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

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**FORM 10-K**

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**(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, 2016**  
**or**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**Commission File Number: 001-36399**

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**ADAMAS PHARMACEUTICALS, INC.**  
**(Exact name of registrant as specified in its charter)**

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)  
**1900 Powell Street, Suite 750**  
**Emeryville, CA 94608**  
**(510) 450-3500**  
(Address, including zip code, and telephone number, including area code, of Principal  
Executive Offices)

**42-1560076**  
(I.R.S. Employer  
Identification Number)

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**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 \$0.001 per share	The NASDAQ Global Market

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. 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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was \$251,571,342 computed by reference to the last sales price of \$15.14 as reported by the NASDAQ Global Market, as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2016. Shares of common stock held by each officer and director, and each entity affiliated with a director, have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of February 23, 2017, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 22,219,774.

**DOCUMENTS INCORPORATED BY REFERENCE**

Part III incorporates information by reference to the definitive proxy statement for the registrant's 2017 Annual Meeting of Stockholders, to be filed within 120 days of the registrant's fiscal year ended December 31, 2016.

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**ADAMAS PHARMACEUTICALS, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2016**  
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“Adamas Pharmaceuticals,” our logo and other trade names, trademarks and service marks of Adamas appearing in this report are the property of Adamas. Other trade names, trademarks and service marks appearing in this report are the property of their respective holders.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the sections titled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases you can identify these statements by forward-looking words, such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “potential,” “seek,” “expect,” “goal” or the negative or plural of these words or similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectation as to the therapeutic profile of our products and product candidates, including the safety and efficacy thereof;
- our expectations as to whether we will be able to obtain and maintain regulatory approval of our product candidates;
- our expectations as to whether we will be able to successfully commercialize any of our products that are approved;
- the rate and degree of market acceptance of our products in the future;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- the anticipated scope, rate of progress and cost of our preclinical studies and clinical trials and other research and development activities;
- the potential cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the anticipated cost and timing of regulatory submissions and approvals;
- our expectation as to the legal proceedings and related stays and terms of settlements;
- our expectations as to the sufficiency of our capital resources to enable us to complete our ongoing clinical studies;
- our expectations as to our ability to obtain and maintain intellectual property protection for our products and product candidates;
- our expectations as to our ability to negotiate manufacturing arrangements and scale up manufacturing of our product candidates to commercial scale;
- the anticipated performance by our collaboration partners over which we do not have control;
- the anticipated receipt and timing of any royalties from our collaborators;
- our expectations as to our ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations;
- the anticipated performance of third parties to conduct our clinical studies;
- the anticipated ability of third-party contract manufacturers to manufacture and supply our product candidates for us;
- our expectations as to our ability to identify, develop, acquire and in-license new products and product candidates;
- our expectations as to our ability to initiate new or continue clinical development programs;
- our expectations as to our ability to initiate sites and enroll patients in our clinical studies at the pace that we project;
- our expectations as to our ability to retain and recruit key personnel;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;
- our anticipated financial performance; and
- our anticipated developments and projections relating to our competitors or our industry.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk factors”. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this report and the documents that we reference in this report and have filed with the Securities and Exchange Commission as exhibits to this report with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a pharmaceutical company that discovers and develops chrono-synchronous therapies to improve the daily lives of people affected by chronic neurologic disorders. Approximately 36 million people in the United States suffer from conditions such as Parkinson's disease, multiple sclerosis, epilepsy, and Alzheimer's disease. Currently available medicines may lead to sub-optimal symptom control in these disorders.

We pioneered a platform to develop medicines for chronic neurologic disorders based upon an understanding of time-dependent biologic processes responsible for disease activity and drug response. We call these medicines chrono-synchronous therapies. These therapies synchronize the temporal pattern of disease activity with the dynamics of drug profiles we invent without disrupting the brain's master clock, e.g. circadian rhythm. We believe the lives of patients with neurologic disorders are improved when these factors operate in unison.

We identify and develop chrono-synchronous therapies for patients by listening to patients, studying the available data/literature, and innovating. To that end, our aim is to enable substantial treatment effects among the existing landscape of medicines. Our portfolio includes:

**ADS-5102:** a chrono-synchronous amantadine therapy with an U.S. Food and Drug Administration ("FDA") accepted New Drug Application ("NDA") for the treatment of levodopa-induced dyskinesia ("LID") in patients with Parkinson's disease. LID is a form of dyskinesia (abnormality or impairment of voluntary movement) associated with levodopa, a drug used to treat Parkinson's disease. Over time, 90% of Parkinson's disease patients on levodopa therapy will develop alternating periods of OFF time (e.g. rigidity) and LID, as their disease progresses. LID is characterized by involuntary movements that are purposeless and unpredictable. The NDA for ADS-5102 in LID has a Prescription Drug User Fee Act ("PDUFA") date, or deadline by which the FDA must review our NDA, of August 24, 2017, and, if approved, we plan to launch ADS-5102 in 2017. If approved, ADS-5102 will be the first and only medicine approved for the treatment of LID, and it will be the only Parkinson's disease medicine demonstrated to reduce both LID and OFF time.

In addition, we believe ADS-5102 has opportunities to provide symptomatic treatment of other hyper- and hypokinetic neurologic disorders, including but not limited to walking impairment in multiple sclerosis patients and other Parkinson's disease indications.

**ADS-4101:** a chrono-synchronous lacosamide therapy in clinical development for the treatment of partial onset seizures in patients with epilepsy. The active ingredient in ADS-4101 is lacosamide, an anti-epileptic previously approved by the FDA, which is currently marketed by UCB as VIMPAT<sup>®</sup> (lacosamide).

**Namenda XR<sup>®</sup>** (memantine hydrochloride) extended-release capsules and **Namzaric<sup>®</sup>** (memantine hydrochloride extended-release and donepezil hydrochloride) capsules: two commercially available drugs currently marketed by Forest Laboratories Holdings Limited ("Forest"), an indirect wholly-owned subsidiary of Allergan plc (collectively, "Allergan"), in the United States for the treatment of moderate to severe Alzheimer's disease. We are eligible to receive royalties on sales of Namenda XR<sup>®</sup> and Namzaric<sup>®</sup> beginning in June of 2018 and May of 2020, respectively.

Our goal is to bring products to market, which are differentiated and distinguished by our platform insights, independently or in collaboration with partners. From prior experience, we appreciate the value that commercial strategic alliances can bring to patients and Adamas stakeholders.

In 2017, we are focused on commercializing ADS-5102 for the treatment of LID in patients with Parkinson's disease. Based on our market research, we expect ADS-5102, if approved, to be well received by physicians, patients, and payers, as there are currently no approved therapeutic treatments for LID, which is an existing Parkinson's disease treatment gap. Our research also indicates that payers recognize the substantial unmet need of patients with LID and the potentially important value proposition of ADS-5102 in LID, as well as its secondary benefit in OFF time, when the symptoms of Parkinson's disease return.

We have developed our current portfolio of chrono-synchronous therapies in a capital efficient manner. As of December 31, 2016, we had raised a total of \$201.3 million from equity financings, including \$61.8 million in net proceeds raised in January 2016 from the sale of 2,875,000 shares of common stock. We also received \$160.0 million in upfront and milestone payments and \$4.1 million in development funding from our partnership with Allergan. At December 31, 2016, we had an accumulated deficit of \$122.2 million and \$135.9 million in cash, cash equivalents, investments and no debt obligations.

**Our strategy**

Our business strategy is to discover, develop, and commercialize clinically differentiated medicines for patients suffering from chronic neurologic disorders independently or in collaboration with partners.

**Chrono-synchronous therapy approach and portfolio**

At Adamas, we recognize that all things in life have a rhythm, including patients, diseases, and medicines. For this reason, we have taken the known concept of chrono-therapy - aligning the timing of drug administration to disease symptoms - a step further. We synchronize three elements - the temporal patterns of disease with the dynamics of the drug profiles we invent without disrupting the brain's master clock. We believe our portfolio of chrono-synchronous therapies demonstrates that patients with neurologic disorders can benefit from this harmony, as it can enable achievement of potentially greater efficacy with manageable tolerability. This can improve the lives of patients in need.

The following table summarizes our portfolio:

Actives / Products and Product Candidates	Target Population	Pre-IND	Phase 1	Phase 2	Phase 3	NDA Rev / Launch	Commercial Rights
<b>Amantadine</b>							
ADS-5102 (Single agent)	Parkinson's - LID						
	MS walking impairment						
	Additional indications						
ADS-8801 (FDC)	Parkinson's disease						
<b>Lacosamide</b>							
ADS-4101 (Single agent)	Epilepsy						
<b>Memantine</b>							
Namenda XR®	Alzheimer's dementia						
Namzaric® (FDC)							

NAMENDA XR® is registered trademark of Merz Pharma GmbH & Co. KGaA; NAMZARIC® is trademark of Merz Pharma GmbH & Co. KGaA.

**ADS-5102 (amantadine)**

ADS-5102 is a chrono-synchronous amantadine therapy with potential applications across a number of chronic neurologic disorders. We are focusing initial development and commercialization (if approved) on the treatment of LID in patients with Parkinson's disease.

We are also investigating ADS-5102 for the treatment of walking impairment in multiple sclerosis patients and are considering developing it for other indications in Parkinson's disease earlier in the Parkinson's disease treatment journey.

**ADS-5102 for levodopa-induced dyskinesia associated with Parkinson's disease**

ADS-5102 is a chrono-synchronous amantadine therapy for the potential treatment of LID in patients with Parkinson's disease. LID is a form of dyskinesia associated with levodopa used to treat Parkinson's disease. Over time, 90% of patients on levodopa therapy will develop LID, which is characterized by involuntary movements that are purposeless and unpredictable. ADS-5102 is dosed once daily at bedtime so that therapeutic levels of amantadine are present during waking hours when LID episodes are most frequent and movement control is needed most. An NDA for ADS-5102 is currently under review by the FDA for the treatment of LID in patients with Parkinson's disease and has a PDUFA date of August 24, 2017. In April 2015, the FDA granted orphan drug status to ADS-5102 for this indication.

Parkinson's disease is a chronic neurodegenerative disorder affecting close to 1 million people in the United States. It is characterized by the progressive loss of dopaminergic neurons, causing lower levels of endogenous dopamine and manifesting as symptoms of bradykinesia (slowness of movement), rigidity, impaired walking, tremor, and postural instability.

As a replacement therapy for the loss of dopaminergic neurons, levodopa is the most effective therapy for Parkinson's disease and is considered the “gold standard”. As the effects of levodopa wear off, the symptoms of Parkinson's disease return. This is known as OFF time. Additionally, as a result of disease progression and chronic levodopa therapy, nearly all Parkinson's disease patients will experience LID depending on their levodopa dose. LID is characterized by involuntary movements that are non-rhythmic, purposeless, and unpredictable. In the U.S. approximately 150,000 to 200,000 Parkinson's patients suffer from LID at any given time, and over time 90% of patients on levodopa therapy will eventually develop it.

The NDA for ADS-5102 is supported by efficacy and safety data compiled from our comprehensive clinical program, which was designed to evaluate ADS-5102 for the treatment of LID in patients with Parkinson's disease. The program included three placebo-controlled trials: a phase 2/3 trial, identified as EASED, and two Phase 3 trials, known as EASE LID and EASE LID 3. The Phase 3 data for ADS-5102 presented in the NDA demonstrate a primary reduction of LID and a secondary reduction in OFF time in Parkinson's disease patients, with a manageable safety and tolerability profile. Specifically, in the Phase 3 trials, ADS-5102 reduced LID by 30% vs placebo and reduced OFF time by 45% vs placebo. Phase 3 trial subjects saw their LID improve by ~ 2 hours & OFF time improve by ~ 1 hour. The NDA is also supported by data from an open-label safety study known as EASE LID 2, which enrolled patients from EASED, EASE LID, and EASE LID 3, as well as LID patients who have undergone deep brain stimulation. The EASE LID 2 trial is ongoing, and patients are being followed for up to two years.

If approved, ADS-5102 will be the first and only medicine approved by the FDA for the treatment of LID in Parkinson's disease patients and the first Parkinson's disease medicine to be proven in controlled studies to reduce both OFF time and LID. At present, physicians manage LID by modifying dopaminergic therapies. Examples include levodopa dose adjustment and dose fractionation and/or the adjunctive use of other branded and generic products including Azilect® (Teva), Requip XL™ (GSK), Mirapex ER™ (Boehringer Ingelheim), Neupro® Patch (UCB), Comtan® (Novartis), Duopa™ (AbbVie), and Rytary® (IMPAX) and in a minority cases of immediate-release amantadine. None of these management strategies are approved for the treatment of LID, and in some cases they may actually increase LID.

#### ***ADS-5102 for other indications in Parkinson's disease earlier in the Parkinson's disease treatment journey***

In our Phase 3 development program, ADS-5102 has demonstrated statistically significant reductions in both LID and OFF time. Both the LID and OFF time responses to ADS-5102 have been shown in our clinical trials to be durable over time. Consequently, ADS-5102 may have the potential for other indications in Parkinson's disease earlier in the Parkinson's disease treatment journey, which our market research shows to be a significant unmet medical need.

#### ***ADS-5102 for multiple sclerosis in patients with walking impairment***

We completed a Phase 2 proof-of-concept study designed to evaluate ADS-5102 in patients with multiple sclerosis who have walking impairment. Trial results showed an approximately 15 percent placebo-adjusted improvement in walking speed that was statistically significant ( $p < 0.05$ ) in the 25-foot walk (“T25FW”) test, which is a well-established outcome measure. Other walking performance measures used in this trial were directionally consistent. Subsequently, we had a positive End-of-Phase 2 Meeting with the FDA and we are evaluating a Phase 3 development pathway.

Multiple sclerosis is a chronic autoimmune-mediated disorder that affects more than 2 million people worldwide and 400,000 people in the United States, where there are approximately 270,000 diagnosed and treated patients. Multiple sclerosis manifests as unpredictable symptoms that can vary in severity and tend to progress over years, in some cases to near total disability. Walking impairment, which affects approximately 80 percent of diagnosed patients, is associated with an increased risk of falls and has a substantial impact on daily activities. Despite therapeutic advances, unmet medical needs remain for multiple sclerosis patients with walking impairment, including the need for a therapeutic agent that delivers an improvement in walking ability during the day.

Currently, the only product approved by the FDA to improve walking in patients with multiple sclerosis is Ampyra® (dalfampridine) (Acorda) Extended Release Tablets.

#### ***Additional indications for ADS-5102***

We have identified additional indications for ADS-5102, including post-stroke walking and complications of anti-psychotic treatment, which include tardive dyskinesia, akathisia, and weight gain. These complications are well suited to chrono-synchronous therapies.

#### ***ADS-8801 fixed-dose combination of amantadine (not disclosed)***

In ADS-8801, we are exploring for approval fixed-dose combinations of ADS-5102 and other single agents to expand the patient treatment reach associated with approved single agent medicines.

### ***ADS-4101 (lacosamide) for the treatment of partial onset seizure in patients with epilepsy***

ADS-4101 is a chrono-synchronous lacosamide therapy in development for partial onset seizures in patients with epilepsy. Lacosamide is a drug ingredient previously approved by the FDA in VIMPAT® (lacosamide) tablets, an anti-epileptic currently marketed by UCB.

We completed the first Phase 1 study of ADS-4101 in healthy volunteers in January 2017. The primary study objectives were to understand the pharmacokinetics and tolerability of a series of chrono-synchronous lacosamide capsule formulations and guide the selection of ADS-4101 formulations for further clinical development. The trial compared the pharmacokinetic profile, safety, and tolerability of single-doses of four oral formulations with VIMPAT® (lacosamide) tablets.

The timing of the ADS-4101 clinical development program and its potential approval is planned to allow us to optimize ADS-4101's intellectual property protections and market opportunity.

Epilepsy is a chronic neurologic disorder characterized by recurrent unprovoked seizures with need for new, clinically differentiated treatment options. Epilepsy affects an estimated 2.2 million Americans. Nearly two-thirds of epilepsy patients suffer from partial onset seizures, which affect one side of the brain. Despite advances, nearly one-third of patients who suffer from epilepsy are unresponsive to therapeutic treatment. ADS-4101 is designed as a once-daily, new high strength lacosamide to provide a clinically meaningful and differentiated treatment option for epilepsy patients.

### ***Namenda XR® and Namzaric® in moderate to severe Alzheimer's disease***

Through a license agreement with Allergan, our portfolio includes two drugs commercially available in the U.S.: Namenda XR® (memantine hydrochloride) extended-release capsules and Namzaric® (memantine hydrochloride extended-release and donepezil hydrochloride) capsules.

The active ingredient in the currently marketed Namenda XR® is memantine hydrochloride. Namenda XR® is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

Namzaric® is a once-daily, fixed-dose combination of memantine hydrochloride, an NMDA receptor antagonist, and donepezil hydrochloride, an acetylcholinesterase inhibitor. Donepezil is the active ingredient in ARICEPT® (donepezil hydrochloride), which is indicated for the treatment of mild to severe dementia of the Alzheimer's type. Namzaric® is indicated for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on 10 mg of donepezil hydrochloride once daily.

Allergan owns the exclusive U.S. commercialization rights to both medicines, while we have the right to develop versions of both medicines in ex-U.S. markets. We are eligible to receive royalties from Allergan for U.S. sales of Namenda XR® and Namzaric® beginning in June 2018 and May 2020, respectively.

Alzheimer's disease dementia is a progressive neurodegenerative condition that affects over five million people in the U.S. There is no known cure for Alzheimer's disease or any of the other conditions that cause dementia. Existing pharmaceutical therapies are approved for the treatment of symptoms of the disease, but have not been shown to alter disease progression. Even if disease modifying therapies are developed and approved, we believe it is likely that there will be a continuing need for symptomatic treatments. In 2014, approximately 2.7 million people in the U.S. were treated for Alzheimer's disease dementia, and U.S. sales of pharmaceutical treatments for Alzheimer's disease were approximately \$2.9 billion. We believe that the number of people treated for Alzheimer's disease will continue to increase as the number of elderly people in the U.S. increases, diagnosis of dementia becomes more common, and health care reform improves access to treatments.

### **License agreement with Allergan**

In November 2012, we granted Allergan an exclusive license, with right to sublicense, certain of our intellectual property rights relating to human therapeutics containing memantine in the United States. In connection with these rights, Allergan markets and sells Namzaric® and Namenda XR® for the treatment of moderate to severe dementia related to Alzheimer's disease. Pursuant to the agreement, Allergan made an upfront payment of \$65.0 million. We earned and received additional cash payments totaling \$95.0 million upon achievement by Allergan of certain development and regulatory milestones. Under the agreement, external costs incurred related to the prosecution and litigation of intellectual property rights are reimbursable.

We are entitled to receive royalties on net sales in the United States by Allergan, its affiliates, or any of its sublicensees of controlled-release versions of memantine products covered by the terms of the license agreement. Beginning in May 2020, we will be entitled to receive royalties in the low to mid-teens from Allergan for sales of Namzaric® in the United States. Beginning in June 2018, we will be entitled to receive royalties in the low to mid-single digits for sales of Namenda XR® in the



United States. Allergan's obligation to pay royalties with respect to fixed-dose memantine-donepezil products, including Namzatic<sup>®</sup>, continues until the later of (i) 15 years after the commercial launch of the first fixed-dose memantine-donepezil product by Allergan in the United States or (ii) the expiration of the Orange Book listed patents for which Allergan obtained rights from us covering such product. Allergan's obligation to pay royalties with respect to Namenda XR<sup>®</sup> continues until the expiration of our Orange Book listed patents covering such products. However, Allergan's obligation to pay royalties for any product covered by the license is eliminated in any quarter where there is significant competition from generics. For further information, see *Litigation* in "Note 8 - Commitments and Contingencies" in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report.

### **Intellectual property**

In developing chrono-synchronous therapies, we search for large treatment effects in the existing landscape of medicines. From that inquiry, we discover temporal patterns of disease activity and drug response, identify and invent new product candidates designed to achieve potentially greater efficacy with manageable safety and tolerability profiles.

Our success does and will significantly depend upon our ability to obtain and maintain patent and other intellectual property and proprietary protection for our product candidates, including usage, pharmacokinetic, composition-of-matter, and formulation patents, as well as patent and other intellectual property and proprietary protection for our novel discoveries and other important technology inventions and know-how. In addition to patents, we rely upon unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position.

We actively protect our proprietary information, in part, by using confidentiality agreements with our commercial partners, collaborators, employees, and consultants and invention assignment agreements with our employees and selected consultants. Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed, or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, please see "Risk factors—Risks related to intellectual property."

As of February 15, 2017, we owned 24 issued U.S. patents, 22 U.S. patent applications and additional patents and patent applications in other jurisdictions. The patent portfolios for Namenda XR<sup>®</sup>, Namzatic<sup>®</sup>, ADS-8704, and ADS-5102 as of February 15, 2017 are summarized below:

#### ***ADS-5102***

ADS-5102 is currently covered by a total of nine issued U.S. patents and 17 additional patent applications containing method and composition claims relating to their pharmacokinetic profile and dosing of amantadine. These patents expire as late as 2030. These patents and patent applications are wholly owned by us and are not subject to any license agreements. We also own additional foreign patent applications covering ADS-5102.

#### ***ADS-4101***

ADS-4101 is currently covered by U.S. and PCT patent applications containing method and composition claims relating to their pharmacokinetic profile and dosing of antiepileptic agents. Patents issuing from these applications, if issued, will expire in 2036. These patent applications are wholly owned by us and are not subject to any license agreements.

