Client Inventions or Client-supplied Materials, or (F) any negligence or willful misconduct by Client or any of its Affiliates, in each case, except to the extent of any Losses that arise out of, relate to or result from any negligence or willful misconduct by any Catalent Indemnitee or breach of representations, warranties or obligations of Catalent set forth in this Agreement.

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified party (A) promptly notifying the indemnifying party of any claim or liability of which the indemnified party becomes aware (including a copy of any related complaint, summons, notice or other instrument); *provided*, *however*, that failure to provide such notice within a reasonable period shall not relieve the indemnifying party of its obligations under this Article 13 except to the extent, if any, the indemnifying party is prejudiced by such failure, (B) allowing the indemnifying party to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense), *provided*, that the indemnifying party shall promptly provide and continuously maintain such defense, (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 EXCEPT FOR CATALENT'S FRAUD, WILLFUL MISCONDUCT, GROSS NEGLIGENCE AND ANY LIABILITY THAT BY APPLICABLE LAW CANNOT BE EXCLUDED OR LIMITED ("**RETAINED LIABILITY**"), CATALENT'S TOTAL LIABILITY PER CLAIM UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED THE GREATER OF (A) […***…] DOLLARS ($[…***…]) OR (B) […***…] DOLLARS ($[…***…]) OVER THE TERM OF THIS AGREEMENT.

14.2 EXCEPT IN THE CASE OF RETAINED LIABILITY, CATALENT'S LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT SUCH CLIENT-SUPPLIED MATERIALS ARE INCORPORATED INTO PRODUCT, SHALL NOT EXCEED THE LESSER OF […***…] PERCENT ([…***…]) […***…] OR […***…] U.S. DOLLARS (US$[…***…]) PER BATCH.

14.3 EXCEPT IN THE CASE OF DAMAGES FOR BREACH OF ARTICLE 10 (SUBJECT TO THE LIABILITY CAP DESCRIBED IN SECTION 14.1), NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 15
INSURANCE

Each party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability and/or Foreign Liability Insurance with a per occurrence limit of $[…***…] or equivalent and an annual aggregate limit of $[…***…] or equivalent; (B) Products and Completed Operations Liability Insurance with a per occurrence limit of not less than $[…***…] or equivalent covering each party's own operations arising out of or in connection with this Agreement, providing coverage for bodily injury and property damage claims; (C) Workers' Compensation as required by any Applicable Law ; and (D) Auto Liability insurance in a minimum amount of $[…***…] or equivalent combined single limit for all vehicles used in connection with the performance of this Agreement. Customer shall, at its own cost and expense, obtain and maintain in full force and effect during the Term, All Risk Property Insurance, including transit coverage, an amount equal to the full replacement value of its property while in, or in transit to, or from, a Catalent facility. Customer shall obtain a waiver of subrogation clause from its property insurance carrier in favor of Catalent. Customer shall not seek reimbursement from Catalent corporate affiliates, and their respective officers, directors, employees, agents, successors and assigns for any property claim or portion thereof that is not fully recovered from Customer's Property Insurance policy. Each party shall be named as an additional insured within the other party's General Liability and / or Foreign Liability insurance and Products Completed Operations Liability policies; provided, that such additional insured status will apply solely to the extent of the insured party's indemnity obligations under this agreement. The policy(ies) under this Agreement will provide, by endorsement or otherwise, that Customer's insurance will be primary insurance and that any other insurance maintained by or otherwise afforded to Catalent, its corporate affiliates, and their respective officers, directors, employees, agents, successors, and assigns will be excess only and non-contributing except where prohibited by law. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least three (3) years thereafter. Each insurance policy that is required under this Agreement shall be obtained from an insurance carrier with an A.M. Best or equivalent rating of at least A- VII or an S&P rating of A. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than $[…***…] United States Dollars or equivalent or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than $[…***…] United States Dollars or equivalent. Waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other party's written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance.

Customer certificates of insurance, which will include the Catalent affiliate contracting party of this Agreement as the certificate holder, will be sent to the following contact:

Catalent Pharma Solutions LLC
Attn: Risk Management
14 Schoolhouse Rd
Somerset, NJ 08822

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the fifth (5th) Contract Year, unless earlier terminated in accordance with Section 16.2 (such term, including any extension in accordance with this Section 16.1, the "**Term**"). Unless this Agreement is terminated in accordance with Section 16.2, the Term shall automatically extend for successive two (2)-year periods unless and until one party gives the other party at least eighteen (18) months' prior written notice of its desire to terminate as of the end of the then-current Term.

16.2 Termination. This Agreement may be terminated immediately without further action:

A. by either party if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within thirty (30) days, or takes any equivalent or similar action in consequence of debt in any jurisdiction.

B. by either party if the other party materially breaches this Agreement and such breach is not cured within ninety (90) days after the giving of written notice requiring the breach to be remedied; *provided*, that in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such payment breach is not cured within thirty (30) days of receipt of notice of non-payment from Catalent.

C. by Client (i) upon thirty (30) days' prior written notice to Catalent in the event a Regulatory Authority takes an enforcement or other regulatory action against the Facility which affects Catalent's ability to Process the Product, or (ii) upon thirty (30) days' prior written notice if any Regulatory Authority takes any action or raises any objection that prevents Client from manufacturing, importing, exporting, purchasing or selling Product, or (iii) if Client otherwise does not obtain Regulatory Approval of Product in the United States or (iv) upon sixty (60) days' prior written notice if Client determines not to launch Product or to discontinue commercialization of Product, in the United States due to safety or efficacy reasons.

16.3 Effect of Expiration or Termination. Expiration or termination of this Agreement shall be without prejudice to any right or obligation that accrued to the benefit of either party prior to such expiration or termination. In the event of an expiration or termination of this Agreement:

A. Catalent shall promptly return to Client, at Client's expense and direction, any remaining inventory of Product or Client-supplied Materials; *provided*, that all outstanding invoices have been paid in full;

B. Client shall pay Catalent all invoiced amounts outstanding hereunder unless disputed in good faith, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), all Product being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii)); and

C. in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), Client shall pay Catalent for all costs and expenses incurred, and all noncancellable commitments made, in connection with Catalent's performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations.

16.4 Survival. Expiration or termination of this Agreement shall not relieve the parties of any obligation or right accruing prior to such expiration or termination. The rights and obligations of the parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 7.4 (Payment Terms), 7.6 (Taxes), 7.7 (Client and Third Party Expenses), 9.1 (Recordkeeping), 9.5 (Recall), 12.3 (Limitations), 16.3 (Effect of Termination) and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

ARTICLE 17
NOTICE

All notices and other communications under this Agreement shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by electronic mail (e-mail); (C) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered, if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

To Client:

ACADIA Pharmaceuticals Inc.
3611 Valley Centre Drive, Suite 300
San Diego, CA 92130
Attn: […***…]
E-Mail: […***…]
Facsimile: […***…]

With a copy to:

ACADIA Pharmaceuticals Inc.
3611 Valley Centre Drive, Suite 300
San Diego, CA 92130
Attn: […***…]
E-Mail: […***…]
Facsimile: […***…]

To Catalent

Catalent Pharma Solutions, LLC
14 Schoolhouse Road
Somerset, New Jersey 08873
USA
Attn: […***…]
E-Mail: […***…]
Facsimile: […***…]

With a copy to:

Catalent Pharma Solutions, LLC
14 Schoolhouse Road
Somerset, NJ 08873
USA
Attn: […***…]
E-Mail: […***…]
Facsimile: […***…]

ARTICLE 18
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement, constitutes the entire understanding between the parties, and supersedes any contract, agreement or understanding (oral or written) of the parties, with respect to its subject matter. For the avoidance of doubt, this Agreement does not supersede any existing generally applicable confidentiality agreement between the parties as it relates to periods prior to the Effective Date or to business dealings not covered by this Agreement. No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided in this Agreement or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (E) the word “or” shall be deemed to include the word “and” (*e.g.*, “and/or”), and (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties shall execute, acknowledge and deliver such further instruments and take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and neither party will incur any debt or make any commitment for the other party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint venturers, co-partners, employer/employee or principal and agent. Neither party shall have any responsibility for the hiring, termination or compensation of the other party's employees or contractors or for any employee benefits of any such employee or contractor.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party's consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning party or the assigning party's business unit responsible for performance under this Agreement, and any assignment in violation of this Section 18.7 shall be void *ab initio*.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any right or remedy upon any individual or entity other than the parties and their respective successors and permitted assigns, except that the Client Indemnitees and the Catalent Indemnitees may invoke the benefits of the indemnification provisions of this Agreement.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of New York, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Alternative Dispute Resolution. Any dispute arising between the parties in connection with this Agreement shall first be presented to the respective senior executives of the parties for their consideration and resolution. If such parties' executives cannot resolve such dispute within […***…] days, then such dispute may be submitted by either party to arbitration by the International Institute for Conflict Prevention and Resolution, 30 E. 33rd Street, 6th Floor, New York, NY 10016 ("**CPR**") by one (1) arbitrator selected by the parties. If no agreement on an arbitrator can be reached within […***…] days after the CPR offers names of potential arbitrators, then the CPR will choose one arbitrator having reasonable experience in commercial transactions of the type described in this Agreement. The arbitration shall take place in the English language in New York City, New York, in accordance with the CPR administered