#### ***Namenda XR<sup>®</sup>, Namzatic<sup>®</sup>***

Namenda XR<sup>®</sup> and Namzatic<sup>®</sup> are covered by a total of 13 of our issued U.S. patents containing method and compositions claims relating to their pharmacokinetic profile and method claims relating to dosing of memantine. These patents expire as late as 2029 and are exclusively licensed to Allergan. We also own additional foreign patents and patent applications covering Namenda XR<sup>®</sup> and Namzatic<sup>®</sup>.

#### ***ADS-8704 (memantine HCl/donepezil HCl, outside of the United States only)***

We have retained the rights and continue to evaluate potential development and commercialization pathways for ADS-8704, a fixed-dose combination of our proprietary controlled-release version of memantine and donepezil for the treatment of moderate to severe dementia related to Alzheimer's disease in various non-U.S. markets.

### **Research and Development**

We continue to maintain our commitment to research and development, and a significant portion of our operating expenses is related to research and development. See "Item 8. Financial Statements and Supplementary Data" of this Annual Report on Form 10-K for costs and expenses related to research and development, and other financial information for each of the fiscal years 2016, 2015 and 2014, which information is incorporated by reference here.

## **Commercial activities, including sales and marketing**

We intend to commercialize ADS-5102 in the United States in 2017, subject to FDA approval, alone or in partnership with another company with targeted and efficient commercialization strategies and tactics. A significant portion of our operating expenses in 2017 will be related to our commercialization activities. Specifically, we estimate that our marketing and sales efforts will be focused on approximately 7,000 physician targets, who treat approximately 90% of LID patients. We will continue to hire and recruit experienced commercial professionals, including sales management, marketing, and market access professionals to support these efforts.

## **Competition**

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our development experience and scientific knowledge provide us with competitive advantages, we may face competition from large pharmaceutical and biotechnology companies, smaller pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, academic institutions, government agencies and research institutions, and others.

Many of our competitors may have significantly greater financial, technical, and human resources than we have. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel technologies that are more effective, safer, or less costly than any that will be commercialized by us, or obtain regulatory approval for their products more rapidly than we may obtain approval for ours. Our success will be based in part on our ability to identify, develop, and manage a portfolio of drugs that are safer, more efficacious, and/or more cost-effective than alternative therapies.

## **ADS-5102**

Currently, there are no FDA or EMA approved drug therapies for the treatment of LID. While a number of pharmaceutical companies, including Merck, Novartis, Osmotica Pharmaceuticals, Avanir Pharmaceuticals, Newron Pharmaceuticals, Neurolix Inc, Amaranthus BioScience, Addex Pharma, and Neurim Pharmaceuticals Ltd have disclosed programs aimed at developing treatments for LID, we believe ADS-5102 is one of the most advanced. The NDA for ADS-5102 for the treatment of LID in Parkinson's disease has been accepted by the FDA for filing and has a PDUFA date of August 24, 2017.

Other products in late stage development for Parkinson's disease include product candidates from Kyowa Hakko, Acorda, Neuroderm, Acadia, Bial-Portela CSA, Biotie Therapies Corp, Genervon Biopharmaceuticals, Pharma Two B, and Depomed. Products approved to treat late stage Parkinson's disease include Azilect<sup>®</sup> (Teva), Requip XL (GlaxoSmithKline), Mirapex ER (Boehringer Ingelheim), Neupro Patch (UCB), Comtan (Novartis), Sinemet<sup>®</sup> (Merck & Co., Inc.), Parcopa<sup>®</sup> (Jazz Pharmaceuticals, Inc.), Apokyn<sup>®</sup> (Bertek), Bromocriptine (Mylan Laboratories, Inc.), Zelapar<sup>®</sup> (Valeant Pharmaceuticals International), Eldepryl<sup>®</sup> (Somerset Pharmaceuticals Inc.), Tasmac<sup>®</sup> (Valeant Pharmaceuticals International), Cogentin<sup>®</sup> (Oaks Pharma Akorn), Exelon<sup>®</sup> (Novartis Pharmaceuticals Corp.), Stalevo<sup>®</sup> (Novartis), Rytary<sup>®</sup> (Impax), Duopa (AbbVie), and generic versions of amantadine and other drugs. Physicians may use these drugs or other strategies to attempt to manage LID. In select cases for late stage patients, physicians and patients/caregivers will consider neurosurgical intervention, such as deep brain stimulation.

## **Namenda XR<sup>®</sup>/Namzaric<sup>®</sup>**

In the market for Alzheimer's disease treatments, Namenda XR<sup>®</sup> and Namzaric<sup>®</sup> compete or will compete with branded and generic products such as galatamine, rivastigmine, and donepezil. In addition, Allergan currently markets Namenda<sup>®</sup>, the immediate-release version of memantine, which physicians and patients may favor instead of Namenda XR<sup>®</sup>, the controlled-release version. In addition, generic versions of Namenda<sup>®</sup> became available in 2015. Several generic manufacturers are currently seeking regulatory approval to market generic versions of Namenda XR<sup>®</sup> and Namzaric<sup>®</sup>. We are also aware that Lundbeck, Otsuka and other biopharmaceutical companies are developing treatments for Alzheimer's disease that may compete with Namenda XR<sup>®</sup> and Namzaric<sup>®</sup>. See *Litigation* in "Note 8 - Commitments and Contingencies" in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report for more information.

### **Third-party reimbursement**

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payers, such as state and federal governmental authorities, including those that administer the Medicare and Medicaid programs, managed care organizations and private insurers. Each insurer, plan, and payer determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, and on what tier of its formulary the drug will be placed. The position of a drug on the formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payers to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Additionally, a third-party payer's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Also, third-party payers are developing increasingly sophisticated methods of controlling healthcare costs. As a result, coverage, reimbursement, and placement determinations are complex, take time, and are often the subject of extensive negotiations between the payer and the maker of the drug.

If approved, coverage, reimbursement, and formulary placement decisions will be negotiated on a plan by plan basis for ADS-5102 for the treatment of LID, after potential approval in August 2017. Coverage, reimbursements, and placement decisions for a new product are based on many factors including the coverage, reimbursement, and placement of already marketed branded drugs for the same or similar indications, the safety and efficacy of the new product, availability of generics for similar indications, and the clinical need for the new product. Currently, there are no drugs approved for the treatment of LID, and generic amantadine is not approved for this indication.

We have done some preliminary research regarding the potential coverage, reimbursement, and placement of ADS-5102 with consultants and representatives of payers, but have not begun formal negotiations with any payers. Based on these discussions, we believe that if ADS-5102 is approved as the first product indicated for the treatment of LID, most payers are likely to extend coverage to it and that its placement on payer formularies and the amount of reimbursement will be influenced by the aforementioned products, generic amantadine, and generic and branded treatments for symptoms of Parkinson's disease. Within the Medicare program, as self-administered drugs, ADS-5102 would be reimbursed under the expanded prescription drug benefit, known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These Part D plans negotiate discounts with drug manufacturers, which are passed on to each of the plan's enrollees. Historically, Part D beneficiaries have been exposed to significant out-of-pocket costs after they surpass an annual coverage limit and until they reach a catastrophic coverage threshold. However, changes made by recent legislation will reduce this patient coverage gap, known as the "donut hole", by transitioning patient responsibility in that coverage range from 100% in 2010 to only 25% in 2020. To help achieve this reduction, since 2011, pharmaceutical manufacturers are required to pay quarterly discounts of 50% off the negotiated price of branded drugs issued to Medicare Part D patients in the donut hole.

If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as applicable, as well as with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, or the OBRA, and the Veterans Health Care Act of 1992, or the VHCA, each as amended. Among other things, the OBRA requires drug manufacturers to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate rebates on pharmaceutical prices, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

An ongoing trend has been for third-party payers, including the U.S. government, to apply downward pressure on the reimbursement of pharmaceutical products. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations may result in lower reimbursement for pharmaceutical products. We expect that these trends will continue as these payers implement various proposals or regulatory policies, including various provisions of the recent health reform legislation that affects reimbursement of these products. There are currently, and we expect that there will continue to be, a number of federal and state proposals to implement controls on reimbursement and pricing, directly and indirectly.

### **Manufacturing**

We currently have no manufacturing facilities and limited personnel with manufacturing experience. We rely on third-party manufacturers to produce bulk drug substance and drug products required for our clinical trials of ADS-5102. We plan to continue to rely upon contract manufacturers to manufacture commercial quantities of our ADS-5102 and other product candidates if and when we receive approval for marketing by the applicable regulatory authorities.

Our current products and product candidates are based upon controlled-release coated pellet products that are difficult to manufacture. These products consist of an inert core, a drug layer, an optional seal coating, and controlled-release coatings. Our products are made in a fluidized bed coating machine in sequential steps. Once the extended or controlled-release coating is applied, the coated pellets are tested to insure that the desired dissolution rate is achieved. These coatings are relatively thin, and susceptible to changes in raw materials, temperature, humidity, and other manufacturing process parameters. We have clinical supplies of ADS-5102 manufactured for us by a contract manufacturing organization under a development agreement, and have put in place a commercial supply agreement. We are seeking to qualify one or more additional manufacturers.

Allergan is responsible for all manufacturing related to Namenda XR<sup>®</sup> and Namzaric<sup>®</sup>.

Our third-party manufacturers, their facilities, and all lots of drug substance and drug products used in our clinical trials are required to be in compliance with current Good Manufacturing Practices, or cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements and FDA satisfaction before any product is approved and we can manufacture commercial products. Our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. These actions could have a material impact on the availability of our products.

### **Government regulation**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state, and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, tracking, approval, import, export, advertising, and promotion of our products.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests, including some that must be conducted in accordance with Good Laboratory Practices;
- submission of an IND, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug candidate for its intended use;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with cGMP and Good Clinical Practices; and
- FDA approval of an NDA to permit commercial marketing for particular indications for use.

The testing and approval process requires substantial time, effort, and financial resources. Prior to commencing the first clinical trial with a product candidate, we must submit an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development. Further, an independent institutional review board for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial commences at that center. Regulatory authorities or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—Studies are initially conducted to test the product candidate for safety, dosage tolerance, absorption, metabolism, distribution, and excretion in healthy volunteers or patients.
- Phase 2—Studies are conducted with groups of patients with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule, and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—These clinical trials are undertaken in larger patient populations to further evaluate dosage, to provide statistically significant evidence of clinical efficacy, and to further test for safety in an expanded patient population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These trials may be done globally to support global registrations.

Our product development strategy often relies on using Phase 2/3 studies as a central element of our clinical development plans. Typically these studies involve the testing of two or more doses of a product candidate, as is characteristic of a Phase 2 study, and also include a sufficient number of patients so that statistically significant evidence of efficacy can be obtained, as is characteristic of a Phase 3 study. In addition, we conduct the studies in a manner that we believe is consistent with the requirements for a Phase 3 study. We believe this approach has the potential to significantly shorten the time frame required for clinical development. The FDA generally requires that sponsors successfully complete two Phase 3 studies to obtain approval for a new drug, though in certain circumstances a single Phase 3 study is sufficient. We design and conduct our Phase 2/3 studies in a manner that is intended to allow the study to qualify as a Phase 3 study for the purposes of approval. The FDA has broad discretion in determining whether or not a completed Phase 2/3 study will be considered the equivalent of a Phase 3 study for the purposes of approval, and there can be no assurance that the FDA will agree with our assessment that the design, conduct, and results of a Phase 2/3 study are such that the study should be treated as a Phase 3 study.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate, as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

#### ***NDA submission and review by the FDA***

The Federal Food, Drug, and Cosmetic Act (“FDCA”) provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b)(1) of the FDCA is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of preclinical and clinical studies conducted by or on behalf of the applicant to characterize and evaluate the product candidate.

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to obtain FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA’s findings of safety and effectiveness for an approved product that acts as the reference listed drug (“RLD”), and submit its own product-specific data—which may include data from preclinical or clinical studies conducted by or on behalf of the applicant—to address differences between the product candidate and the RLD. Our current and anticipated product candidates based upon ADS-5102 are or will be based on already approved active pharmaceutical ingredients (“API”), rather than new chemical entities, and a formulation that has been evaluated in Phase 1 studies. Accordingly, we expect to be able to rely on information from previously conducted studies involving our ADS-5102 formulation in our clinical development plans and our NDA submissions. For product candidates that involve novel fixed-dose combinations of existing drugs or for studies of an existing

product or product candidate in a new indication, we expect that we will generally be able to initiate Phase 2/3 studies without conducting any new non-clinical or Phase 1 studies. In those instances where our product candidate includes previously unapproved API, we will need to conduct certain non-clinical and Phase 1 studies to confirm the safety and pharmacokinetic profile of the product candidate prior to conducting Phase 2/3 studies.

The submission of an NDA under either Section 505(b)(1) or Section 505(b)(2) generally requires payment of a substantial user fee to the FDA. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually has followed such recommendations. The FDA may determine that a Risk Evaluation and Mitigation Strategy ("REMS"), is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug or biological product in relevant pediatric populations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Once the NDA submission has been accepted for filing, which occurs, if at all, within 60 days after submission of the NDA, the FDA's goal for a non-priority review of an NDA is ten months from submission for Section 505(b)(2) applications, although the review process can be and often is significantly extended by FDA requests for additional information, studies, or clarification. Upon completion of its review, the FDA will respond to the applicant by approving the application or issuing a Complete Response letter. A Complete Response letter outlines deficiencies in the NDA and may request additional information, including additional preclinical or clinical data. Even if an applicant submits this additional information, the FDA may determine that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. The timing of approval, if any, of any NDA we submit will depend on when the FDA determines that the NDA satisfies all requirements for approval. Also, even if the FDA approves an NDA, such approval may entail limitations on the uses or conditions for which such product may be marketed, or the FDA may require Phase 4 post-marketing studies to monitor the safety or efficacy of the product, and may further limit the marketing of the product based on the results of these post-marketing studies. The FDA may withdraw approval of an NDA if the sponsor does not comply with extensive post-marketing regulatory requirements (as described below) or if problems occur after the product reaches the marketplace.

#### ***The Hatch-Waxman Act***

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, established two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products: the 505(b)(2) NDA pathway, described above, and the abbreviated new drug application ("ANDA"). To facilitate these abbreviated approval pathways, NDA applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is published in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA (1) that no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) that such patent has expired; (3) the date on which such patent expires; or (4) that such patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. If the competitor has provided a Paragraph IV certification to the FDA, the competitor must also send notice of the Paragraph IV certification to the holder of the NDA for the RLD and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. If the NDA holder or patent owner files a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification, the FDA may not approve the 505(b)(2) application or ANDA until the earlier of 30 months from the date the NDA or patent holder receives the certification, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. If a listed patent claims a method of using the approved drug, the ANDA or 505(b)(2) NDA applicant may, instead of submitting a certification to the patent, submit a "Section VIII" statement certifying that the labeling for the proposed product does not contain, or carves out, any language regarding the patented method-of-use. We and Forest have received notices of ANDAs submitted to the FDA requesting permission to manufacture and market generic versions of Namenda XR<sup>®</sup>, and we, Forest, Forest Laboratories, Inc., Merz

Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH are currently in litigation with the notifying parties. For further information, see *Litigation* in “Note 8 - Commitments and Contingencies” in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report.

The Hatch-Waxman Act also provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a new chemical entity, or NCE—generally meaning that the active moiety has never before been approved in any drug—there is a period of five years from the product’s approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor makes a Paragraph IV certification challenging a listed patent. Because of relevant statutory and regulatory provisions, as well as the time it takes for the FDA to review and approve an application, five-year NCE exclusivity usually effectively means an ANDA or 505(b)(2) application is not approved for a period well beyond five years after approval of the RLD.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains clinical data that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of the ANDA or 505(b)(2) application; rather, the FDA may not grant final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. For example, if an NDA is submitted for a product that seeks approval for a new indication, and clinical data were required to demonstrate the safety or effectiveness of the product for that use, the FDA could not approve an ANDA or 505(b)(2) application for another product with that active moiety for that use.

The Hatch-Waxman Act also established provisions for patent term restoration, under which some of the term of a patent is extended, in order to compensate for time spent developing the product and for the FDA review and approval process. Generally, if an NDA represents the first time an active ingredient has been approved, the applicant can seek extension of one patent that claims the product. The additional patent term cannot exceed five years, and cannot extend the patent more than 14 years after the date of product approval. We currently do not anticipate applying for patent term extension for our product candidates.

#### ***Orphan Drug designation and exclusivity***

The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States. If a sponsor demonstrates that a drug or biologic is intended to treat a rare disease or condition and meets other qualifying criteria, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. In general, a drug that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity, and during that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity.

We obtained orphan drug designation for ADS-5102 for the treatment of LID in 2015, and we submitted our 505(b)(2) NDA in October 2016. Osmotica Pharmaceutical Corporation also received orphan drug designation for its amantadine product for the treatment of LID in 2015. If our NDA is the first application approved for our active ingredient for the treatment of LID, we expect to receive orphan drug exclusivity for our product for seven years.

In addition to orphan drug exclusivity and 3-year and 5-year exclusivity established under Hatch-Waxman Act, the FDCA includes other regulatory exclusivities for drug products under specific circumstances, such as pediatric exclusivity established by the Best Pharmaceuticals for Children Act of 2002. We currently do not anticipate that these other exclusivities will benefit our product candidates.

#### ***Post-approval requirements***

Any drug products we manufacture, market, or distribute pursuant to FDA approvals are subject to continuing regulation by the FDA. For example, drug manufacturers and their subcontractors must register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by regulatory authorities, including by the FDA for compliance with cGMP, which imposes significant manufacturing-related requirements. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other regulatory requirements imposed by the FDA or other regulatory authorities. If we or our present or future suppliers are not able to comply with FDA requirements, for example, the FDA may take enforcement action, including, but not limited to, halting our clinical trials, requiring us to recall a product from distribution, or seeking to withdraw approval of an NDA or other necessary licenses.

The FDA closely regulates the marketing and promotion of drugs. A company’s promotional claims about the safety and efficacy of its drug products must be consistent with FDA-approved labeling, truthful, and non-misleading. Failure to

comply with these requirements can result in adverse publicity, warning or untitled letters, corrective advertising, and potential civil and criminal penalties. Physicians may legally prescribe approved drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such "off-label" use is common in some areas of medicine and reflects physicians' professional judgment that such use is an appropriate treatment option for patients under certain circumstances. The FDA does not regulate physicians' practice of medicine, but the FDA does restrict manufacturers' communications about their drug products, including communications about unapproved uses of approved products.

In addition to these post-marketing requirements, companies that manufacture or distribute drug products or that hold approved NDAs must comply with numerous other post-marketing regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records.

The extensive laws and regulations that apply to the research, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising, and promotion of drug products and product candidates in the United States are subject to change. For example, in December 2016, the 21<sup>st</sup> Century Cures Act ("Cures Act") was signed into law. The Cures Act included numerous provisions that may be relevant to our product candidates, including provisions designed to speed development of innovative therapies and provide funding for certain brain-related research and technology development. Because the Cures Act has only recently been enacted, it is difficult to know whether, how, and when it may affect our business. Similarly, further legislative and regulatory changes appear possible in the 115<sup>th</sup> United States Congress and under the Trump Administration, and it is difficult to foresee whether, how, and when such changes may affect our business.

### ***Other healthcare regulations***

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the Centers for Medicare and Medicaid Services, and state and local governments. Our business activities must comply with numerous healthcare laws, including but not limited to, the federal Anti-Kickback Statute, the False Claims Act, the Veterans Health Care Act, and similar state laws.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. Liability under the Anti-Kickback Statute may be established without a person or entity having actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. We seek to comply with these exceptions and safe harbors whenever possible, but the exceptions and safe harbors are drawn narrowly and our business practices may be subject to scrutiny if they do not qualify for an exception or safe harbor or if there is no exception or safe harbor available. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Many pharmaceutical and other healthcare companies have been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

We and our business activities are subject to the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.



Additionally, the federal Open Payments program requires manufacturers of drugs, devices, biological, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report (with certain exceptions) information related to payments or other transfers of value made to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and federal False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. These include state laws that require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states; restrict when pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities; and/or require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Outside the U.S., we may be subject to similar regulations in those countries where we market and sell products.

In addition, we may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that negatively affects our business. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"). HIPAA and its implementing regulations impose certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates-independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we will have to comply with the Veterans Health Care Act of 1992 ("VHCA"). The VHCA requires manufacturers to offer their covered drugs (biologics and single source and innovator multiple source drugs) for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs ("VA"), on a Federal Supply Schedule contract, at a price no higher than the statutory Federal Ceiling Price ("FCP"). The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we will have to calculate and report to the VA on a quarterly and annual basis. In addition, the Federal Supply Schedule contract requires compliance with applicable federal procurement laws.

Depending on the circumstances, failure to comply with these laws can result in penalties, including criminal, civil, and/or administrative criminal penalties, damages, fines, disgorgement, exclusion of products from reimbursement under government programs, "qui tam" actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits, and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our business.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, in March 2010, the Patient Protection and Affordable Care Act ("PPACA") was passed, which has substantially changed how health care is financed by both governmental and private insurers, and has significantly impacted the U.S. pharmaceutical industry. The PPACA, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program

("MDRP") are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the MDRP, extended the MDRP to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government's comparative effectiveness research, and provided for a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Legislative and regulatory changes to the PPACA remain possible and appear likely in the 115th United States Congress and under the Trump Administration. We expect that the PPACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of any of our product candidates that we successfully commercialize. There have also been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries. If any of these proposals are adopted, they could result in us owing additional rebates, which could have a negative impact on revenues from sales of any of our product candidates that we successfully commercialize.