arbitration rules then in effect, and judgment upon any award rendered in such arbitration will be binding and may be

entered in any court having jurisdiction of the matter. The arbitration shall commence within […***…] days of the date on which an arbitrator is selected. The arbitrator's decision shall set forth a reasoned basis for any award of damages or finding of liability. The arbitrator shall not have power to award damages in excess of actual compensatory damages and shall not multiply actual damages or award punitive damages. The arbitrator shall award to the prevailing party, if any, its costs and attorneys' fees and expenses reasonably incurred in connection with the arbitration, in accordance with Section 18.11.

18.11 Prevailing Party. In any dispute resolution proceeding between the parties in connection with this Agreement, the prevailing party will be entitled to recover its reasonable attorney's fees and costs in such proceeding, including any subsequent or related enforcement proceeding, from the other party.

18.12 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall obtain the prior approval of the other party, which shall not be unreasonably withheld or delayed, as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Right to Dispose and Settle. If Catalent requests in writing from Client direction with respect to disposal of any inventories of Product, Client-supplied Materials, equipment, samples or other items belonging to Client and is unable to obtain a response from Client within a reasonable period after making reasonable efforts to do so (provided that Client has not responded to Catalent for at least […***…] months from Catalent's initial request), Catalent shall be entitled in its sole discretion to (A) dispose of all such items and (B) set-off any and all amounts due to Catalent or any of its Affiliates from Client against any credits Client may hold with Catalent or any of its Affiliates.

18.14 Force Majeure. Except as to payments required under this Agreement, neither party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such party's performance hereunder if such default or delay is caused by events beyond such party's reasonable control, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, any act of terrorism, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, vendors, public utilities or common carriers; *provided*, that the party seeking relief under this Section 18.14 shall promptly notify the other party of such cause(s) beyond such party's reasonable control. The party that may invoke this Section 18.14 shall use commercially reasonable efforts to reinstate its ongoing obligations to the other party as soon as practicable. If the cause(s) shall continue unabated for one hundred eighty (180) days, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument.

Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused their respective duly authorized Representatives to execute this Agreement effective as of the Effective Date.

CATALENT PHARMA SOLUTIONS, LLC	**ACADIA PHARMACEUTICALS INC.**
By:/s/ Thomas A. Yezza	By:/s/ Bob Mischler
Name: Thomas A. Yezza	Name: Bob Mischler
Title: Vice President & General Manager	Title: SVP, Strategy & Technical Operations

ATTACHMENT A

VALIDATION SERVICES

As set forth in the Quote agreed by the Parties on September 14, 2017 entitled “Pimavanserin 34 mg IR Capsule Validation Manufacture”

ATTACHMENT B
SPECIFICATIONS

I. Client-Supplied Materials

Pimavanserin Tartrate	[…***…]

II. Product Specifications

Product Code:	[…***…]
Batch Size:	[…***…] capsules

III. Raw Materials

[…***…]	[…***…]
[…***…]	[…***…]

IV. Client-Specific Raw Materials

Capsules	[…***…]

ATTACHMENT C

UNIT PRICING AND FEES

ricing	Pricing shall be as follows: •Qualification and validation services: Separately set forth in the Quote agreed by the Parties on September 14, 2017 entitled "Pimavanserin 34 mg IR Capsule Validation Manufacture" •API release testing: […***…]/batch; […***…]/batch. •Bulk capsules: # of batches per orderUnit Cost*[…***…]$[…***…][…***…]$[…***…][…***…]$[…***…] oBulk capsule pricing assumptions: ▪[…***…]; ▪[…***…]; ▪Pricing includes […***…]. ▪Processing Assumptions: •[…***…] •[…***…] ▪Testing Assumptions: •[…***…] •[…***…] •Scale-up process pricing estimate (Non-binding): o[…***…] ▪$[…***…]/capsule estimate o[…***…] ▪$[…***…]/capsule estimate •Other services: (stability, mock PAI, etc. to the extent not covered by the APMF as described below): pricing to be established when additional services are agreed upon.

* One unit ("**Unit**") is one capsule. Unit Pricing also does not include […***…].

The Minimum Commitment owed by Client to Catalent is as described in Section 4.1.