### ***Pharmaceutical pricing and reimbursement***

Our ability to commercialize our product candidates successfully, and to attract commercialization partners for our products, will depend in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the U.S., governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. We intend to participate in and then will have certain price reporting and other obligations to the Medicaid Drug Rebate program and other governmental pricing programs. These obligations are discussed in greater detail under the heading "If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs that we may join if we successfully commercialize any of our product candidates, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects" in Part 1, Item 1A. Risk Factors, of this Annual Report on Form 10-K. Political, economic, and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell any of our product candidates that we successfully commercialize profitably. We expect to experience pricing pressure in the U.S. in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations, additional legislative proposals to curb healthcare costs, and negative publicity regarding pricing and price increases generally, which could limit the prices that we charge for any of our product candidates that we successfully commercialize, limit our commercial opportunity, and/or negatively impact revenues from sales of our products. We anticipate that the U.S. Congress, state legislatures, and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs, particularly given the current atmosphere of mounting criticism of prescription costs in the U.S. These cost containment measures include controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; pharmaceutical cost transparency bills that aim to require drug companies to justify their prices; controls on healthcare providers; challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and public funding for cost effectiveness research, which may be used by government and private third-party payers to make coverage and payment decisions. For example, much attention has been paid to legislation proposing federal rebates on Medicare Part D and Medicare Advantage utilization for drugs issued to certain groups of lower income beneficiaries and the desire to change the provisions that treat these dual-eligible patients differently from traditional Medicare patients. Any such changes could have a negative impact on revenues from sales of any of our product candidates that we successfully commercialize.

Third-party payers decide which drugs they will pay for and establish reimbursement and co-pay levels. Third-party payers are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of any of our product candidates that we successfully commercialize. Even with studies, any of our product candidates that we successfully commercialize may be considered less safe, less effective, or less cost-effective than other products, and third-party payers may not provide coverage and reimbursement for any of our product candidates that we commercialize, in whole or in part. The process for determining whether a payer will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the product once coverage is approved. Third-party payers may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. For example, third-party payers have started to require

discounts and/or exclusivity arrangements with some drug manufacturers in exchange for including a specific product on their formularies. Any such requirements could have a negative impact on revenues from sales of our products.

Payers also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. Both Medicare and Medicaid are administered by the Centers for Medicare and Medicaid Services (“CMS”). CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It is difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover our products.

### ***The Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act (“FCPA”) prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

### ***Foreign regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. Under an agreement with Forest, we hold the rights to manufacture and market an extended-release memantine and a fixed-dose combination of memantine and donepezil in ex-U.S. markets. However, we have not yet taken any steps to market these products. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country.

Under the European Union regulatory system, we may submit applications for marketing authorizations either under a centralized, decentralized, or mutual recognition marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the European Commission on the basis of a positive opinion by the EMA. A centralized marketing authorization is valid for all European Union member states and three of the four EFTA States (Iceland, Liechtenstein and Norway). The decentralized procedure and the mutual recognition procedure apply between European Union member states. The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authority of all European Union member states in which the product is to be marketed. One national competent authority, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other European Union member states are subsequently required to grant marketing authorization for their territory on the basis of this assessment, except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national competent authorities of European Union member states by the competent authorities of other European Union member states. The holder of a national marketing authorization may submit an application to the competent authority of a European Union member state requesting that this authority recognize the marketing authorization delivered by the competent authority of another European Union member state for the same medicinal product.

Medicinal products that are (a) used to treat or prevent life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the European Union; or (b) used to treat or prevent life-threatening or chronically debilitating conditions and that, for economic reasons, would be unlikely to be developed without incentives; and (c) where no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition, may be granted an orphan designation in the European Union. The application for orphan designation must be submitted to the EMA and approved before an application is made for marketing authorization for the product. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity. During this ten year period, with a limited number of exceptions, neither the competent authorities of the European Union member states, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal

product with the same orphan indication if this latter product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity.

We are subject to the U.K. Bribery Act and other third country anti-corruption laws and regulations pertaining to our financial relationships with foreign government officials. The U.K. Bribery Act, which applies to any company incorporated or doing business in the UK, prohibits giving, offering, or promising bribes in the public and private sectors, bribing a foreign public official or private person, and failing to have adequate procedures to prevent bribery amongst employees and other agents. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances. Liability in relation to breaches of the Bribery Act is strict. This means that it is not necessary to demonstrate elements of a corrupt state of mind. However, a defense of having in place adequate procedures designed to prevent bribery is available.

## **Employees**

As of December 31, 2016, we had 69 full-time equivalent employees. Of these employees, 29 were engaged in research and development. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

## **Corporate and other Information**

We were incorporated in Delaware in November 2000 under the name NeuroMolecular, Inc. In December 2004, we changed our name to NeuroMolecular Pharmaceuticals, Inc., and in July 2007 we changed our name to Adamas Pharmaceuticals, Inc.

Our principal executive offices are located at 1900 Powell Street, Suite 750, Emeryville, California 94608, and our telephone number is (510) 450-3500. Our website address is [www.adamaspharma.com](http://www.adamaspharma.com). References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

We make available, free of charge on our corporate website, copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. The public may also read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. This information may also be obtained from the SEC's on-line database, which is located at [www.sec.gov](http://www.sec.gov). Our common stock is traded on the NASDAQ Stock Market under the symbol "ADMS".

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation. We will remain an emerging growth company until the earlier of (1) December 31, 2019, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least \$1.0 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

## Item 1A. Risk Factors

*We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations, and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our condensed consolidated financial statements and related notes.*

### **Risks related to the development, regulatory approval, and commercialization of our current and future product candidates, including ADS-5102**

*Our success depends heavily on the timely approval and successful commercialization of our product candidates, including ADS-5102. If we are unable to successfully commercialize our product candidates or if we experience significant delays in doing so, our business will be materially harmed.*

We have invested a significant portion of our efforts and financial resources into the development and potential commercialization of our product candidates, including ADS-5102, an oral once daily extended-release version of the FDA-approved drug amantadine, for the treatment of levodopa-induced dyskinesia (“LID”), for the treatment of walking impairment in patients with multiple sclerosis, and potentially other indications, as well as ADS-4101 for the treatment of partial onset seizures in epilepsy. Our ability to generate product revenue will depend heavily on the successful development, regulatory approval, and eventual commercialization of ADS-5102 and these other product candidates. The success of our product candidates will depend on numerous factors, including:

- successfully completing the development program for ADS-5102 and other product candidates in a timely manner;
- receiving marketing approval for ADS-5102 and other product candidates from the FDA in a timely manner;
- successfully establishing and maintaining commercial manufacturing with third parties;
- commercializing ADS-5102 and other product candidates, if approved, including marketing, sales, and distribution of the product independently or in partnership with another company;
- acceptance by the medical community and patients of the approved product;
- the placement of ADS-5102 on payers’ formulary tiers and the reimbursement rates established for the approved products;
- effectively competing with other approved or used medicines;
- continued demonstration of an acceptable safety profile of the approved products following approval; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

***If ADS-5102 for the treatment of LID fails to receive approval by regulatory authorities, our business will be adversely impacted and substantially harmed.***

Our new drug application (“NDA”) for ADS-5102 for the treatment of LID in patients with Parkinson’s disease was accepted for filing by the FDA in January 2017 and we have a Prescription Drug User Fee Act (“PDUFA”) date of August 24, 2017. We cannot give any assurance that our NDA for ADS-5102 for the treatment of LID will be approved by regulatory authorities. Although we have substantially completed the clinical trial program for ADS-5102 for the treatment of LID, except for the long-term open-label safety study of ADS-5102 for the treatment of LID, we do not know if the clinical package for ADS-5102 for the treatment of LID will adequately demonstrate sufficient safety and efficacy to the satisfaction of the FDA to achieve regulatory approval.

In addition, NDAs are complex, multipart documents that must meet strict regulatory requirements to be acceptable for regulatory approval. NDAs must include preclinical and clinical study data and chemistry, manufacturing, and controls data. Our contract manufacturer of ADS-5012 is subject to inspection for Good Manufacturing Practice compliance, our contract

analytical testing facilities may be subject to pre-approval inspection for Good Laboratory Practice and data integrity, and our ADS-5102 LID clinical trial sites may be subject to bioresearch monitoring inspections for Good Clinical Practice compliance and data integrity. Adverse inspectional findings at our contract manufacturer, at any of our contract analytical testing facilities, or at any of our clinical trial sites may lead to our receipt of a Complete Response Letter rather than NDA approval. Additionally, this is our first NDA that we have submitted. As a result, we do not know whether or not our NDA submission will meet the strict regulatory requirements for regulatory approval or will adequately demonstrate sufficient safety and efficacy to the satisfaction of the FDA to achieve regulatory approval. Failure to achieve regulatory approval for ADS-5102 for the treatment of LID would harm our business.

***Our product candidates, including ADS-5102, may fail to achieve the degree of market acceptance by physicians, patients, healthcare payers, and others in the medical community necessary for commercial success, negatively impacting our business.***

Our product candidates, including ADS-5102, may fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payers, and others in the healthcare community. The degree of market acceptance of our products, after FDA approval, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- efficacy, duration of response, and potential advantages compared to alternative treatments;
- the price;
- the willingness of physicians to change their current treatment practices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- the availability of third-party insurance coverage or reimbursement.

The failure of our product candidates, including ADS-5102, to achieve market acceptance would negatively impact our business.

***We currently have only limited commercial capabilities with no sales personnel. If we are unable to develop or obtain through outsourcing or other means our commercial capabilities, we will not be successful in commercializing ADS-5102 or other future product candidates.***

We have only a limited commercial infrastructure and have limited experience in the commercialization, sale, marketing, or distribution of pharmaceutical products, like ADS-5102, if approved. To achieve commercial success for any approved product, including ADS-5102, we must either develop a sales and marketing organization or outsource these functions to third parties. We expect that the primary focus of our commercialization efforts will be in the United States. We intend to commercialize ADS-5102 and our other product candidates through use of our own sales force, a contract sales organization, or through partnership agreements with a pharmaceutical company. Commercialization of ADS-5102 and other future product candidates outside of the United States, to the extent pursued, is likely to require collaboration with one or more third parties.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming, and if our product candidates fail to gain approval, our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

In addition, we also may not be successful in entering into arrangements with third parties to sell and market our future product candidates or may be unable to do so on terms that are favorable to us. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our future products, including ADS-5102.

***Failure to successfully obtain coverage and reimbursement of our products in the United States will substantially harm our business.***

Our ability to commercialize any products successfully in the United States will depend in part on the extent to which coverage and reimbursement for these products becomes available from third-party payers, including government health administration authorities, such as those that administer the Medicare and Medicaid programs, and private health insurers. Third-party payers decide which medications they will cover by placement on their formularies and at what reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payers are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for products that we commercialize and, if reimbursement is available, we cannot guarantee what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop, including ADS-5102.

There may be significant delays in obtaining coverage and reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, distribution, marketing, and sale. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product, the clinical setting in which it is used, and generic competitor availability, and may be based on initial payments for generic competitors or payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private third-party payers and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the United States, private third-party payers often rely upon Medicare coverage and reimbursement policies and payment limitations in setting their own coverage and reimbursement policies. Our inability to promptly obtain coverage, reimbursement, and profitable payment rates from both government funded and private third-party payers for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

***We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.***

The development and commercialization of new pharmaceutical products is highly competitive. We face competition with respect to our current product candidates, including ADS-5102, and will face competition with respect to any future products that we may seek to develop or commercialize from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. For example, ADS-5102, if approved for the treatment of LID, may face competition from various drugs approved for treatment of Parkinson's disease, though not LID, such as Azilect (Teva Pharmaceuticals Industries, Ltd.), Requip XL (GlaxoSmithKline plc), Mirapex ER (Boehringer Ingelheim Pharmaceuticals Inc.), Neupro Patch (UCB, Inc.), Sinemet (Merck & Co., Inc.), Parcopa (Jazz Pharmaceuticals, Inc.), Rytary (Impax), Duopa (AbbVie), and immediate-release amantadine. ADS-5102 may also face competition from drugs currently in development for LID from a number of pharmaceutical companies, such as Merck, Novartis, Osmotica Pharmaceuticals Corp., or Osmotica, Avanir Pharmaceuticals, Newron Pharmaceuticals S.p.A, Neurolaxis, Amaranthus BioScience, Addex Pharma, and Neurim Pharmaceuticals Ltd. Other products in late stage development for Parkinson's disease includes product candidates from Kyowa Hakko, Acorda, Neuroderm, Acadia, Bial-Portela CSA, Genervon Biopharmaceuticals, Pharma Two B, and Depomed.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals, and commercializing approved products than we do. These third parties will compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites, and patient registration for clinical studies, as well as in acquiring technologies and products complementary to, or necessary for, our programs. Finally, many of our competitors are large pharmaceutical companies that will have a greater ability to reduce prices for their competing drugs in an effort to gain market share and undermine the value proposition that we might otherwise be able to offer to payers.

ADS-5102 will face competition from generic versions of immediate-release amantadine and potentially from other extended-release versions of amantadine that may be in development. For example, while immediate-release amantadine is not approved for use in Parkinson's disease for the treatment of LID, some physicians may still prescribe it for such conditions. In

addition, one competitor, Osmotica, has posted a notice on [clinicaltrials.gov](http://clinicaltrials.gov) regarding its conduct of two Phase 3 clinical trials of extended-release amantadine for LID.

***If manufacturers obtain approval for generic versions of our products, including ADS-5102, or of products with which we compete, our business may suffer.***

Under the U.S. Food, Drug and Cosmetic Act, or FDCA, the FDA can approve an Abbreviated New Drug Application, or ANDA, for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form, route of administration and that it is bioequivalent to the branded product.

The FDCA requires that an applicant for approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book, or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon receipt of the paragraph IV notice, the owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. The discovery, trial, and appeals process in such suits can take several years. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. This type of litigation is often time-consuming and costly and may result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. Such litigation has been commenced by Forest Laboratories Holdings Limited ("Forest"), an indirect wholly-owned subsidiary of Allergan plc (collectively, "Allergan") and us to enforce certain patents related to Namenda XR<sup>®</sup> and Namzaric<sup>®</sup>. See *Litigation* in "Note 8 - Commitments and Contingencies" in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report for more information.

If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs. Once an ANDA is approved by the FDA, the generic manufacturer may market and sell the generic form of the branded drug in competition with the branded medicine.

***If we are unable to obtain orphan exclusivity for ADS-5102 for the treatment of LID, our business could be substantially harmed.***

Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. Generally, if a drug product with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the drug product is entitled to a period of marketing exclusivity, which may preclude the FDA from approving another marketing application for the same drug product for the same therapeutic indication. The applicable period of exclusivity is up to seven (7) years in the United States. Even though we have orphan drug designation for ADS-5102 for the treatment of LID, we may not be the first to obtain marketing approval. With respect to LID, both ADS-5102 and Osmotica's amantadine product candidate for the treatment of LID have been granted orphan drug designation. If Osmotica were to obtain regulatory approval for its product candidate prior to ADS-5102, it would obtain orphan drug exclusivity for their product candidate and the marketing application for ADS-5102 could be delayed for so long as Osmotica has orphan drug exclusivity for its product. The NDA for ADS-5102 for LID is currently under review by the FDA with a PDUFA date of August 24, 2017. We are unaware of the status of the Osmotica clinical development program in LID.

Even if we are first to obtain marketing approval for ADS-5102 for the treatment of LID, the FDA could still subsequently approve the same drug with the same active moiety for the same condition, if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. As a matter of law, orphan drug designation does not shorten a drug's development or regulatory review time, nor does it give the drug any advantage in the regulatory review or approval process.

***The marketing and promotion of ADS-5102, if approved, will be limited to use in the treatment of a specific indication. If we want to expand the indications for which this product candidate may be marketed, we will need to obtain additional regulatory approvals, which may not be granted.***

In October 2016, we submitted an NDA seeking regulatory approval of ADS-5102 for the treatment of LID. If this product candidate is approved, we will be permitted to market or promote it only for the treatment of LID and not for other uses. We are developing ADS-5102 for at least one additional indication, treatment of walking impairment in patients with multiple sclerosis, and potentially others. In order to market and promote ADS-5102 for these additional indications, we will need to conduct additional clinical trials that will likely be time-consuming and expensive, and to obtain regulatory approval



for such uses. We may not be successful in those efforts. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

***If our product candidates are approved for marketing and we are found to have improperly promoted unapproved uses of such products, or if physicians misuse our products, we may be subject to restrictions on the sale or marketing of our products, significant fines, penalties, and sanctions, product liability claims, and our image and reputation within the industry and marketplace could be harmed.***

The FDA and other regulatory agencies, including regulatory authorities outside the United States, strictly regulate the marketing and promotional claims that are made about drug products, such as ADS-5102, if approved. In particular, promotion for a product must be consistent with its labeling approved by the FDA or by regulatory agencies in other countries. For example, if we receive marketing approval for ADS-5102 for the treatment of LID, the first indication we are pursuing, we cannot prevent physicians from prescribing ADS-5102 for indications or uses that are inconsistent with the approved label. If, however, we are found to have promoted such unapproved uses prior to the FDA's approval for an additional indication, we may, among other consequences, receive untitled or warning letters and become subject to significant liability, which would materially harm our business. Both the U.S. federal government and foreign regulatory authorities have levied significant civil and criminal fines against companies and individuals for alleged improper promotion and have entered into settlement agreements with pharmaceutical companies to limit inappropriate promotional activities. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged.

Physicians' prescribing of our products for unapproved uses may also subject us to product liability claims, to the extent such uses lead to adverse events, side effects, or injury. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Furthermore, the use of our products for indications other than those approved by the FDA or regulatory authorities outside the United States may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Any of these events could harm our business and results of operations and cause our stock price to decline.

***The commercial manufacturing process for our product candidates have not been fully validated. However, we have successfully scaled up the manufacturing process for ADS-5102 and process validation is currently in progress. There are risks associated with developing and validating manufacturing and packaging processes on a timely basis.***

The commercial manufacturing process for our product candidates has not been fully validated. However, we have successfully scaled up the manufacturing process for ADS-5102 and process validation is currently in progress. There are risks associated with validating manufacturing and packaging processes and scaling up including, among others, delaying approval of the NDA, inability to gain regulatory approval, higher manufacturing costs, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, capacity constraints, and timely availability of raw materials or equipment.

***Our product candidates, including ADS-5102, are complex to manufacture, and manufacturing disruptions may occur that could delay the launch or commercialization of our product candidates.***

Our product candidates, including ADS-5102, include extended-release versions of existing drugs. The manufacture of extended-release versions of drugs are more complex than the manufacture of the immediate-release versions of drugs. Even after the manufacturing process for an extended-release product has been scaled up to commercial levels and numerous commercial lots have been produced, manufacturing disruptions may occur. Such problems may prevent the production of lots that meet the specifications required for sale of the product and may be difficult and expensive to resolve. If any such issues were to arise with respect to ADS-5102 or our future product candidates, our business, financial results, or stock price could be adversely affected.

***Although we have completed clinical trials of ADS-5102 for the treatment of LID, a clinical trial with ADS-5102 is ongoing for LID and clinical trials in other indications are planned that could result in clinical findings not consistent with previously reported positive clinical results. This could lead us to experience failure to receive regulatory approval, which would have a material and adverse impact on our business.***

In completing our clinical trial program for ADS-5102 for the treatment of LID, and pursuing clinical trials in other indications for ADS-5102, we may experience numerous unforeseen events during, or as a result of, clinical studies that could delay or prevent our ability to receive regulatory approval or commercialize ADS-5102, including that:

- clinical studies may produce negative or inconclusive results or raise significant safety concerns, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- even if clinical studies demonstrate statistically significant efficacy and acceptable safety, the FDA or similar authorities outside the United States may not consider the results of our studies to be sufficient for approval of ADS-5102;
- our clinical sites and clinical investigators may fail to comply with, or inconsistently apply, the trial protocols, regulatory requirements including Good Clinical Practices, contractual obligations, and the rating assessments;
- our third-party vendors, including our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies for various reasons, including a finding that our product candidates have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of ADS-5102 or other materials necessary to conduct clinical studies may be insufficient or inadequate.

Additionally, if we are required by the FDA to conduct additional non-clinical studies, clinical studies, or other testing of ADS-5102 beyond those that we currently contemplate, if we are unable to successfully complete clinical studies or other testing of ADS-5102, if the results of these studies or tests are not positive or are only modestly positive, or if there are safety concerns, we may:

- be delayed in obtaining marketing approval;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed, marketed, or used.

Any of these unforeseen events could impair our ability to gain approval of ADS-5102 or commercialize ADS-5102 and harm our business and results of operations.

***We will face risks in the development of ADS-5102 for additional indications and other product candidates.***

The risks relating to the development of ADS-5102 for additional indications and other product candidates are the same as, or similar to, the risks relating to the development of ADS-5102 for LID.