ADDITIONAL FEES		
Type of Fee	**Amount**	**Payable**
Product Maintenance Services Annual Fee	US$[…***…]	As set forth in Article 7

ATTACHMENT D

PRODUCT MAINTENANCE SERVICES & OTHER RELATED SERVICES

Product Maintenance Services:

Product Maintenance Services cover an array of Product support activities, which are irrespective of manufactured Product volumes and include the following:

1. Regulatory inspection support (i.e., pre- and post-approval inspection(s), if any, by the FDA or other applicable Regulatory Authority. […***…]);
2. Product license or permits from local, state and federal authorities;
3. […***…] (as further described in Section 9.4);
4. regulatory inspections (as further described in Section 9.3) by a Regulatory Authority that is a Major Regulatory Authority (defined below);
5. […***…] Product review (within the meaning of 21 CFR § 211.180);
6. drug master file updates for the Territory, if applicable;
7. access to document library over and above the Quality Agreement, including additional copies of Batch paperwork or other Batch documentation;
8. assistance in preparing Regulatory Approvals;
9. Product document and sample storage relating to cGMP requirements;
10. vendor re-qualification;
11. maintenance and storage of raw material vendor audit reports;
12. maintenance, updates and storage of master batch records and audit reports;
13. tooling and filter bag maintenance, as applicable; and
14. customer support.

The following services and items are *not* included in Product Maintenance Services:

1. […***…];
2. […***…];
3. […***…];
4. […***…];
5. […***…];
6. […***…]; and
7. […***…].

The services and fees for items 2-7 above, if requested by Client, shall be made in accordance with Section 2.4 of the Agreement.

"**Major Regulatory Authority**" means […***…]

Exhibit 21.1

List of Subsidiaries

NAME OF SUBSIDIARY	JURISDICTION OF INCORPORATION
ACADIA Pharmaceuticals A/S	Denmark
ACADIA Pharmaceuticals GmbH	Switzerland
ACADIA Pharma Limited	United Kingdom

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-171722, 333-185639, and 333-210571) of ACADIA Pharmaceuticals Inc.,
(2) Registration Statement (Form S-8 No. 333-115956) pertaining to the 1997 Stock Option Plan, 2004 Equity Incentive Plan, and 2004 Employee Stock Purchase Plan of ACADIA Pharmaceuticals Inc.,
(3) Registration Statements (Form S-8 Nos. 333-128290, 333-137557, 333-146398, 333-153346, and 333-161057) pertaining to the 2004 Equity Incentive Plan and 2004 Employee Stock Purchase Plan of ACADIA Pharmaceuticals Inc.,
(4) Registration Statements (Form S-8 Nos. 333-168667, 333-190400 and 333-213109) pertaining to the 2010 Equity Incentive Plan and the 2004 Employee Stock Purchase Plan of ACADIA Pharmaceuticals Inc.,
(5) Registration Statements (Form S-8 Nos. 333-176212, 333-183151 and 333-197872) pertaining to the 2004 Employee Stock Purchase Plan of ACADIA Pharmaceuticals Inc., and
(6) Registration Statements (Form S-8 Nos. 333-207971 and 333-219785) pertaining to the 2010 Equity Incentive Plan of ACADIA Pharmaceuticals Inc.;

of our reports dated February 27, 2018, with respect to the consolidated financial statements and schedule of ACADIA Pharmaceuticals Inc. and the effectiveness of internal control over financial reporting of ACADIA Pharmaceuticals Inc. included in this Annual Report (Form 10-K) of ACADIA Pharmaceuticals Inc. for the year ended December 31, 2017.

/s/ Ernst & Young LLP

San Diego, California
February 27, 2018

EXHIBIT 31.1

CERTIFICATION
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

I, Stephen Davis, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2017 of ACADIA Pharmaceuticals Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2018

/s/ STEPHEN DAVIS
Stephen Davis
President and Chief Executive Officer
(Registrant's Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION
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

I, Todd Young, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2017 of ACADIA Pharmaceuticals Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2018

/s/ TODD YOUNG

Todd Young
Executive Vice President and Chief Financial Officer
(Registrant's Principal
Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ACADIA Pharmaceuticals Inc. (the "Company") on Form 10-K for the period ended December 31, 2017, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Stephen Davis, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: February 27, 2018

/s/ STEPHEN DAVIS
Stephen Davis
President and Chief Executive Officer
(Registrant's Principal Executive Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ACADIA Pharmaceuticals Inc. (the "Company") on Form 10-K for the period ended December 31, 2017, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Todd Young, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: February 27, 2018

/s/ Todd Young
Todd Young
Executive Vice President and Chief Financial Officer
(Registrant's Principal
Financial and Accounting Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.