***If serious or other adverse side effects are identified during the development of ADS-5102 or any other product candidates, we may need to abandon our development of that product candidate, which would materially and adversely harm our business.***

Our product candidate, ADS-5102, along with our other earlier stage product candidates, are still in clinical or preclinical development. The risk of failure during development is high. It is impossible to predict when or if any of our product candidates will demonstrate safety and efficacy sufficient to warrant regulatory approval. Although the safety profile of amantadine, the active pharmaceutical ingredient in ADS-5102, is already characterized in the approved label for amantadine (i.e., Symmetrel®), there can be no assurance that our Phase 3 program for ADS-5102 for the treatment of LID, our Phase 2 program for ADS-5102 for walking impairment associated with multiple sclerosis or future studies in other indications, will not reveal additional safety or tolerability issues. In such an event, we might need to delay or abandon development and potential approval of ADS-5102 entirely or for certain indications. If we are forced to delay or abandon development of our product candidates, our business, results of operations, and financial condition will be materially and adversely harmed.

***If ADS-5102 is approved by regulatory authorities, post-marketing safety issues with ADS-5102, its reference product, or other components of ADS-5102 could decrease the potential sales of ADS-5102, result in adverse labeling changes, use restrictions, product withdrawal, or product liability litigation.***

Discovery of previously unknown problems, or increased focus on a known problem, with an approved product may result in restrictions on its permissible uses, including withdrawal of the medicine from the market.

If we or others identify additional undesirable side effects caused by ADS-5102 after approval:

- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications, or field alerts to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the product and require us to take our approved drugs off the market;
- we may be required to change the way the product is administered, conduct additional clinical trials, change the labeling of the product, or implement a Risk Evaluation and Mitigation Strategy (REMS);
- we may have limitations on how we promote our drugs;
- third-party payers may limit coverage or reimbursement for ADS-5102;
- sales of ADS-5102 may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from its sale.

ADS-5102 may also be affected by the safety and tolerability of its parent drugs or drugs with similar mechanisms of action. Although amantadine, which is a component of ADS-5102, has been used in patients for many years, newly observed toxicities or worsening of known toxicities in preclinical studies or in subjects in clinical studies receiving amantadine, or reconsideration of known toxicities of compounds in the setting of new indications, could result in increased regulatory scrutiny of our products and product candidates. The FDA has substantial discretion in the NDA approval process and may refuse to approve our current NDA and any future application if the FDA concludes that the risk/benefit analysis of a potential drug treatment for a specific indication does not warrant approval. Thus, although the parent drug for, or a drug related to, one of our product candidates may be approved by the FDA in a particular indication, the FDA may conclude that our product candidate's risk/benefit profile does not warrant approval in a different indication, and the FDA may refuse to approve our product candidate in that indication. Such conclusion and refusal would prevent us from developing and commercializing our product candidates and severely harm our business and financial condition. Following consumption, ADS-5102 capsules are broken down by the body, during which time the active drug and other breakdown substances are released into the bloodstream. While these breakdown substances are generally regarded as safe, it is possible that there could be unexpected toxicity associated with them that will cause ADS-5102 to be poorly tolerated by, or toxic to, humans. Any unexpected toxicity of, or suboptimal tolerance to, the product or product candidates could reduce their sales of approved products and delay or prevent commercialization of our product candidates.

In addition, problems with approved products marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as amantadine could adversely affect the commercialization of ADS-5102.

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- the inability to commercialize any products that we may develop;
- injury to our reputation and significant negative media attention;

- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation;
- substantial monetary awards to patients; and
- loss of revenue.

We currently hold \$10.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur at our current stage of development. Insurance coverage is increasingly expensive. If and when our product candidates are approved and we launch such products commercially, we may not be able to obtain insurance coverage at a reasonable cost or in amounts adequate to satisfy any liability or associated costs that may arise in the future. These events could harm our business and results of operations and cause our stock price to decline.

***The post-marketing safety risks relating to Namzaric® and Namenda XR® are the same as those facing ADS-5102 in the prior risk factor.***

The post-marketing safety risks relating to Namzaric® and Namenda XR® are the same as those facing ADS-5102 in the prior risk factor.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we have chosen to focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our investment in current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

#### **Risks related to our financial condition and need for additional capital**

***If we do not have adequate funds to cover all of our development and commercial activities, we may have to raise additional capital or curtail or cease operations.***

While we are a clinical-stage pharmaceutical company and do not currently market any products, if approved, we expect to commercialize ADS-5102 in 2017. The completion of the development and the potential commercialization of our product candidates, including ADS-5102, should they receive approval, will require substantial funds. In addition, funds are required for the continued operation of our business, as we seek to advance additional product candidates through the research and clinical development to regulatory approval and commercialization. As of December 31, 2016, we had approximately \$135.9 million in cash, cash equivalents, and investments. We believe that our available cash, cash equivalents, and investments will be sufficient to fund our anticipated level of operations for at least the next 12 months, but there can be no assurance that this will be the case.

We have financed our operations primarily through proceeds from our license agreement with Allergan, public and private equity offerings, and, to a lesser extent, government grants, venture debt, and benefits from tax credits made available under a federal stimulus program supporting drug development. We have devoted substantially all of our efforts to research and development, including clinical studies, of our product candidates, including ADS-5102 for the treatment of LID in patients with Parkinson's disease. We anticipate that our expenses will increase substantially as we:

- enhance operational, financial, and information management systems and hire more personnel, including personnel to support development of our product candidates and, if a product candidate is approved, our commercial operations;
- commercialize ADS-5102, if it is approved by the FDA, including establishing distribution, marketing, and sales capabilities;
- manufacture ADS-5102 for commercial use, if approved by the FDA;

- investigate ADS-5102 in preclinical and clinical trials for the treatment of walking impairment in patients with MS, and potentially other indications;
- conduct preclinical and clinical trials of ADS-4101 for the treatment of epilepsy (partial onset seizures);
- seek regulatory approvals for our product candidates that successfully complete clinical studies;
- continue the research, development, and manufacture of our current product candidates; and
- seek to discover or in-license additional product candidates.

If we do not have adequate funds to support these activities, our business opportunities could be hindered.

***If we need additional funds to operate our business and if we cannot raise additional capital when needed, or if additional capital is not available to us on favorable terms, our stockholders may be adversely affected or our business may be harmed.***

If we need additional funds to support our business and additional funding is not available on favorable terms or at all, we may need to delay or reduce the scope of our research and clinical development programs or commercialization efforts. We do not have any committed external source of funds or other support for our development efforts other than our license agreement with Allergan, which may be terminated by Allergan upon delivery of notice. We expect to finance future cash needs through a combination of public or private equity offerings, debt financings, royalty financings, collaborations, strategic alliances, licensing arrangements, asset sales, and other marketing and distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms. If we raise additional capital through royalty financings, collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams, or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, in addition to the repayment of principal and interest on negotiated terms, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.***

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Any future revenue will depend on the successful commercialization and sales of our product candidates, including ADS-5102 for the treatment of LID, if approved, the payment of royalties to us from Allergan under terms of our licensing agreement regarding Namenda XR<sup>®</sup> and Namzaric<sup>®</sup>, or the establishment of potential future collaboration and license agreements, if any, and the achievement of any upfront or milestone payments provided thereunder. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including:

- the level of demand for our products, should any of our product candidates receive regulatory approval, which may vary significantly as they are launched and compete for position in the marketplace;
- pricing and reimbursement policies with respect to our product candidates, if approved, and the competitive response from existing and potential future therapeutic approaches that compete with our product candidates;
- the cost of manufacturing our product candidates, which may vary due to a number of factors, including the terms of our agreements with contract manufacturing organizations, or CMOs;
- the timing, cost, level of investment, and success or failure of research and development activities relating to our preclinical and clinical-stage product candidates, which may change from time to time;
- expenditures that we may incur to acquire and develop additional product candidates and technologies;
- the timing and success or failure of clinical studies for competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing and magnitude of upfront and milestone payments under any potential future collaboration and licensing agreements;

- future accounting pronouncements or changes in our accounting policies; and
- changing or volatile U.S., European, and global economic environments.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated operating results and/or earnings guidance that we may provide.

### **Risks related to our reliance on third parties**

***We rely on third-party contract manufacturing organizations to manufacture and supply our product candidates, including ADS-5102, for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face delays in the development, commercialization, and supply of our product candidates.***

We currently have limited experience in, and we do not own facilities for, clinical and commercial manufacturing of our product candidates and we rely upon third-party contract manufacturing organizations to manufacture and supply drug product for our clinical studies and, upon regulatory approval, to meet potential future commercial demand. The manufacture of pharmaceutical products in compliance with the FDA's current Good Manufacturing Practices, or cGMPs, 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, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements, and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to gain approval of the NDA for ADS-5102 or to provide study drugs in our clinical trials and future commercial supply would be jeopardized. Any delay or interruption in the supply of clinical study materials or commercial product could cause delays in our clinical programs, harm our ability to gain approval from regulatory authorities, and potentially disrupt patient access to our future approved products. These events would substantially harm our business, reputation and stock price.

All third-party manufacturers of our product candidates and ingredients thereof must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging, or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical studies, regulatory submissions, approvals, commercialization or supply of our product candidates, entail higher costs, impair our reputation, and potentially disrupt patient access or our future approved products.

***We rely on a single source third-party contract manufacturing organization for the manufacture and supply of our product candidates, including ADS-5102.***

We currently rely on single source suppliers for our product candidates, including ADS-5102, and continue to seek additional long-term supply agreements. A failure of our single source manufacturer or our failure to qualify at least one other manufacturer on a timely basis and validate the manufacturing process employed at that CMO would delay approval of an NDA and commercialization of our product candidates, including ADS-5102. Although we believe alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange and negotiate acceptable long-term contracts, which would adversely affect our business. New suppliers of any product candidate would be required to be qualified under applicable regulatory requirements, including demonstration of bioequivalence of the product made at the new supplier,

and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs, which may be passed on to us. Qualifying and negotiating long-term contracts with manufacturers and providers of packaging services is a lengthy process. If at any time, one or more of our qualified contract organizations were not able to manufacture our drug substance or drug product or provide the requisite services, our business and financial condition would be materially adversely affected.

***If we decide to enter into future collaborations or partnerships, we will likely not be able to control all aspects of the development and commercialization of our product candidates, including ADS-5102. This lack of control could subject us to additional risks that could harm our business.***

Collaborations or license agreements involving our current or future products are subject to numerous risks, which may include that:

- partners have significant discretion in determining the efforts and resources that they will apply to collaborations;
- partners may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical study results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- partners may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a product candidate, repeat or conduct new clinical studies, or require a new formulation of a product candidate for clinical testing;
- partners could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a partner with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our partners that would prevent us from collaborating with others;
- Allergan and future partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- Allergan and future partners may not aggressively or adequately pursue litigation against ANDA filers or may settle such litigation on unfavorable terms, and as Allergan substantially controls the current ANDA litigation and terms of settlement and has different economic interests than ours, Allergan may grant licenses to generic manufacturers that permit them to make and sell generic versions of Namenda XR<sup>®</sup>, which would negatively impact the royalties we receive under our license with Allergan;
- disputes may arise between us and a partner that causes the delay or termination of the research, development, or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- agreements may be terminated, sometimes at-will, without penalty, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- partners may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- a partner's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

***We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of these trials.***

We do not independently conduct clinical studies of our product candidates. Instead, we rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities, but does not relieve

us of our responsibilities. For example, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practice, for conducting, recording, and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of patients in clinical studies are protected, even though we are not in control of these processes. These third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. The FDA may inspect certain of our clinical trial sites from the ADS-5102 development program for Good Clinical Practice compliance and data integrity prior to being able to approve, if at all, our NDA for LID. Adverse findings in such inspections could result in the issuance of a Complete Response Letter to our NDA.

We also rely on other third parties to store and distribute supplies for our clinical studies. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

### **Risks related to Namenda XR<sup>®</sup> and Namzanic<sup>®</sup>**

***Under our license agreement with Allergan, if Allergan fails to successfully commercialize Namenda XR<sup>®</sup> and Namzanic<sup>®</sup> for any reason or if the license agreement with Allergan is terminated, the potential royalties we expect to receive under our license agreement with Allergan may not occur or be minimal, and would have a negative impact on our revenue potential and harm our business.***

In November 2012, we entered into a license agreement with Allergan pursuant to which we granted Allergan a right to develop and commercialize Namenda XR<sup>®</sup> and Namzanic<sup>®</sup> in the United States. Under that agreement, we expect to receive future royalties from Allergan on the net sales of Namenda XR<sup>®</sup> and Namzanic<sup>®</sup>, starting in 2018 and 2020, respectively. If Allergan fails to successfully commercialize Namenda XR<sup>®</sup> and, more importantly, Namzanic<sup>®</sup>, on which we are eligible to receive double digits percentage royalties for any reason, we may not receive such future royalties or receive minimal amounts, and our business will be harmed.

Under the license agreement, we are reliant on Allergan to commercialize Namenda XR and Namzanic and in that capacity Allergan has as the discretion to:

- determine the efforts and resources that they apply towards commercialization;
- market, manufacture, and distribute the licensed products or to otherwise not perform satisfactorily in carrying out these activities; and
- to terminate the agreement without penalty and, such termination, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products.

***Under the license agreement, Allergan substantially controls the intellectual property rights subject to the agreement and the current ANDA litigation and potential settlement thereof, and has economic interests different from ours. Accordingly, Allergan may manage the litigation and settlements on terms which may have a material and negative impact on our business.***

We and Allergan are currently involved in ANDA litigation to enforce our intellectual property rights against generic manufacturers, who are seeking to bring generic versions of Namenda XR<sup>®</sup> and Namzanic<sup>®</sup> to the market. See *Litigation* in “Note 8 - Commitments and Contingencies” in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report. Under the terms of that license agreement, Allergan has the right to enforce such intellectual property rights and control such litigation. Specifically, Allergan has the discretion to:

- maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; and
- not adequately pursue litigation against ANDA filers or settle such litigation on unfavorable terms, and as Allergan substantially controls the current ANDA litigation and terms of settlement and has different economic interests than ours, Allergan may grant licenses to generic manufacturers that permit them to make and sell generic versions of Namenda XR<sup>®</sup>, which would negatively impact the royalties we receive under our license with Allergan.



We have a right to participate in, but not control, such litigations. If Allergan decides not to enforce the intellectual property rights licensed under the agreement or the litigation is resolved in favor of the generic manufacturers or if the FDA approves the ANDA filed by the generic manufacturers, such manufacturers may be able to market and sell the generic form of the branded drug in competition with Namenda XR<sup>®</sup> and Namzaric<sup>®</sup>. This could harm our business.

### **Risks related to the operation of our business**

#### ***Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain, and motivate qualified personnel.***

We are highly dependent on our chief executive officer and the other members of our executive and scientific teams. Our executives may terminate their employment with us at any time. The loss of the services of any of these people could impede the achievement of our research, development, and commercialization objectives. We maintain “key person” insurance for our chief executive officer, but not for any other executives or employees. Any insurance proceeds we may receive under this “key person” insurance would not adequately compensate us for the loss of our chief executive officer’s services.

Recruiting and retaining qualified scientific, clinical, manufacturing, and commercial personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

#### ***We expect to expand our development, regulatory, and sales and marketing capabilities, and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

As of December 31, 2016, we had 69 full-time equivalent employees. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, informational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

#### ***We are an “emerging growth company,” and we cannot be certain whether the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

#### ***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, fires, extreme weather conditions, medical epidemics, and other natural or manmade disasters or business interruptions. The

occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our corporate headquarters is located in California and certain clinical sites for our product candidates, operations of our existing and future partners, and suppliers are or will be located near major earthquake faults and fire zones. The ultimate impact on us, our significant partners, suppliers, and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire, or other natural or manmade disaster.

***Any future operations or business arrangements with entities outside the United States present risks that could materially adversely affect our business.***

If we obtain approval to commercialize any approved products or utilize CMOs outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. If any product candidates that we may develop are approved for commercialization outside the United States, we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- difficulties in assuring compliance with foreign corrupt practices laws;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes or typhoons, floods, and fires.

***Our internal computer systems, or those of our CROs, CMOs, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.***

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs or commercialization efforts. For example, the loss of clinical study data from completed or ongoing clinical studies for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. While we back-up our internal computer systems periodically and store such data off-site or in the cloud, we can offer no assurance that such off-site storage of data will allow us to continue our business without interruptions to our operations, which could result in a material disruption of our drug development programs or commercialization efforts. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

***Risks generally associated with a company-wide implementation of information systems, including an enterprise resource planning (ERP) system, may adversely affect our business and results of operations or the effectiveness of our internal controls over financial reporting.***

In support of our anticipated growth and future commercial-stage operations, we intend to select and implement a number of company-wide information systems, including a new human resource information system, adding new functionality to our enterprise resource planning (“ERP”), and other similar systems. Many of these systems are complex and their successful and timely implementation is not assured, requires significant capital expenditures, and can be disruptive to our

business operations. We recently purchased and implemented a new ERP system. This project has required and may continue to require investment of capital and human resources, the re-engineering of processes of our business, including our procurement process, and the attention of many employees who would otherwise be focused on other aspects of our business. Any deficiencies in the design and implementation of the new ERP system could result in potentially much higher costs than we had incurred and could adversely affect our ability to develop and launch solutions, provide services, fulfill contractual obligations, file reports with the SEC in a timely manner, operate our business, or otherwise affect our controls environment. Any of these consequences could have an adverse effect on our results of operations and financial condition.

### **Risks related to intellectual property**

***Our ability to successfully commercialize our technology and products may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our technologies and product candidates.***

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain or enforce the patents, covering technology or products that we license to third parties or that we may license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us or from us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the United States Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights is highly uncertain.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In March 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a “first to invent” to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear, as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the “first-to-file” provisions, only became effective in March 2013. In addition, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our

patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

From time to time, we may become involved in opposition, interference, derivation, *inter partes* review, or other proceedings challenging our patent rights or the patent rights of others, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us or Allergan, without payment to us.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of our owned or licensed patents being narrowed, invalidated, or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our product candidates in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***Obtaining and maintaining our patent protection depends upon compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent prosecution process and following the issuance of a patent. Our failure to comply with such requirements could result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case if our patent were in force.

***We may become involved in lawsuits or other proceedings to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming, and unsuccessful.***

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we or our licensees may be required to file infringement claims, which can be expensive and time-consuming. For example, we, Forest, Forest Laboratories, Inc., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH filed patent infringement lawsuits under Forest's patents and patents owned by us and licensed to Forest, against several manufacturers of generic pharmaceuticals that have filed ANDAs with the FDA seeking approval to manufacture and sell generic versions of Namzaric<sup>®</sup> and Namenda XR<sup>®</sup>. We anticipate that the prosecution of the lawsuits will require a significant amount of time and attention of our chief executive officer and other senior executives. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any of the Forest litigations or any other litigation or proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Such a result could limit our ability to prevent others from using or commercializing similar or identical technology and products, limit our ability to prevent others from launching generic versions of our products

and could limit the duration of patent protection for our products, all of which could have a material adverse effect on our business. A successful challenge to our patents could reduce or eliminate our right to receive royalties from Forest. Furthermore, because of the substantial amount of 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.

***Third parties may initiate legal proceedings alleging that we or our partners are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends upon our ability and the ability of our partners to develop, manufacture, market, and sell our product candidates and to use our proprietary technologies without infringing, misappropriating, or otherwise violating the proprietary rights or intellectual property of third parties. We or our partners may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, re-examination, *inter partes* review, post-grant review, opposition, or similar proceedings before the USPTO and its foreign counterparts. The costs of these proceedings could be substantial, and the proceedings may result in a loss of such intellectual property rights. Some of our competitors may be able to sustain the costs of complex patent disputes and litigation more effectively than we can, because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any disputes or litigation could adversely affect our ability to raise the funds necessary to continue our operations. Third parties may assert infringement claims against us or our partners based on existing patents or patents that may be granted in the future. Under our license agreement with Allergan we are obliged to indemnify Allergan under certain circumstances and our royalty entitlements may also be reduced. Our indemnification obligation to Allergan, while subject to customary limitations, has no monetary cap, and our right to receive royalties from Allergan may be eliminated in any calendar quarter in which certain third party generic competition exists. If we or our partners are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***We may be unable to protect the confidentiality of our trade secrets, thus harming our business and competitive position.***

In addition to our patented technology and products, we rely upon trade secrets, including unpatented know-how, technology, and other proprietary information, to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees, our partners, and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. However, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute such agreements, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. In addition, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement.

While to our knowledge the confidentiality of our trade secrets has not been compromised, if the employees, consultants or partners that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated, or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect our intellectual property to the same extent as the laws of the United States. If our trade secrets are disclosed or misappropriated, it would harm our ability to protect our rights and adversely affect our business.

## Risks related to government regulation

***The regulatory approval process is expensive, time consuming, and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.***

The research, development, manufacturing, quality control, labeling, approval, safety, effectiveness, storage, record keeping, reporting, selling, import, export, advertising, promotion, marketing, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, and by regulatory authorities in other countries, with different regulations from country to country. Neither we nor our collaboration partners are permitted to market our product candidates in the United States or in third countries until we receive FDA approval of an NDA. We have not received marketing approval for any of our product candidates. Obtaining approval of an NDA or analogous marketing authorization outside of the United States can be a lengthy, expensive, and uncertain process.

To receive approval to commercialize any of our product candidates in the United States, we and our collaboration partners must demonstrate with substantial evidence from adequate and well-controlled clinical studies, and to the satisfaction of the FDA, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we and our collaboration partners believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA. Administering any of our product candidates to humans may produce undesirable side effects, which could interrupt, delay, or cause suspension of clinical studies of our product candidates and result in the denial of approval of our product candidates for any or all targeted indications.

FDA approval of an NDA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense we invest, failure can occur at any stage, and we could encounter problems that require us to repeat clinical studies, perform additional preclinical studies and clinical studies, or abandon development and commercialization of a product candidate altogether. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on, among other factors, the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. The FDA can delay, limit, or deny approval of a product candidate for many reasons, including, but not limited to:

- disagreement with the design or implementation of our clinical trials;
- failure of clinical trials to show the level of statistical significance or clinical meaningfulness needed for approval;
- failure to demonstrate that a product candidate is safe or effective;
- insufficient data from preclinical and clinical studies to support an application;
- a finding by an institutional review board (IRB), Data Safety Monitoring Board (DSMB), Data Monitoring Committee (DMC), or the FDA that the clinical trial exposes subjects or patients to an unacceptable health risk;
- disapproval of our or our third-party manufacturer's processes or facilities; or
- changes to FDA's approval policies or regulations.

If any of our product candidates fails to demonstrate safety and efficacy in clinical studies or does not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

***If the FDA concludes that our product candidates do not satisfy the requirements for approval under the Section 505(b)(2) regulatory approval pathway, or if the requirements for approval under Section 505(b)(2) are not as we expect, the approval pathway for our products will likely take significantly longer, cost significantly more, and entail significantly greater complications and risks than anticipated, and in any case may not be successful. Similar obstacles may arise in other countries.***

We are developing our current and future product candidates, including ADS-5102, with the expectation that they will be eligible for approval through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the FDCA allows an NDA to rely in part on the FDA's prior conclusions regarding the safety and effectiveness of an approved drug product, or reference listed drug (RLD). Use of the Section 505(b)(2) regulatory pathway could reduce the time required for the development programs of our product candidates by, for example, potentially decreasing the amount of preclinical and/or clinical data specific to a product candidate that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide

additional data and information, and meet additional standards for product approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and the complications and risks associated with regulatory approval would likely substantially increase. Moreover, our inability to pursue the Section 505(b)(2) regulatory pathway may result in competitive products reaching the market more quickly than our product candidates, which would adversely impact our competitive position and prospects. Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee that utilizing this pathway will ultimately lead to faster product development or earlier approval for ADS-5102 or any other product candidate that we may attempt to develop and commercialize.

An NDA submitted through the Section 505(b)(2) regulatory pathway for a drug product with an active moiety that has been previously approved in another product (e.g., amantadine) may be entitled to three years of regulatory exclusivity if the NDA contains data from clinical investigations (other than bioavailability or bioequivalence studies) conducted by or for the sponsor and deemed essential to FDA's approval of the NDA. This regulatory exclusivity precludes, among other things, approval of another 505(b)(2) NDA for a product with the same conditions of approval. Although obtaining such exclusivity for our product candidates could provide a competitive benefit for us, the availability of such exclusivity to competitors, if their products were to be approved before our product candidates, presents a risk. If a competing product were approved in our target indication and granted three years of exclusivity, and if the FDA were to find that our product candidate does not differ with respect to the relevant conditions of approval of the approved competing product, then approval of the 505(b)(2) NDA for our product candidate in the target indication may be delayed for as long as the competitor has exclusivity.

With a Section 505(b)(2) NDA, we also must certify to the FDA concerning any patents listed for the RLD in the Orange Book. A certification that our product candidate does not infringe the RLD's Orange Book-listed patents, or that such patents are invalid (known as a paragraph iv certification) would require providing notice of that certification to the patent holder and the sponsor of the RLD NDA, and we could then be challenged in court by the patent owner or the holder of the approved NDA for the RLD. If such a lawsuit were to be filed within a specified timeframe, it would lead to a 30-month period during which FDA would be precluded from approving our NDA.

***Even if we receive regulatory approval for a particular product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.***

Once regulatory approval has been granted for a particular product candidate, the manufacturing, marketing, and further development of the approved product are subject to continual review by the FDA and/or analogous non-U.S. regulatory authorities. Any regulatory approval that we or our collaboration partners receive for our product candidates will be subject to limitations on the indicated uses for which the product may be marketed, and may be subject to requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. In addition, if the FDA and/or analogous non-U.S. regulatory authorities approve any of our product candidates, we will be subject to extensive and ongoing regulatory requirements with regard to the labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion, tracking, recordkeeping, and periodic reporting for our products. Further, we and our contract manufacturers of our drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance and maintenance of records and documentation. Regulatory authorities must approve manufacturing facilities before they can be used to manufacture our drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. Certain changes to the manufacturing processes for our product candidates, if approved, would also be subject to pre-approval by regulatory authorities. In addition, if we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, its manufacturer, or us, including but not limited to requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or applicable non-U.S. regulatory authorities, we could be subject to administrative or other sanctions, including:

- warning letters or untitled letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension, variation, or withdrawal of regulatory approval;
- suspension of ongoing clinical studies;
- voluntary or mandatory product recalls;

- requirements for dissemination of corrective information or modifications to promotional materials;
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications filed by us;
- refusal to permit import or export of our products;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products.

Regulatory requirements and policies may change, and we may need to comply with additional laws and regulations that are enacted. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market, or continue to market, our future products and our business may suffer.

***Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.***

We may decide to seek marketing authorizations to commercialize ADS-5102, ADS-4101, and other future product candidates outside of the United States. To market our future products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals.

Specifically, in the EU, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. Before granting an MA, the European Medicines Agency or the competent authorities of the member states of the EU make an assessment of the risk-benefit balance of the product on the basis of a Common Technical Document including, among other information, scientific criteria concerning its quality, safety, and efficacy.

Similarly to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU member states both before and after grant of the manufacturing and Marketing Authorizations. This includes control of compliance with cGMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures. We and our third-party manufacturers are required to ensure that all of our processes, methods, and equipment are compliant with cGMP. Failure by us or by any of our third-party partners, including suppliers, manufacturers, and distributors to comply with EU laws and the related national laws of individual EU member states governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products, both before and after grant of marketing authorization, and marketing of such products following grant of authorization may result in administrative, civil, or criminal penalties. These penalties could include delays in or refusal to authorize the conduct of clinical trials or to grant Marketing Authorization, product withdrawals and recalls, product seizures, suspension, or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties.

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from and be longer than that required to obtain FDA approval. Clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval as well as additional, different risks.

There is no assurance that we will be able to obtain marketing authorizations in foreign countries on a timely basis, if at all. We may not be able to file for foreign regulatory approvals, and even if we file we may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain non-U.S. regulatory approval to market our product candidates in other countries, we may not be able to achieve the financial results we project and our stock price could decline.

***Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payer cost-containment initiatives, may negatively impact our ability to generate revenues from or could limit or prevent our product candidates' commercial success.***

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in



significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, the PPACA was passed, which has substantially changed how healthcare is financed by both governmental and private insurers, and has significantly impacted the U.S. pharmaceutical industry. Details of changes under the PPACA are discussed in the business heading “Other healthcare regulations” in Part I, Item 1, of this Annual Report on Form 10-K.

Legislative and regulatory changes to the PPACA remain possible and appear likely in the 115th United States Congress and under the Trump Administration. We expect that the PPACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products. There have also been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries. If any of these proposals are adopted, they could result in our owing additional rebates, which could have a negative impact on revenues from sales of our products.

The continuing efforts of the government, insurance companies, managed care organizations, and other payers of healthcare services to contain or reduce costs of healthcare may, among other things, adversely affect:

- our ability to set a price we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Our ability to commercialize our products successfully, and to attract commercialization partners for our products, will depend in significant part on the availability of adequate financial coverage and reimbursement from third party payers, including, in the U.S., governmental payers such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Details of these considerations are discussed in the business heading “Other healthcare regulations” in Part I, Item 1, of this Annual Report on Form 10-K.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs that we may join if we successfully commercialize any of our product candidates, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

We intend to participate in and then will have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs.

Under the Medicaid Drug Rebate program, a manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to the Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

The PPACA made significant changes to the Medicaid Drug Rebate program, as discussed under the heading “Other healthcare regulations” in Part I, Item 1, of this Annual Report on Form 10-K. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the PPACA. These regulations became effective on April 1, 2016. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program may increase our costs and the complexity of compliance and could have a material adverse effect on our results of operations if we participate in the Medicaid Drug Rebate Program if and when we successfully commercialize any of our product candidates.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service’s 340B drug pricing program in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The PPACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts “orphan drugs” from the ceiling price

requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's final regulations implementing those changes also could affect the 340B ceiling price calculations for any of our product candidates that we successfully commercialize and could negatively impact our results of operations.

The PPACA obligates the Secretary of the HHS to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration, or HRSA, recently initiated the process of updating the agreement with participating manufacturers. The PPACA also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program. In 2015, HRSA issued proposed omnibus guidance that addresses many aspects of the 340B program, and in August 2016, HRSA issued a proposed regulation regarding an administrative dispute resolution process for the 340B program. It is unclear when or whether the guidance or regulation will be released in final form under the Trump Administration. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The March 6, 2017 effective date of this regulation is subject to a temporary delay directed by the Trump Administration, and the regulation could be subject to further delay or other modification by the Trump Administration. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate, if and when we successfully commercialize any of our product candidates and if we participate in the 340B program. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by the reporting manufacturer, governmental or regulatory agencies and the courts. In the case of Medicaid pricing data, if we join the Medicaid Drug Rebate Program and become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we will be obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations would increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we would be required to offer any of our product candidates that we successfully commercialize under the 340B drug discount program.

We will be liable for errors associated with any submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted any false price information to the government, we may be liable for civil monetary penalties in the amount of \$178,156 per item of false information. Our failure to submit the required price data on a timely basis could result in a civil monetary penalty of \$17,816 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we will participate in the Medicaid program if we join the program if and when we successfully commercialize any of our product candidates. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for any of our product candidates that we successfully commercialize.

CMS and the OIG have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions, if we participate in the federal programs if and when we successfully commercialize any of our product candidates, will not be found by CMS to be incomplete or incorrect.

In order to be eligible to have any of our product candidates that we successfully commercialize paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs ("VA"), Department of Defense, Public Health Service, and Coast Guard (the "Big Four agencies"), and certain federal grantees, we are required to participate in the VA Federal Supply Schedule ("FSS") pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make any of our product candidates that we successfully commercialize that meet the statutory definition of "covered drug" (biologics and single and innovator multiple source drugs) available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price ("FCP"), which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the "non-federal average manufacturer price" ("Non-FAMP"), which we will be required to calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of \$178,156 for each item of false information. The FSS contract also contains extensive disclosure and certification requirements.

Under Section 703 of the National Defense Authorization Act for FY 2008, we will be required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. If we overcharge the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects if we successfully commercialize any of our product candidates.

***If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations, and financial condition could be adversely affected.***

Healthcare providers, physicians, distributors, and third-party payers play a primary role in the distribution, recommendation, and prescription of any pharmaceutical product for which we obtain marketing approval. Our arrangements with third-party payers and customers expose us to broadly applicable federal and state fraud and abuse and other laws and regulations that may constrain the business or financial arrangements through which we market, sell and distribute any products for which we have obtained or may obtain marketing approval. The laws and regulations that may affect our ability to operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, lease, arrangement or recommendation of, any good, facility, item, or service for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs. Liability under the Anti-Kickback Statute may be established without a person or entity having actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- the federal civil False Claims Act, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds, or knowingly using false records or statements, to obtain payment from the federal government. In recent years, several pharmaceutical and other health care companies have faced enforcement actions under the False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government healthcare programs, providing free product to customers with the expectation that the customers would bill federal programs, product and patient assistance programs, including reimbursement services, and marketing products for off-label or unapproved uses;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which prohibits, 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 payer (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 statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. HIPAA also imposes obligations on certain entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, also governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to the federal government information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members; and

- analogous state laws and regulations, such as anti-kickback, and false claims laws, which may be broader in scope and apply to items or services reimbursed by any third-party payer, including commercial insurers. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-relating activities, including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and/or administrative penalties, damages, fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these or other 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.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. Moreover, the requirements governing drug pricing and reimbursement vary widely from country to country. For example, in the European Union the sole legal instrument at the European Union level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC (the Price Transparency Directive). The aim of the Price Transparency Directive is to ensure that pricing and reimbursement mechanisms established in European Union member states are transparent and objective, do not hinder the free movement and trade of medicinal products in the European Union, and do not hinder, prevent or distort competition on the market. The Price Transparency Directive does not, however, provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual European Union member states. The national authorities of the individual European Union member states are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some individual European Union member states adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other European Union member states adopt a system of reference pricing, basing the price or reimbursement level in their territory either, on the pricing and reimbursement levels in other countries, or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Furthermore, some European Union member states impose direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some European Union member states. These countries include the United Kingdom, France, Germany, and Sweden. The HTA process in the European Union member states is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the national healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA may influence the pricing and reimbursement status for specific medicinal products within individual European Union member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of a specific medicinal product vary between the European Union member states.

In 2011, Directive 2011/24/EU was adopted at European Union level. This Directive concerns the application of patients' rights in cross-border healthcare. The Directive is intended to establish rules for facilitating access to safe and high-quality cross-border healthcare in the European Union. Pursuant to Directive 2011/24/EU, a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This could lead to harmonization between European Union member states of the criteria taken into account in the conduct of HTA in pricing and reimbursement decisions and negatively impact price in at least some European Union member states.

***If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.***

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state

health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”). Although we are not directly subject to HIPAA—other than potentially with respect to providing certain employee benefits—we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient’s information and our research efforts could be delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

EU member states and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland has adopted similar restrictions. Data protection authorities from the different EU member states may interpret the applicable laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. Although there are legal mechanisms to allow for the transfer of personal data from the EU to the U.S., the decision of the European Court of Justice in the *Schrems* case (Case C-362/14 Maximilian Schrems v. Data Protection Commissioner) invalidated the Safe Harbor framework and increased uncertainty around compliance with European Union restrictions on cross-border data transfers. As a result of the decision, it was no longer possible to rely on safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the U.S. On February 29, 2016, however, the European Commission announced an agreement with the United States Department of Commerce (“DOC”) to replace the invalidated Safe Harbor framework with a new EU-U.S. “Privacy Shield.” On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. U.S. companies have been able to certify to the U.S. DOC their compliance with the privacy principles of the Privacy Shield since August 1, 2016. On September 16, 2016, the Irish privacy advocacy group Digital Rights Ireland brought an action for annulment of the European Commission decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). Case T-670/16 is still pending. If, however, the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the European Union to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. U.S.-based companies are permitted to rely either on their adherence to the EU-US Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the EU Data Protection Directive.

In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, introducing new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules, was agreed between the European Parliament, the Council of the European Union, and the European Commission. The EU General Data Protection Regulation entered into force on May 24, 2016 and will apply from May 25, 2018. The EU Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process and we will also face substantial fines for breaches of the data protection rules. We may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. Furthermore, there is a growth towards the public disclosure of clinical trial data in the European Union which adds to the complexity of processing health data from clinical trials.

If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EU or Switzerland to the U.S. (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the European Union or Switzerland is restricted.

## Risks related to ownership of our common stock

### *Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.*

Our stock price has fluctuated in the past and may be volatile in the future. The stock market in general and the market for securities of pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investments in our stock.

In addition, the clinical development stage of our operations may make it difficult for investors to evaluate the success of our business to date and to assess our future viability. The market price for our common stock may be influenced by many factors, including:

- whether or not our NDA for ADS-5102 for the treatment of LID in patients with Parkinson’s disease is approved by the FDA;
- the success of competitive products or technologies;
- results of clinical studies of our product candidates or those of our competitors;
- introductions and announcements of new products and product candidates by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our or our competitors’ products, product candidates, clinical studies, manufacturing process, or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be comparable to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing and our commercialization partners;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our current or future products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare reimbursement systems;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our current or future products;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry, and market conditions; and
- the other risks described in this “Risk Factors” section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Additionally, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of

management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations, and growth prospects.

***Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

***Concentration of ownership of our common stock among our existing executive officers, directors, and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own a significant percentage of our outstanding common stock. These persons, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

***We will continue to incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, and we could fail to successfully improve our systems, procedures, and controls, which could affect our operating results.***

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as well as new rules implemented by the SEC and the NASDAQ Stock Market LLC. We expect that we will need to continue to improve existing, and implement new operational, financial, and information management systems, procedures, and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures, or controls may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective.

***An active trading market for our common stock may not be maintained.***

Our stock is currently traded on NASDAQ, but we can provide no assurance that we will be able to maintain an active trading market on NASDAQ or any other exchange in the future or that the daily trading volume will be adequate to allow orderly purchases or sales of our common stock without significantly impacting the price per share. If an active market for our common stock is not maintained, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about us or our business, our stock price and trading volume could decline.***

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may cease to publish research on our company at any time in their discretion. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. In addition, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If our operating results fail to meet the forecast of analysts, our stock price will likely decline.

***Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our corporate charter and our bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include that:

- our board of directors is divided into three classes with staggered three-year terms, which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to change the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders may not act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors or the chairman of the board and chief executive officer;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may issue, without stockholder approval, shares of undesignated preferred stock, and the ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.***

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.



**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

The Company leases approximately 18,500 square feet of office space in Emeryville, California, under an operating lease that expires April 2020. We believe that our existing facility will be sufficient for our needs for the foreseeable future.

**ITEM 3. LEGAL PROCEEDINGS**

For information regarding legal proceedings, refer to *Litigation* in “Note 8 - Commitments and Contingencies” in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report, which information is incorporated by reference here.

**ITEM 4. MINE SAFETY DISCLOSURES**

The disclosure required by this item is not applicable.

**PART II****ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****PRICE RANGE OF COMMON STOCK**

Our common stock has been listed on The NASDAQ Global Market under the symbol “ADMS” since April 10, 2014. Prior to that date, there was no public trading market for our common stock. Our initial public offering was priced at \$16.00 per share on April 9, 2014. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market:

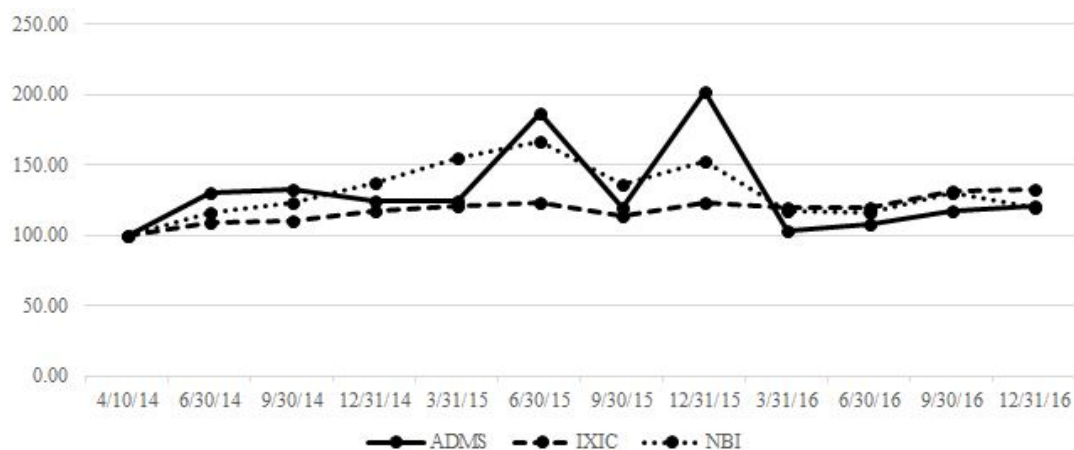
	<u>Low</u>	<u>High</u>
<b>Fiscal Year ended December 31, 2015</b>		
First Quarter	\$ 16.02	\$ 18.15
Second Quarter	\$ 16.55	\$ 27.60
Third Quarter	\$ 16.08	\$ 30.86
Fourth Quarter	\$ 12.73	\$ 31.84
<b>Fiscal Year ended December 31, 2016</b>		
First Quarter	\$ 12.02	\$ 28.23
Second Quarter	\$ 13.94	\$ 19.15
Third Quarter	\$ 12.81	\$ 19.50
Fourth Quarter	\$ 12.10	\$ 17.74

On February 23, 2017, the last reported sale price of our common stock as reported on The NASDAQ Global Market was \$17.25 per share.

As of February 23, 2017, there were 22,219,774 shares of our common stock issued and outstanding with 35 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

## STOCK PRICE PERFORMANCE GRAPH

The following stock performance graph compares our total stock return with the total return for (i) the NASDAQ Composite Index and the (ii) the NASDAQ Biotechnology Index for the period from April 10, 2014 (the date our common stock commenced trading on the NASDAQ Global Market) through December 31, 2016. The figures represented below assume an investment of \$100 in our common stock at the closing price of \$14.01 on April 10, 2014 and in the NASDAQ Composite Index and the NASDAQ Biotechnology Index on April 10, 2014 and the reinvestment of dividends into shares of common stock. The comparisons in the table are required by the Securities and Exchange Commission, or SEC, and are not intended to forecast or be indicative of possible future performance of our common stock. This graph shall not be deemed “soliciting material” or be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



## DIVIDEND POLICY

We have never declared or paid, and do not anticipate declaring, or paying in the foreseeable future, any cash dividends on our capital stock. Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our operating results, financial conditions, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

**ITEM 6. SELECTED FINANCIAL DATA**

You should read the following selected financial data together with the section of this report entitled “Management’s discussion and analysis of financial condition and results of operations” and our financial statements and the related notes included in this report. The statement of operations data for the years ended December 31, 2016, 2015, and 2014, and the balance sheet data as of December 31, 2016 and 2015, are derived from our audited financial statements included elsewhere in this report. Statement of operations data for the year ended December 31, 2013 and 2012, and balance sheet data as of December 31, 2014, 2013, and 2012, are derived from our audited financial statements not included herein. We have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results to be expected in the future, and our unaudited interim results are not necessarily indicative of the results to be expected for the full year or any other period.

	Years Ended December 31,				
	2016	2015	2014	2013	2012
(in thousands, except per share data)					
<b>Consolidated Statement of Operations data:</b>					
Revenue	\$ 572	\$ 1,916	\$ 55,846	\$ 71,095	\$ 37,471
Operating expenses					
Research and development	31,230	35,895	21,860	7,410	9,192
General and administrative, net	30,326	23,458	15,472	6,667	8,330
Total operating expenses	61,556	59,353	37,332	14,077	17,522
Income (loss) from operations	(60,984)	(57,437)	18,514	57,018	19,949
Interest and other income (expense), net	811	363	(917)	(4,906)	(1,913)
Income (loss) before income taxes	(60,173)	(57,074)	17,597	52,112	18,036
Provision (benefit) for income taxes	(115)	(5,272)	7,374	1,191	300
Net income (loss)	\$ (60,058)	\$ (51,802)	\$ 10,223	\$ 50,921	\$ 17,736
Net income (loss) attributable to common stockholders:					
Basic	\$ (60,058)	\$ (51,802)	\$ 8,968	\$ 33,068	\$ 11,441
Diluted	\$ (60,058)	\$ (51,802)	\$ 9,069	\$ 35,353	\$ 11,596
Net income (loss) per share attributable to common stockholders:					
Basic	\$ (2.77)	\$ (2.86)	\$ 0.60	\$ 3.48	\$ 1.21
Diluted	\$ (2.77)	\$ (2.86)	\$ 0.53	\$ 2.99	\$ 1.17
Weighted average number of shares used in computing net income (loss) attributable to common stockholders:					
Basic	21,711	18,111	14,837	9,506	9,488
Diluted	21,711	18,111	17,107	11,806	9,924

To date, substantially all of our revenue has been generated from our collaboration agreements, and we have not generated any commercial product revenue. Revenue in the years ended December 31, 2014, 2013, and 2012, includes recognition of revenue relating to upfront and milestone payments called for within our license agreement with Forest Laboratories Holdings Limited (“Forest”), an indirect wholly-owned subsidiary of Allergan plc (collectively, “Allergan”), effective November 13, 2012, of \$55.0 million, \$69.6 million, and \$35.4 million, respectively. See the section of this report entitled “Management’s discussion and analysis of financial condition and results of operations—Financial operations overview—Revenue” for a more detailed description of our revenue recognition with respect to these agreements.

	As of December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, and available-for-sale securities	\$ 135,944	\$ 119,960	\$ 158,722	\$ 85,612	\$ 62,957
Working capital	107,244	101,380	110,982	81,790	25,715
Total assets	142,473	128,743	161,189	86,216	64,303
Warrant liability	—	—	—	6,232	1,706
Total liabilities	10,290	12,556	14,115	10,462	40,186
Convertible preferred stock	—	—	—	19,149	19,149
Total stockholders' equity	132,183	116,187	147,074	56,605	4,968

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with the section of this report entitled "Selected financial data" and our financial statements and related notes included elsewhere in this report. This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk factors."*

### Overview

We are a pharmaceutical company that discovers and develops chrono-synchronous therapies to improve the daily lives of people affected by chronic neurologic disorders. Approximately 36 million people in the United States suffer from conditions such as Parkinson's disease, multiple sclerosis, epilepsy, and Alzheimer's disease. Currently available medicines may lead to sub-optimal symptom control in these disorders.

We pioneered a platform to develop medicines for chronic neurologic disorders based upon an understanding of time-dependent biologic processes responsible for disease activity and drug response. We call these medicines chrono-synchronous therapies. These therapies synchronize the temporal pattern of disease activity with the dynamics of drug profiles we invent without disrupting the brain's master clock, e.g. circadian rhythm. We believe the lives of patients with neurologic disorders are improved when these factors operate in unison.

We identify and develop chrono-synchronous therapies to patients by listening, studying, and innovating. To that end, our aim is to enable substantial treatment effects among the existing landscape of medicines. Our portfolio includes:

**ADS-5102:** a chrono-synchronous amantadine therapy with a U.S. Food and Drug Administration ("FDA") accepted New Drug Application ("NDA") for the treatment of levodopa-induced dyskinesia ("LID") in patients with Parkinson's disease. LID is a form of dyskinesia (abnormality or impairment of voluntary movement) associated with levodopa, a drug used to treat Parkinson's disease. Over time, 90% of Parkinson's disease patients on levodopa therapy will develop alternating periods of OFF time (e.g. rigidity) and LID, as their disease progresses. LID is characterized by involuntary movements that are purposeless and unpredictable. The NDA for ADS-5102 in LID has a Prescription Drug User Fee Act ("PDUFA") date, or deadline by which the FDA must review the NDA, of August 24, 2017, and, if approved, we plan to launch ADS-5102 in 2017. If approved, ADS-5102 will be the first and only medicine approved for the treatment of LID, and it will be the only Parkinson's disease medicine demonstrated to reduce both LID and OFF time.

In addition, we believe ADS-5102 has opportunities to provide symptomatic treatment of other hyper- and hypokinetic neurologic disorders, including but not limited to walking impairment in multiple sclerosis patients and other Parkinson's disease indications.

**ADS-4101:** a chrono-synchronous lacosamide therapy in clinical development for the treatment of partial onset seizures in patients with epilepsy. The active ingredient in ADS-4101 is lacosamide, an anti-epileptic previously approved by the FDA, which is currently marketed by UCB as VIMPAT® (lacosamide).

**Namenda XR®** (memantine hydrochloride) extended-release capsules and **Namzaric®** (memantine hydrochloride extended-release and donepezil hydrochloride) capsules: two commercially available drugs currently marketed by Forest Laboratories Holdings Limited ("Forest"), an indirect wholly-owned subsidiary of Allergan plc (collectively, "Allergan"), in the United States for the treatment of moderate to severe Alzheimer's disease. We are eligible to receive royalties on sales of Namenda XR® and Namzaric® beginning in June of 2018 and May of 2020, respectively.

Our goal is to bring products to market, which are differentiated and distinguished by our platform insights, independently or in collaboration with partners. From prior experience, we appreciate the value that commercial strategic alliances can bring to patients and Adamas stakeholders.

In 2017, we are focused on commercializing ADS-5102, if approved, for the treatment of LID in patients with Parkinson's disease. Based on our market research, we expect ADS-5102 to be well received by physicians, patients, and payers, as there are currently no approved therapeutic treatments for LID, which is an existing Parkinson's disease treatment gap. Our research also indicates that payers recognize the substantial unmet need of patients with LID and the potentially important value proposition of ADS-5102 in LID, as well as its secondary benefit in OFF time, when the symptoms of Parkinson's disease return.

**Financial operations overview****Summary**

Our revenue to date has been generated primarily from license, milestone, and development revenue pursuant to our license agreement with Allergan. We have not generated any commercial product revenue. As of December 31, 2016, we had an accumulated deficit of \$122.2 million. Although we reported net income in each of the years ended December 31, 2014, 2013, and 2012, this was primarily due to the recognition of revenue pursuant to our license agreement with Allergan. There are no further milestone payments to be earned under our license agreement with Allergan. We incurred significant losses in 2016, 2015, and prior to 2012, and expect to continue to incur significant losses as we advance our product candidates into later stages of development and, if approved, commercialization.

We plan to commercialize ADS-5102 for LID, if approved, and potentially other wholly-owned product candidates by developing a commercial organization, including either our own sales force or a contract sales organization, targeting neurologists and movement disorder specialists in the United States, or possibly through partnership agreements with pharmaceutical companies. Consequently, we expect general and administrative expenses to increase as we approach a potential product launch of ADS-5102 for LID anticipated to be later in 2017. In addition, we expect to continue to incur significant research and development expenses as we continue to advance our product candidates through clinical development. Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to predict the timing or amount of expenses incurred or when, or if, we will be able to achieve or maintain profitability.

Under our agreement with Allergan, beginning in May 2020, we are entitled to receive tiered royalties in the low to mid-teens for net sales of Namzaric® in the United States. In addition, we are also entitled to receive tiered royalties in the low to mid-single digits from Allergan for net sales of Namenda XR® in the United States beginning in June 2018; however, we do not expect the Namenda XR® royalties will make a significant financial contribution to our business. Pursuant to the agreement, we received a non-refundable upfront license fee of \$65.0 million in 2012, which we recognized on a straight-line basis from November 2012 to February 2013. We also earned and received additional cash payments totaling \$95.0 million upon achievement by Allergan of certain development and regulatory milestones, which we recognized in 2013 and 2014.

Prior to our initial public offering of our common stock, or IPO, in April 2014, we had raised an aggregate of approximately \$87.2 million through the sale of convertible preferred stock and \$1.0 million through the exercise of preferred stock warrants. In 2014, we issued and sold 3,081,371 shares of common stock in our IPO and received net proceeds of approximately \$42.6 million, which included partial exercise of the underwriters' option to purchase additional shares and after deducting underwriting discounts and offering expenses. In connection with the completion of our IPO, all convertible preferred stock converted into common stock. In June 2015, we entered into a Controlled Equity Offering Sales Agreement, pursuant to which we were able to issue and sell shares of common stock having an aggregate offering value of up to \$25.0 million, which was terminated in November 2016. During the term of the agreement, we issued 509,741 shares of common stock and raised net proceeds of \$9.7 million under the Sales Agreement. In January 2016, we raised \$61.8 million from the sale of 2,875,000 shares of common stock in a follow-on public offering.

As of December 31, 2016, we had cash, cash equivalents, and available-for-sale securities of \$135.9 million.

**Revenue**

We have not generated any revenue from commercial product sales to date. Our revenue to date has been generated primarily from non-refundable upfront license payments, milestone payments, reimbursements for research and development expenses and full-time equivalents assigned under our license agreement with Allergan, and to a lesser degree reimbursement for research and development expenses from NIH grants and government contracts.

The following table summarizes the sources of our revenue for the years ended December 31, 2016, 2015, and 2014 (in thousands):

	December 31,		
	2016	2015	2014
<b>Allergan:</b>			
Recognition of upfront license fees and milestones	\$ —	\$ —	\$ 55,040
Reimbursement of development costs	317	1,434	558
Allergan Total	317	1,434	55,598
NIH grants and government contracts	255	482	248
<b>Total revenue</b>	<b>\$ 572</b>	<b>\$ 1,916</b>	<b>\$ 55,846</b>

We recognized collaboration revenue of zero in both 2016 and 2015, and \$55.0 million in 2014, pursuant to our license agreement with Allergan. We also recognized revenue from Allergan of \$0.3 million, \$1.4 million, and \$0.6 million in reimbursements for research and development expenses for the years ended December 31, 2016, 2015, and 2014, respectively. We do not expect to recognize any further milestone payments under our license agreement with Allergan, and we expect reimbursements for full-time equivalents assigned to the license agreement to remain at modest levels in future periods. Beginning in May 2020, we will be entitled to receive royalties in the low to mid-teens from Allergan for net sales of Namzaric® in the United States, and in June 2018 we will be entitled to receive royalties in the low to mid-single digits for net sales of Namenda XR® in the United States; however, we do not expect the Namenda XR® royalties will make a significant financial contribution to our business. We were also awarded a continuation of an NIH grant for \$1.0 million in August 2014 that terminated in July 2016, which we administered, but conducted through subcontractors.

### **Research and development expenses**

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our wholly-owned product candidates and, to a lesser degree, the development of product candidates pursuant to our agreement with Allergan. We recognize all research and development costs as they are incurred.

Research and development expenses consist of:

- fees paid to clinical investigators, clinical trial sites, consultants, and vendors, including clinical research organizations, or CROs, in conjunction with implementing, conducting, and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as for investigator grants, patient screening fees, laboratory work, and statistical compilation and analysis;
- expenses related to production of clinical supplies, including fees paid to contract manufacturing organizations, or CMOs;
- expenses related to compliance with regulatory requirements;
- other consulting fees paid to third parties; and
- employee-related expenses, which include salaries, benefits, and stock-based compensation.

The following table summarizes our research and development expenses incurred during the years ended December 31, 2016, 2015, and 2014 (in thousands):

	December 31,		
	2016	2015	2014
ADS-5102	\$ 25,223	\$ 32,231	\$ 21,074
ADS-4101	1,659	—	—
Other research and development expenses	4,348	3,664	786
<b>Total research and development expenses</b>	<b>\$ 31,230</b>	<b>\$ 35,895</b>	<b>\$ 21,860</b>

The program-specific expenses summarized in the table above include costs directly attributable to our product candidates. Other research and development expenses include costs for early stage programs and costs not allocated to a specific program. We allocate research and development salaries, benefits, stock-based compensation, and indirect costs to our product candidates on a program-specific basis, and we include these costs in the program-specific expenses. We begin to track and report program-specific expenses for early stage programs once they have been nominated and selected for further development and clinical-stage work has commenced.

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. We anticipate incurring significant research and development expenses as we continue to support the FDA's review of ADS-5102 for LID, clinical trials for ADS-5102 in indications beyond LID, including but not limited to walking impairment in multiple sclerosis patients and other Parkinson's disease indications earlier in the Parkinson's disease treatment journey, ADS-4101 for treatment of epilepsy, and potentially additional clinical-stage programs in more indications or for future product candidates. The process of conducting the necessary clinical research to obtain FDA approval is costly and time consuming. We consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each product candidate and clinical program may be affected by a variety of factors, including but not limited to the quality of the product candidate, early clinical data, investment in the program, competition, manufacturing capability, and commercial viability. Furthermore, in the past we have entered into licensing arrangements with other pharmaceutical companies to develop and



commercialize our product candidates, and we may enter into additional licensing arrangements or collaborations in the future. In situations in which third parties have control over the clinical development of a product candidate, the estimated completion dates are largely under the control of such third parties and not under our control. We cannot forecast with any degree of certainty which of our product candidates, if any, will be subject to future licensing or collaboration arrangements or how such arrangements would affect our development plans or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

***General and administrative expenses, net***

General and administrative expenses, net, consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses, as well as increasingly the costs associated with establishing commercial capabilities in support of the potential launch of ADS-5102 for LID, reduced to a small degree by reimbursement from Allergan for external costs related to supporting prosecution and litigation of intellectual property rights under our license agreement. We anticipate our general and administrative expenses will increase significantly as we continue to establish our commercial capabilities and support our potential commercial-stage programs. If ADS-5102 is approved by the FDA, we plan to market and sell through our own sales force or through a contract sales organization, targeting neurologists and movement disorder specialists in the United States, or possibly through collaboration and license agreements with pharmaceutical companies.

***Interest and other income (expense), net***

Interest and other income (expense), net, consists primarily of interest received on our investments, as well as gains and losses resulting from the remeasurement of our convertible preferred stock warrant liability. We recorded adjustments to the estimated fair value of the convertible preferred stock warrants until they were exercised or expired. Subsequent to the IPO, we reclassified the convertible preferred stock warrant liability as additional paid-in capital and we no longer recorded any related periodic fair value adjustments.

**Critical accounting policies and significant judgments and estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We have discussed the development, selection, and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 of our financial statements included in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

**Revenue Recognition**

We recognize revenue when all four of the following criteria have been met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable, and (iv) collectability is reasonably assured. We recognize revenue under license arrangements based on the performance requirements of the contract. We make determinations of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered based on management's judgments regarding the fixed nature of the fees charged for deliverables and the collectability of those fees. Should changes in conditions cause management to determine that these criteria are not met for any new or modified transactions, revenue recognized could be adversely affected.

We generate revenue from collaboration and license agreements for the development and commercialization of products. Collaboration and license agreements may include non-refundable upfront license fees, partial or complete reimbursement of research and development costs, contingent consideration payments based on the achievement of defined objectives, and royalties on sales of commercialized products. Our performance obligations under the collaboration and license agreements may include the license or transfer of intellectual property rights, obligations to provide research and development services and related materials, and obligations to participate on certain development and/or commercialization committees with the partners.

For revenue agreements with multiple-element arrangements, we allocate revenue to each non-contingent element based on the relative-selling-price of each element in an arrangement. When applying the relative-selling-price method, we determine the selling price for each deliverable using the following estimation hierarchy: (i) vendor-specific objective evidence of fair value of the deliverable, if it exists, (ii) third-party evidence of selling price, if vendor-specific objective evidence is not available or (iii) the vendor's best estimate of selling price, if neither vendor-specific nor third-party evidence is available. Revenue allocated is then recognized when the four basic revenue recognition criteria, mentioned above, are met for each element.

We recognize payments that are contingent upon achievement of a substantive milestone in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can only be achieved based on our performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. We do not consider events that are contingent only on the passage of time or only on counterparty performance to be milestones subject to this guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms within the agreement and commensurate with our performance to achieve the milestone after commencement of the agreement.

We recognize amounts related to research and development funding and full-time equivalents assigned to the license agreement with Allergan as the related services or activities are performed, in accordance with the contract terms.

### Stock-Based Compensation

We account for stock-based compensation of stock options granted to employees and directors and for employee stock purchase plan shares by estimating the fair value of stock-based awards using the Black-Scholes option-pricing model. We account for stock-based compensation of restricted stock units granted to employees based on the closing price of our common stock on the date of grant. We recognize and amortize the fair value of stock-based awards, net of estimated forfeitures, over the applicable vesting period. We account for all stock options awarded to non-employees at the fair value of the consideration received or the fair value of the equity instrument issued, as calculated using the Black-Scholes model. We subject stock options granted to non-employees to periodic revaluation at each reporting date as the underlying equity instruments vest.

In order to estimate the value of share-based awards, we use the Black-Scholes model, which requires the use of certain subjective assumptions. The most significant subjective assumptions are management's estimates of the expected volatility and the expected term of the award. In addition, judgment is also required in estimating the amount of share-based awards that are expected to be forfeited. If actual results differ significantly from any of these estimates, stock-based compensation expense and our results of operations could be materially impacted.

### Clinical Trial Accruals

Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites, as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations ("CROs") that conduct and manage clinical trials on our behalf.

We estimate clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. In accruing service fees, we obtain the reported level of patient enrollment at each site and estimate the time period over which services will be performed and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

## Results of operations

### Comparison of the years ended December 31, 2016 and 2015

The following table summarizes our results of operations for the years ended December 31, 2016 and 2015 (in thousands, except percentages):

	December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2016	2015		
Revenue	\$ 572	\$ 1,916	\$ (1,344)	(70)%
Research and development expenses	31,230	35,895	(4,665)	(13)%
General and administrative expenses, net	30,326	23,458	6,868	29 %
Interest and other income, net	811	363	448	123 %

### Revenue

Revenue decreased by \$1.3 million, or 70%, to \$0.6 million for the year ended December 31, 2016 from \$1.9 million for the year ended December 31, 2015. Revenue for both periods in 2016 and 2015 was primarily related to reimbursement of certain expenses as provided for in our license agreement with Allergan, as well as from government contracts.

### Research and development expenses

Research and development expenses decreased by \$4.7 million, or 13%, to \$31.2 million for the year ended December 31, 2016 from \$35.9 million for the year ended December 31, 2015. The decrease in research and development expenses was mainly attributable to costs associated with the clinical development of ADS-5102, which decreased by \$7.0 million, or 22%, to \$25.2 million from \$32.2 million for the years ended December 31, 2016 and 2015, respectively, due to the conclusion of two Phase 3 clinical trials assessing ADS-5102 for the treatment of LID. The decrease was offset in part by increased efforts to support the preparation of the new drug application for ADS-5102 for the treatment of LID, in addition to increased expenses related to preclinical and clinical work associated with ADS-4101 for the treatment of partial onset seizures in patients with epilepsy in 2016 over the prior year period. Research and development expenses associated with other indications of ADS-5102 were flat year over year when comparing 2016 to 2015. Included in research and development expenses was stock-based compensation expense, which was \$2.9 million compared to \$3.2 million for the years ended December 31, 2016 and 2015, respectively.

### General and administrative expenses, net

General and administrative expenses, net, increased by \$6.9 million, or 29%, to \$30.3 million for the year ended December 31, 2016 from \$23.5 million for the year ended December 31, 2015. The increase in general and administrative expenses was primarily due to increased costs associated with establishing commercial capabilities in anticipation of the commercial launch of ADS-5102 for the treatment of LID, pending regulatory approval, including an increase in headcount-related expenses. General and administrative expenses also included stock-based compensation expense of \$7.7 million compared to \$6.8 million for the years ended December 31, 2016 and 2015, respectively.

### Interest and Other income, net

Interest and other income, net, increased by \$0.4 million, or 123%, to \$0.8 million for the year ended December 31, 2016, from \$0.4 million for the year ended December 31, 2015. Net interest income is primarily due to interest income earned on investments.

### Comparison of the years ended December 31, 2015 and 2014

The following table summarizes our results of operations for the years ended December 31, 2015 and 2014 (in thousands, except percentages):

	December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2015	2014		
Revenue	\$ 1,916	\$ 55,846	\$ (53,930)	(97)%
Research and development expenses	35,895	21,860	14,035	64 %
General and administrative expenses, net	23,458	15,472	7,986	52 %
Interest and other income (expense), net	363	(917)	1,280	140 %

### Revenue

Revenue decreased by \$53.9 million, or 97%, to \$1.9 million for the year ended December 31, 2015 from \$55.8 million for the year ended December 31, 2014. Revenue from license fees and milestones decreased to zero for the year ended December 31, 2015 from \$55.0 million for the year ended December 31, 2014 entirely due to the timing, magnitude, and nature of specified amounts recognized under our license agreement with Allergan. No further license fees or milestones are due under our license agreement with Allergan. Reimbursement of development expenses relating to our license agreement with Allergan increased by \$0.9 million to \$1.4 million for the year ended December 31, 2015 from \$0.6 million for the year ended December 31, 2014.

### Research and development expenses

Research and development expenses increased by \$14.0 million, or 64%, to \$35.9 million for the year ended December 31, 2015 from \$21.9 million for the year ended December 31, 2014. The increase in research and development expenses was attributed to our continued development of ADS-5102, which increased by \$11.2 million, or 53%, to \$32.2 million from \$21.1 million for the years ended December 31, 2015 and 2014, respectively. The increase related primarily to

manufacturing of clinical supplies, increased headcount, as well as continued enrollment in our Phase 3 program in support of ADS-5102 for LID and our Phase 2 trial for the treatment of walking impairment associated with multiple sclerosis. There were also increased expenses not allocated to specific programs of \$2.9 million in 2015 over the prior year period, which were mostly comprised of consultant expenses. Included in research and development expenses was stock-based compensation expense, which was \$3.2 million compared to \$2.5 million for the years ended December 31, 2015 and 2014, respectively.

***General and administrative expenses, net***

General and administrative expenses, net, increased by \$8.0 million, or 52%, to \$23.5 million for the year ended December 31, 2015 from \$15.5 million for the year ended December 31, 2014. The increase in general and administrative expenses was primarily due to the increase in headcount-related expenses to expand our capabilities as a public and pre-commercial company. General and administrative expenses also included stock-based compensation expense of \$6.8 million compared to \$4.7 million for the years ended December 31, 2015 and 2014, respectively.

***Interest and other income (expense), net***

Interest and other income (expense), net increased by \$1.3 million or 140%, to a net interest and other income of \$0.4 million for the year ended December 31, 2015 from a net expense of \$0.9 million for the year ended December 31, 2014. Net interest income for the year ended December 31, 2015 was primarily due to interest income earned on investments. In the year ended December 31, 2014, we recorded other expense, primarily attributed to the remeasurement of preferred stock warrants and recognition of the change in fair value.

**Liquidity, capital resources and plan of operation**

We have funded our operations primarily through \$160.0 million of payments received pursuant to our license agreement with Allergan, \$88.2 million sales of convertible preferred stock and warrants, and \$114.1 million pursuant to sales of our common stock. In April 2014, we completed our IPO and raised net proceeds of \$42.6 million, including the underwriters' partial exercise of their option to purchase additional shares. On June 1, 2015, we entered into a Controlled Equity Offering Sales Agreement, pursuant to which we were able to, from time to time, issue and sell shares of common stock having an aggregate offering value of up to \$25.0 million. As of December 31, 2016, we had issued 509,741 shares of common stock and raised net proceeds of \$9.7 million under the Sales Agreement. The Sales Agreement was terminated in November 2016. On January 6, 2016, we completed a follow-on public offering of 2,875,000 shares of common stock, which includes the exercise in full by the underwriters of their option to purchase 375,000 shares of common stock, at an offering price of \$23.00 per share. Proceeds from the follow-on public offering were approximately \$61.8 million, net of underwriting discounts and offering-related transaction costs.

We have not generated any revenue from the sale of products. We incurred losses and generated negative cash flows from operations since inception through the year ended December 31, 2011. Although we recognized a profit and positive cash flow in 2014, 2013, and 2012 as a result of payments received pursuant to our license agreement with Allergan, we received our final milestone payment from Allergan in December 2014. We do not currently receive any royalties from Allergan, nor do we have other license agreements or collaborations from which we might expect milestone or royalty revenue. Consequently, we expect to incur substantial and increasing losses for the foreseeable future. Our principal sources of liquidity were our cash, cash equivalents, and investments, which totaled \$135.9 million and \$120.0 million at December 31, 2016 and 2015, respectively.

We believe our existing cash, cash equivalents, and investments will be sufficient to fund our projected operating requirements, including operations related to the continued development and potential commercialization of ADS-5102 for the treatment of LID, for at least the next 12 months. However, it is possible that we will not achieve the progress that we expect, because the actual costs and timing of drug development, particularly clinical studies, and regulatory approvals are difficult to predict, subject to substantial risks and delays, and often vary depending on the particular indication and development strategy. Moreover, the costs associated with commercializing drugs are high and market acceptance is uncertain.

We expect to continue significant spending in connection with the development and commercialization of our product candidates, particularly for ADS-5102 for the treatment of LID, as well as other indications. In order to continue these activities, we may decide to raise additional funds through a combination of public or private equity offerings, debt financings, royalty financings, collaborations, strategic alliances, licensing arrangements, asset sales, and other marketing and distribution arrangements. Sufficient additional funding may not be available on acceptable terms, or at all. If adequate funds are not available in the future, we may need to delay, reduce the scope of, or put on hold our clinical studies, research and development programs, or commercialization efforts.

## Comparison of 2016 and 2015

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2016	2015
Net cash (used in) provided by:		
Operating activities	\$ (48,068)	\$ (47,210)
Investing activities	(26,709)	8,058
Financing activities	65,408	10,810
Net decrease in cash and cash equivalents	\$ (9,369)	\$ (28,342)

Net cash used in operating activities was \$48.1 million for the year ended December 31, 2016, compared to \$47.2 million for the year ended December 31, 2015. Net loss of \$60.1 million for the year ended December 31, 2016 included net non-cash adjustments of \$11.1 million, which consisted primarily of stock-based compensation of \$10.6 million. Net loss of \$51.8 million for the year ended December 31, 2015 included net non-cash adjustments of \$11.3 million, which consisted primarily of stock-based compensation of \$10.0 million. The primary use of cash was to fund the ongoing clinical studies and product development activities related to ADS-5102 for LID.

Net cash used in investing activities was \$26.7 million for the year ended December 31, 2016, compared to \$8.1 million of net cash provided by investing activities for the year ended December 31, 2015. Net cash used in investing activities for the year ended 2016 was a result of \$25.1 million in net purchases of available-for-sale securities, offset by \$1.6 million in purchases of property and equipment. Net cash provided by investing activities for the year ended 2015 was a result of \$9.5 million in net maturities of available-for-sale securities and \$1.4 million in purchases of property and equipment.

Net cash provided by financing activities was \$65.4 million for the year ended December 31, 2016, compared to \$10.8 million for the year ended December 31, 2015. In the year ended 2016 we received net cash proceeds of \$61.8 million related to the sale of common stock under a follow-on public offering coupled with \$3.6 million related to the exercise of stock options and from purchases of common stock under the Employee Stock Purchase Plan (ESPP). In year ended 2015 we received net cash proceeds of \$9.7 million related to the sale of common stock under a controlled equity offering coupled with \$1.2 million related to the exercise of stock options and from purchases of common stock under the ESPP.

## Comparison of 2015 and 2014

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2015	2014
Net cash (used in) provided by:		
Operating activities	\$ (47,210)	\$ 27,793
Investing activities	8,058	(97,380)
Financing activities	10,810	45,421
Net decrease in cash and cash equivalents	\$ (28,342)	\$ (24,166)

Net cash used in operating activities was \$47.2 million for the year ended December 31, 2015, compared to \$27.8 million of net cash provided by operating activities for the year ended December 31, 2014. Net loss of \$51.8 million for the year ended December 31, 2015 included net non-cash adjustments of \$11.3 million, which consisted primarily of stock-based compensation of \$10.0 million. Net income of \$10.2 million for the year ended December 31, 2014 included \$55.0 million in development milestone payments under our license agreement with Allergan. Net cash provided by operating activities for the year ended December 31, 2014 also included non-cash adjustments of \$7.1 million, primarily related to \$7.2 million in stock-based compensation and a change in the preferred stock warrant value of \$1.0 million, offset by net amortization of investment premiums of \$1.4 million. The primary use of cash was to fund the ongoing clinical studies and product development activities related to ADS-5102 for LID.

Net cash provided by investing activities was \$8.1 million for the year ended December 31, 2015, compared to \$97.4 million of net cash used in investing activities for the year ended December 31, 2014. Net cash provided by investing activities for the year ended 2015 was a result of \$9.5 million in net maturities of available-for-sale securities, offset by \$1.4 million in purchases of property and equipment. Net cash used in investing activities for the year ended 2014 resulted from the purchase of \$96.1 million of available-for-sale securities and \$1.3 million of property and equipment.

Net cash provided by financing activities was \$10.8 million for the year ended December 31, 2015, compared to \$45.4 million for the year ended December 31, 2014. In the year ended 2015 we received net cash proceeds of \$9.7 million related to the sale of common stock under a controlled equity offering, compared to \$42.6 million of net cash proceeds received from our initial public offering in the year ended 2014. In both the year ended 2015 and 2014 we received cash proceeds of \$1.2 million related to the exercise of stock options and from purchases of common stock under the ESPP.

#### Off-balance sheet arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities, or variable interest entities.

#### Contractual obligations

Our future contractual obligations at December 31, 2016 were as follows (in thousands):

	Total	Payments Due by Period			
		Less than 1 Year	2 - 3 Years	4 - 5 Years	More than 5 Years
<b>Contractual obligations:</b>					
Operating lease obligations	\$ 2,125	\$ 614	\$ 1,287	\$ 224	\$ —
Total contractual obligations	\$ 2,125	\$ 614	\$ 1,287	\$ 224	\$ —

#### Recent Accounting Pronouncements

For a discussion of new accounting pronouncements, see “Note 2 - Summary of Significant Accounting Policies” in the accompanying “Notes to Consolidated Financial Statements” in this annual report.

#### JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. As of December 31, 2016, we had cash, cash equivalents, and investments of \$135.9 million, consisting of cash and cash equivalents, as well as short and long-term investment grade available-for-sale securities. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration and our holdings in US government bonds and corporate debt securities mature prior to our expected need for liquidity, we believe that our exposure to interest rate risk is not significant and, as a consequence, a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**ADAMAS PHARMACEUTICALS, INC.  
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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders  
of Adamas Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive income (loss), of convertible preferred stock and stockholders' equity and cash flows present fairly, in all material respects, the financial position of Adamas Pharmaceuticals, Inc. and its subsidiaries (the "Company") as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California  
February 28, 2017



**ADAMAS PHARMACEUTICALS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share and per share data)

	December 31,	
	2016	2015
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 23,735	\$ 33,104
Available-for-sale securities	89,917	73,691
Accounts receivable	794	1,284
Prepaid expenses and other current assets	2,541	5,108
Total current assets	116,987	113,187
Property and equipment, net	3,156	2,353
Available-for-sale securities, non-current	22,292	13,165
Other assets	38	38
Total assets	\$ 142,473	\$ 128,743
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable	\$ 3,589	\$ 3,052
Accrued liabilities	5,867	8,457
Other current liabilities	287	298
Total current liabilities	9,743	11,807
Non-current liabilities	547	749
Total liabilities	10,290	12,556
Commitments and Contingencies (Note 8)		
Stockholders' equity		
Preferred stock, \$0.001 par value — 5,000,000 shares authorized, and zero shares issued and outstanding at December 31, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value — 100,000,000 shares authorized, 22,013,644 and 18,505,462 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	27	23
Additional paid-in capital	254,558	178,473
Accumulated other comprehensive loss	(193)	(158)
Accumulated deficit	(122,209)	(62,151)
Total stockholders' equity	132,183	116,187
Total liabilities and stockholders' equity	\$ 142,473	\$ 128,743

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

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

	Years Ended December 31,		
	2016	2015	2014
<b>Revenue</b>	\$ 572	\$ 1,916	\$ 55,846
<b>Operating expenses</b>			
Research and development	31,230	35,895	21,860
General and administrative, net	30,326	23,458	15,472
Total operating expenses	61,556	59,353	37,332
Income (loss) from operations	(60,984)	(57,437)	18,514
Interest and other income (expense), net	811	363	(917)
Income (loss) before income taxes	(60,173)	(57,074)	17,597
Provision (benefit) for income taxes	(115)	(5,272)	7,374
Net income (loss)	\$ (60,058)	\$ (51,802)	\$ 10,223
Net income (loss) attributable to common stockholders:			
Basic	\$ (60,058)	\$ (51,802)	\$ 8,968
Diluted	\$ (60,058)	\$ (51,802)	\$ 9,069
Net income (loss) per share attributable to common stockholders:			
Basic	\$ (2.77)	\$ (2.86)	\$ 0.60
Diluted	\$ (2.77)	\$ (2.86)	\$ 0.53
Weighted average number of shares used in computing net income (loss) attributable to common stockholders:			
Basic	\$ 21,711	\$ 18,111	\$ 14,837
Diluted	\$ 21,711	\$ 18,111	\$ 17,107

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

**ADAMAS PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**  
**(in thousands)**

	<u>Years Ended December 31,</u>		
	<u>2016</u>	<u>2015</u>	<u>2014</u>
Net income (loss)	\$ (60,058)	\$ (51,802)	\$ 10,223
Unrealized gain (loss) on available-for-sale securities	(35)	22	(180)
Comprehensive income (loss)	<u>\$ (60,093)</u>	<u>\$ (51,780)</u>	<u>\$ 10,043</u>

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

**ADAMAS PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY**

(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholder's Equity
	Shares	Amount	Shares	Amount				
<b>Balances at December 31, 2013</b>	4,719,174	\$ 19,149	9,515,528	\$ 14	\$ 77,163	\$ —	\$ (20,572)	\$ 56,605
Exercise of stock options	—	—	738,539	1	480	—	—	481
Excess tax benefit of stock option exercises	—	—	—	—	1,599	—	—	1,599
Exercise of common stock warrants	—	—	199,837	—	453	—	—	453
Issuance of Series AA preferred stock from the exercise of preferred stock warrants	622,660	8,747	—	—	—	—	—	—
Conversion of preferred stock to common stock in April 2014 in connection with the IPO	(5,341,834)	(27,896)	4,003,225	4	27,892	—	—	27,896
Issuance of common stock in initial public offering ("IPO"), net of discounts, commissions and issuance costs	—	—	3,081,371	3	42,629	—	—	42,632
Net unrealized loss on available-for-sale securities	—	—	—	—	—	(180)	—	(180)
Stock issued under employee stock purchase plan	—	—	12,875	—	162	—	—	162
Stock-based compensation	—	—	—	—	7,203	—	—	7,203
Net income	—	—	—	—	—	—	10,223	10,223
<b>Balances at December 31, 2014</b>	—	\$ —	17,551,375	\$ 22	\$ 157,581	\$ (180)	\$ (10,349)	\$ 147,074
Exercise of stock options	—	—	409,683	—	761	—	—	761
Vesting of common stock	—	—	—	—	112	—	—	112
Issuance of common stock in conjunction with Controlled Equity Offering, net of commissions and issuance costs	—	—	509,741	1	9,656	—	—	9,657
Issuance of common stock in conjunction with warrant exercises	—	—	3,484	—	—	—	—	—
Net unrealized gain on available-for-sale securities	—	—	—	—	—	22	—	22
Stock issued under employee stock purchase plan	—	—	31,179	—	407	—	—	407
Stock-based compensation	—	—	—	—	9,956	—	—	9,956
Net income	—	—	—	—	—	—	(51,802)	(51,802)
<b>Balances at December 31, 2015</b>	—	\$ —	18,505,462	\$ 23	\$ 178,473	\$ (158)	\$ (62,151)	\$ 116,187
Exercise of stock options	—	—	586,956	1	3,041	—	—	3,042
Vesting of common stock	—	—	—	—	34	—	—	34
Issuance of common stock in conjunction with Secondary Offering, net of commissions and issuance costs	—	—	2,875,000	3	61,819	—	—	61,822
Net unrealized gain on available-for-sale securities	—	—	—	—	—	(35)	—	(35)
Stock issued under employee stock purchase plan	—	—	46,226	—	620	—	—	620
Stock-based compensation	—	—	—	—	10,571	—	—	10,571
Net loss	—	—	—	—	—	—	(60,058)	(60,058)
<b>Balances at December 31, 2016</b>	—	\$ —	22,013,644	\$ 27	\$ 254,558	\$ (193)	\$ (122,209)	\$ 132,183

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

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

	Years Ended December 31,		
	2016	2015	2014
<b>Cash flows from operating activities</b>			
Net income (loss)	\$ (60,058)	\$ (51,802)	\$ 10,223
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities			
Depreciation	808	435	155
Stock-based compensation	10,571	9,956	7,203
Change in preferred stock warrant value	—	—	983
Net accretion of discounts and amortization of premiums of available-for-sale securities	(301)	875	(1,361)
Loss on fixed asset disposal	—	—	111
Changes in assets and liabilities			
Accrued interest of available-for-sale securities	(2)	110	—
Prepaid expenses and other assets	2,643	(4,416)	(381)
Accounts receivable	490	(760)	(395)
Accounts payable	502	(788)	1,521
Accrued liabilities and other liabilities	(2,721)	(820)	9,734
Net cash provided by (used in) operating activities	<u>(48,068)</u>	<u>(47,210)</u>	<u>27,793</u>
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(1,624)	(1,399)	(1,285)
Purchases of available-for-sale securities	(103,528)	(59,828)	(96,095)
Maturities of available-for-sale securities	78,443	69,285	—
Net cash provided by (used in) investing activities	<u>(26,709)</u>	<u>8,058</u>	<u>(97,380)</u>
<b>Cash flows from financing activities</b>			
Proceeds from public offerings, net of offering costs	61,822	9,657	42,632
Proceeds from issuance of common stock upon exercise of stock options	2,966	746	1,011
Proceeds from employee stock purchase plan	620	407	162
Repurchase of common stock	—	—	(370)
Proceeds from issuance of common and preferred stock upon exercise of warrants	—	—	1,986
Net cash provided by financing activities	<u>65,408</u>	<u>10,810</u>	<u>45,421</u>
Net decrease in cash and cash equivalents	<u>(9,369)</u>	<u>(28,342)</u>	<u>(24,166)</u>
Cash and cash equivalents at beginning of period	33,104	61,446	85,612
Cash and cash equivalents at end of period	<u>\$ 23,735</u>	<u>\$ 33,104</u>	<u>\$ 61,446</u>
<b>Supplemental disclosure</b>			
Cash paid for income taxes	\$ —	\$ 4,691	\$ 341
<b>Supplemental disclosure of noncash investing and financing activities</b>			
Purchases of property and equipment included in accounts payable and accrued expense	\$ 148	\$ 161	\$ —
Stock option exercise settled after period end	\$ 76	\$ —	\$ —

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**1. DESCRIPTION OF BUSINESS**

Adamas Pharmaceuticals, Inc. (the “Company”) is a pharmaceutical company that discovers and develops chrono-synchronous therapies to improve the daily lives of people affected by chronic neurologic disorders. The Company pioneered a platform to develop medicines for chronic neurologic disorders based upon an understanding of time-dependent biologic processes responsible for disease activity and drug response. The Company calls these medicines chrono-synchronous therapies. The Company’s portfolio includes:

**ADS-5102:** a chrono-synchronous amantadine therapy with a U.S. Food and Drug Administration (“FDA”) accepted New Drug Application (“NDA”) for the treatment of levodopa-induced dyskinesia (“LID”) in patients with Parkinson’s disease. LID is a form of dyskinesia (abnormality or impairment of voluntary movement) associated with levodopa, a drug used to treat Parkinson’s disease. The NDA for ADS-5102 in LID has a Prescription Drug User Fee Act (“PDUFA”) date, or deadline by which the FDA must review its NDA, of August 24, 2017, and, if approved, the Company plans to launch ADS-5102 later in 2017.

**ADS-4101:** a chrono-synchronous lacosamide therapy in clinical development for the treatment of partial onset seizures in patients with epilepsy. The active ingredient in ADS-4101 is lacosamide, an anti-epileptic previously approved by the FDA, which is currently marketed by UCB as VIMPAT<sup>®</sup> (lacosamide).

**Namenda XR<sup>®</sup>** (memantine hydrochloride) extended-release capsules and **Namzaric<sup>®</sup>** (memantine hydrochloride extended-release and donepezil hydrochloride) capsules: two commercially available drugs currently marketed by Forest Laboratories Holdings Limited (“Forest”), an indirect wholly-owned subsidiary of Allergan plc (collectively, “Allergan”) in the United States for the treatment of moderate to severe Alzheimer’s disease. The Company is eligible to receive royalties on net sales of Namenda XR<sup>®</sup> and Namzaric<sup>®</sup> beginning in June of 2018 and May of 2020, respectively.

In January 2016, the Company completed a follow-on public offering of 2,875,000 shares of its common stock, which includes the exercise in full by the underwriters of their option to purchase 375,000 shares of common stock, at an offering price of \$23.00 per share. Proceeds from the follow-on public offering were approximately \$61.8 million, net of underwriting discounts and offering-related transaction costs.

The Company was incorporated in the State of Delaware on November 15, 2000. The Company’s headquarters and operations are located in Emeryville, California. The Company has four insignificant subsidiaries.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES****Basis of Presentation**

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

**Use of Estimates**

The preparation of the accompanying consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in the consolidated financial statements and the accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, clinical trial accruals, fair value of assets and liabilities, income taxes, and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results may differ from those estimates.

**Liquidity and Financial Condition**

To date, a substantial majority of the Company’s resources have been dedicated to the research and development of its products. The Company has not generated any commercial revenue from the sale of its products, and does not anticipate the generation of any commercial product revenue until it receives the necessary regulatory approval to launch one of its products.

Based upon the current status of, and plans for, its product development and commercialization, the Company believes that the existing cash, cash equivalents, and investments of \$135.9 million as of December 31, 2016 will be adequate to satisfy the Company’s capital needs through at least the next twelve months. However, the process of developing and commercializing

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

products requires significant research and development, preclinical testing and clinical trials, manufacturing arrangements, as well as regulatory approvals. These activities, together with the Company's general and administrative expenses, are expected to result in significant operating losses until the commercialization of the Company's products or license agreements generate sufficient revenue to offset expenses. While the Company had net income during 2014, 2013, and 2012, it has not generated any commercial revenue from sales of its products. Under its license agreement with Allergan, the Company received the final milestone payment in 2014, and is not entitled to receive any royalties for net sales of Namzaric® until mid-2020 and Namenda XR® until mid-2018. To achieve sustained profitability, the Company, alone or with others, must successfully develop its product candidates, obtain required regulatory approvals, and successfully manufacture and market its products.

**Forward Stock Split**

In March 2014, the Board of Directors of the Company and stockholders approved a forward stock split of the Company's common and preferred stock. As a result, common and preferred stock, stock options, and warrants to purchase common and preferred stock were adjusted in the ratio of 2:1, effective March 24, 2014. All common and preferred shares and per share amounts presented in these condensed consolidated financial statements for all periods have been retroactively adjusted to reflect the 2-for-1 forward stock split. No fractional shares were issued.

**Cash and Cash Equivalents**

Cash and cash equivalents consist of highly liquid investments with original maturities, when purchased, of less than three months.

**Investments**

The Company classifies its investments as "available-for-sale." In general, these investments are free of trading restrictions. The Company carries these investments at fair value, based on quoted market prices or other readily available market information. Quoted market prices for U.S. government and corporate bonds include both principal and accrued interest components. Unrealized gains and losses are included in accumulated other comprehensive income, which is reflected as a separate component of stockholders' equity in its Consolidated Balance Sheets. Gains and losses are recognized when realized in its Consolidated Statements of Income. When the Company determines that an other-than-temporary decline in fair value has occurred, the amount of the decline that is related to a credit loss is recognized in income. Gains and losses are determined using the specific identification method. The Company considers all marketable debt securities with a maturity of less than one year to be short-term investments, with all others considered to be long-term investments.

All of the Company's available-for-sale securities are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. Factors considered in determining whether a loss is temporary include the length of time and extent to which the investments' fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, extent of the loss related to credit of the issuer, the expected cash flows from the security, its intent to sell or hold the security, and whether or not the Company will be required to sell the security before the recovery of its amortized cost.

**Consolidation**

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

**Segments**

In accordance with ASC 280-10-50, Segment Reporting, operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company operates in one reportable segment: the development and commercialization of therapeutics targeting chronic disorders of the central nervous system.

**Revenue Recognition**

The Company recognizes revenue when all four of the following criteria have been met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable, and (iv) collectability is reasonably assured. Revenue under license arrangements is recognized based on the performance requirements of the contract. Determinations of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments regarding the fixed nature of the fees charged for deliverables and the collectability of those fees. Should changes in conditions cause management to determine that these criteria are not met for any new or modified transactions, revenue recognized could be adversely affected.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company generates revenue from collaboration and license agreements for the development and commercialization of products. Collaboration and license agreements may include non-refundable upfront license fees, partial or complete reimbursement of research and development costs, contingent consideration payments based on the achievement of defined objectives, and royalties on sales of commercialized products. The Company's performance obligations under the collaboration and license agreements may include the license or transfer of intellectual property rights, obligations to provide research and development services and related materials, and obligations to participate on certain development and/or commercialization committees with the partners.

For revenue agreements with multiple-element arrangements, the Company allocates revenue to each non-contingent element based on the relative-selling-price of each element in an arrangement. When applying the relative-selling-price method, the Company determines the selling price for each deliverable using the following estimation hierarchy: (i) vendor-specific objective evidence of fair value of the deliverable, if it exists, (ii) third-party evidence of selling price, if vendor-specific objective evidence is not available, or (iii) the vendor's best estimate of selling price, if neither vendor-specific nor third-party evidence is available. Revenue allocated is then recognized when the four basic revenue recognition criteria, mentioned above, are met for each element.

The Company recognizes payments that are contingent upon achievement of a substantive milestone in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can only be achieved based on the Company's performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones subject to this guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms within the agreement and commensurate with the Company's performance to achieve the milestone after commencement of the agreement.

Amounts related to research and development funding and full-time equivalents assigned to the license agreement are recognized as the related services or activities are performed, in accordance with the contract terms.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents and short and long-term investments. Cash, cash equivalents, and investments are deposited with financial institutions or invested in security issuers that management believes are creditworthy. Deposits may, at times, exceed the amount of insurance provided on such deposits. To date, the Company has not experienced any losses on invested cash and cash equivalents.

**Risk and Uncertainties**

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, rapid technological change, uncertainty of results of clinical trials and reaching milestones, uncertainty of market acceptance of the Company's products, competition from substitute products and larger companies, protection of proprietary technology, strategic relationships, and dependence on key individuals.

Products developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that the products will receive the necessary approvals. If the Company is denied approval, approval is delayed, or the Company is unable to maintain approval, it could have a materially adverse impact on the Company.

The Company has expended and will continue to expend substantial funds to conduct research, development, and clinical testing of its product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of products that receive regulatory approval. The Company may require additional funds to conduct research and development activities and commercialize its products. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs or alter its product commercialization plans, which may materially and adversely affect its business, financial condition, and operations.

**Property and Equipment**

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and ten years. Leasehold improvements are amortized on a straight-line basis



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

over the lesser of their useful life or the term of the lease, which is five years. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is reflected in operations in the period realized.

**Leases**

At the inception of a lease, the Company evaluates the lease agreement to determine whether the lease is an operating, capital or build-to-suit lease using the criteria in ASC 840, "Leases." Certain lease agreements also require the Company to make additional payments for taxes, insurance, and other operating expenses incurred during the lease period, which are expensed as incurred. For operating leases, the Company recognizes rent expense on a straight-line basis over the lease term and records the difference between cash rent payments and the recognition of rent expense as a deferred liability. Where lease agreements contain rent escalation clauses, rent abatements and/or concessions, such as rent holidays and tenant improvement allowances, the Company applies them in the determination of straight-line expense over the lease term.

**Accounting for Long-Lived Assets**

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by the comparison of the carrying amount to the future net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There have been no such impairments of long-lived assets as of December 31, 2016.

**Clinical Trial Accruals**

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations ("CROs") that conduct and manage clinical trials on the Company's behalf.

The Company estimates clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage clinical trials on its behalf. In accruing service fees, the Company obtains the reported level of patient enrollment at each site and estimates the time period over which services are to be performed and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

**Research and Development**

Research and development ("R&D") expenses include salaries and related compensation, contractor and consultant fees, external clinical trial expenses performed by contract research organizations ("CRO"), licensing fees, acquired intellectual property with no alternative future use, and facility and administrative expense allocations. In addition, the Company funds R&D at research institutions under agreements that are generally cancelable at its option. Research costs typically consist of applied research and preclinical and toxicology work. Pharmaceutical manufacturing development costs consist of product formulation, chemical analysis, and the transfer and scale-up of manufacturing at facilities operated by the Company's contract manufacturers. Clinical development costs include the costs of Phase 1, Phase 2, and Phase 3 clinical trials. These costs are a significant component of the Company's research and development expenses.

The Company accrues costs for clinical trial activities performed by contract research organizations and other third parties based upon the estimated amount of work completed on each study as provided by the CRO. These estimates are reviewed for reasonableness by the Company's internal clinical personnel, and the Company aims to match the accrual to actual services performed by the organizations as determined by patient enrollment levels and related activities. The Company monitors patient enrollment levels and related activities using available information; however, if the Company underestimates activity levels associated with various studies at a given point in time, the Company could be required to record significant additional R&D expenses in future periods when the actual activity level becomes known. The Company charges all such costs to R&D expenses. Non-refundable advance payments are capitalized and expensed as the related goods are delivered or services are performed.

**Convertible Preferred Stock**

The Company classifies the convertible preferred stock as temporary equity on the balance sheets due to certain change of control events that are outside the Company's control, including liquidation, sale, or transfer of the Company, as

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

holders of the convertible preferred stock could have caused redemption of the shares. Shares of convertible preferred stock were converted to common stock upon close of the IPO in April 2014.

### Convertible Preferred Stock Warrants

The Company accounts for its convertible preferred stock warrants as a liability based upon the characteristics and provisions of each instrument. Convertible preferred stock warrants classified as a liability are recorded on the Company's balance sheet at their fair value on the date of issuance and were revalued on each subsequent balance sheet, with fair value changes recognized as increases or reductions in the statements of operations. The Company adjusted the liability for changes in fair value of these warrants until the earlier of: (i) exercise of warrants, (ii) expiration of warrants, (iii) a change of control of the Company, or (iv) the closing of the Company's IPO. At those times, the convertible preferred stock warrant liability was adjusted to fair value in the condensed consolidated statements of operations and comprehensive income and, upon the closing of the Company's IPO in April 2014, the final fair value was reclassified to additional paid-in capital.

### Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, short-term investments, accounts receivable, long-term investments and other current assets, other assets, accounts payable, accrued liabilities approximate fair value due to the short-term nature or determinable value of these items. The fair value of convertible preferred stock warrants is determined using readily available market information.

See also Note 4 for further details of the Company's fair value instruments.

### Income Taxes

The Company accounts for income taxes under the asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company follows the provisions of ASC 740, Income Taxes, under which it assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

### Basic and Diluted Net Income (Loss) Per Share

Basic net income (loss) per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is based upon the weighted average number of common shares outstanding and dilutive common stock equivalents outstanding during the period. Common stock equivalents are options granted under the Company's stock awards plans and are calculated under the treasury stock method. Common equivalent shares from unexercised stock options, unvested restricted stock units, and convertible preferred stock warrants are excluded from the computation when there is a loss as their effect is anti-dilutive, or if the exercise price of such options is greater than the average market price of the stock for the period.

Prior to April 10, 2014, the Company calculated its basic and diluted net income (loss) per share attributable to common stockholders in conformity with the two-class method required for companies with participating securities. Under the two-class method, the Company determined whether it had net income attributable to common stockholders, which includes the results of operations less current period convertible preferred stock non-cumulative dividends. If it was determined that the Company had net income attributable to common stockholders during a period, the related undistributed earnings were then allocated between common stock and the convertible preferred stock based on the weighted average number of shares outstanding during the period to determine the numerator for the basic net income per share attributable to common stockholders. In computing diluted net income attributable to common stockholders, undistributed earnings are re-allocated to reflect the potential impact of dilutive securities to determine the numerator for the diluted net income per share attributable to common stockholders.

### Stock-Based Compensation

The Company accounts for stock-based compensation of stock options granted to employees and directors and for employee stock purchase plan shares by estimating the fair value of stock-based awards using the Black-Scholes option-pricing model. The Company accounts for stock-based compensation of restricted stock units granted to employees based on the closing price of the Company's common stock on the date of grant. The fair value of stock-based awards are recognized and amortized over the applicable vesting period. All stock options awarded to non-employees are accounted for at the fair value of the consideration received or the fair value of the equity instrument issued, as calculated using the Black-Scholes model. Stock options granted to non-employees are subject to periodic revaluation at each reporting date as the underlying equity instruments vest.

In order to estimate the value of share-based awards, the Company uses the Black-Scholes model, which requires the use of certain subjective assumptions. The most significant subjective assumptions are management's estimates of the expected volatility and the expected term of the award. In addition, judgment is also required in estimating the amount of share-based awards that are expected to be forfeited. If actual results differ significantly from any of these estimates, stock-based compensation expense and the Company's results of operations could be materially impacted.

### Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*. The amendment in this ASU provides guidance on the revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The core principle of this update provides guidance to identify the performance obligations under the contract(s) with a customer and how to allocate the transaction price to the performance obligations in the contract. It further provides guidance to recognize revenue when (or as) the entity satisfies a performance obligation. This standard will replace most existing revenue recognition guidance. On July 9, 2015, the FASB approved a one-year deferral of the effective date of this standard to 2018 for public companies, with an option that would permit companies to adopt the standard as early as the original effective date of 2017. Early adoption prior to the original effective date is not permitted. Since the issuance of ASU 2014-09, the FASB has issued several amendments which clarify certain points, including ASU 2016-08, *Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, ASU 2016-10, *Identifying Performance Obligations and Licensing*, ASU 2016-11, *Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting*, and ASU 2016-12, *Narrow-Scope Improvements and Practical Expedients*. The Company plans to adopt the new standard in the first quarter of fiscal year 2018. The Company is currently evaluating the method of adoption and effect the new guidance will have on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This ASU provides guidance on management's responsibility in evaluating whether there is substantial doubt about a Company's ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about the company's ability to continue as a going concern within one year from the date the financial statements are issued. The amendments in this update are effective for annual periods ending after December 15, 2016, and for interim periods within annual periods beginning after December 15, 2016 with early adoption permitted. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. Under ASU 2015-17, a reporting entity is required to classify deferred tax assets and liabilities as noncurrent in a classified statement of financial position. Current guidance requiring the offsetting of deferred tax assets and liabilities of a tax-paying component of an entity and presentation as a single noncurrent amount is not affected. This ASU is effective for public business entities issuing financial statements for the annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for financial statements as of the beginning of an interim or annual reporting period. Entities may apply the update prospectively to all deferred tax assets and liabilities and taxes, or retrospectively for all periods presented. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The authoritative guidance significantly amends the current accounting for leases. Under the new provisions, all lessees will report a right-of-use asset and a liability for the obligation to make payments for all leases with the exception of those leases with a term of 12 months or less. All other leases will fall into one of two categories: (i) a financing lease or (ii) an operating lease. Lessor accounting remains substantially unchanged with the exception that no leases entered into after the effective date will be classified as leveraged leases. For sale leaseback transactions, a sale will only be recognized if the criteria in the new revenue recognition standard are met. For public

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

business entities, this guidance is effective for fiscal periods beginning after December 15, 2018 and interim periods thereafter. Early adoption is permitted. The Company is currently evaluating the effect the new guidance will have on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation*. The new guidance simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This guidance is effective for fiscal years beginning after December 15, 2016. Early adoption is permitted. The Company adopted ASU No. 2016-09 in the fourth quarter of fiscal 2016 and the implementation of this standard did not have a material impact on the consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments*. The new guidance changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. This guidance is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the effect the new guidance will have on its consolidated financial statements.

## 3. BALANCE SHEET COMPONENTS

## Prepaid expenses and other current assets (in thousands)

	December 31,	
	2016	2015
Income tax receivable	\$ 168	\$ 4,293
Prepaid expenses	1,279	545
Prepaid clinical trial	37	255
Other current assets	1,057	15
Prepaid expenses and other current assets	<u>\$ 2,541</u>	<u>\$ 5,108</u>

## Property and equipment, net (in thousands)

	December 31,	
	2016	2015
Computer equipment and software	\$ 2,128	\$ 869
Equipment	252	62
Furniture and fixtures	466	429
Leasehold improvements	1,645	1,619
	<u>4,491</u>	<u>2,979</u>
Less: Accumulated depreciation and amortization	(1,335)	(626)
Property and equipment, net	<u>\$ 3,156</u>	<u>\$ 2,353</u>

Depreciation expense was \$808,000, \$435,000, and \$155,000 for the years ended December 31, 2016, 2015, and 2014, respectively.

## Accrued liabilities (in thousands)

	December 31,	
	2016	2015
Accrued salaries and related benefit expenses	\$ 3,696	\$ 3,372
Clinical trial accruals	1,041	4,097
Accrued consulting and other professional fees	864	749
Income and other taxes	37	53
Other	229	186
Accrued liabilities	<u>\$ 5,867</u>	<u>\$ 8,457</u>

#### 4. FAIR VALUE MEASUREMENTS

In accordance with ASC 820-10, Fair Value Measurements and Disclosures, the Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1 inputs, which include quoted prices in active markets for identical assets or liabilities;
- Level 2 inputs, which include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability. For available-for-sale securities, the Company reviews trading activity and pricing as of the measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data; and
- Level 3 inputs, which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies, or similar valuation techniques, as well as significant management judgment or estimation.

The following table represents the fair value hierarchy for the Company's financial assets and liabilities which require fair value measurement on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2016			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market	\$ 192	\$ 192	\$ —	\$ —
Corporate debt	51,233	—	51,233	—
U.S. Treasury notes	60,976	—	60,976	—
<b>Total assets measured at fair value</b>	<b>\$ 112,401</b>	<b>\$ 192</b>	<b>\$ 112,209</b>	<b>\$ —</b>

	Fair Value Measurements at December 31, 2015			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market	\$ 23,430	\$ 23,430	\$ —	\$ —
Corporate debt	56,787	—	56,787	—
U.S. Treasury notes	30,069	—	30,069	—
<b>Total assets measured at fair value</b>	<b>\$ 110,286</b>	<b>\$ 23,430</b>	<b>\$ 86,856</b>	<b>\$ —</b>

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

Corporate debt and U.S. Treasury notes are measured at fair value using Level 2 inputs. The Company reviews trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

Upon issuance of the convertible preferred stock warrants, the Company estimated the fair value of the liability and subsequent remeasurement using the option pricing model at each reporting date, using the following inputs: the risk-free interest rates, the expected dividend rates, the remaining expected life of the warrants, and the expected volatility of the price of the underlying stock. The estimates were based, in part, on subjective assumptions and could differ materially in future periods. This results in the classification of the preferred stock warrant liability as Level 3 of the fair value hierarchy.

The following table includes a roll forward of the financial instruments classified within Level 3 of the fair value hierarchy (in thousands):

Fair Value Using Level 3 Inputs	Convertible Preferred Stock Warrant Liability
<b>Balance at December 31, 2013</b>	\$ 6,232
Change in fair value recorded in Other (income) expense, net	983
Exercise of warrants	(7,215)
<b>Balance at December 31, 2014</b>	—
<b>Balance at December 31, 2015</b>	—
<b>Balance at December 31, 2016</b>	\$ —

There were no transfers to or from Level 1 and Level 2 during the years ended December 31, 2016 and 2015.

## 5. INVESTMENTS

The Company's investments consist of corporate debt and U.S. Treasury notes classified as available-for-sale securities.

The Company limits the amount of investment exposure as to institution, maturity, and investment type. To mitigate credit risk, the Company invests in investment grade corporate debt and United States Treasury notes. Such securities are reported at fair value, with unrealized gains and losses excluded from earnings and shown separately as a component of accumulated other comprehensive income (loss) within stockholders' equity. Realized gains and losses are reclassified from other comprehensive income (loss) to other income (expense) on the condensed consolidated statements of operations when incurred. The Company may pay a premium or receive a discount upon the purchase of available-for-sale securities. Interest earned and gains realized on available-for-sale securities and amortization of discounts received and accretion of premiums paid on the purchase of available-for-sale securities are included in investment income.

The following table is a summary of amortized cost, unrealized gain and loss, and the fair value of available-for-sale securities as of December 31, 2016 and 2015 (in thousands):

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>Investments:</b>				
Corporate debt	\$ 51,354	\$ —	\$ (121)	\$ 51,233
U.S. Treasury notes	61,048	5	(77)	60,976
Total	\$ 112,402	\$ 5	\$ (198)	\$ 112,209
<b>Reported as:</b>				
Short-term investments	\$ 90,050	\$ 1	\$ (134)	\$ 89,917
Long-term investments	22,352	4	(64)	22,292
Total	\$ 112,402	\$ 5	\$ (198)	\$ 112,209
	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>Investments:</b>				
Corporate debt	\$ 56,892	\$ —	\$ (105)	\$ 56,787
U.S. Treasury notes	30,122	1	(54)	30,069
Total	\$ 87,014	\$ 1	\$ (159)	\$ 86,856
<b>Reported as:</b>				
Short-term investments	\$ 73,817	\$ 1	\$ (127)	\$ 73,691
Long-term investments	13,197	—	(32)	13,165
Total	\$ 87,014	\$ 1	\$ (159)	\$ 86,856

Short-term and long-term investments include accrued interest of \$0.3 million and \$0.1 million, respectively, as of December 31, 2016. Short-term and long-term investments includes accrued interest of \$0.4 million and \$36,000, respectively, as of December 31, 2015. The Company has not incurred any realized gains or losses on investments for the years ended December 31, 2016 and 2015. Investments are classified as short-term or long-term depending on the underlying investment's maturity date. Long-term investments held by the Company have a maturity date range of greater than 12 months and a maximum of 16 months as of December 31, 2016.

## 6. LICENSE AGREEMENTS

In November 2012, the Company granted Allergan an exclusive license, with right to sublicense, certain of the Company's intellectual property rights relating to human therapeutics containing memantine in the United States. In connection with these rights, Allergan markets and sells Namzaric® and Namenda XR® for the treatment of moderate to severe dementia related to Alzheimer's disease. Pursuant to the agreement, Allergan made an upfront payment of \$65.0 million. The Company earned and received additional cash payments totaling \$95.0 million upon achievement by Allergan of certain development and regulatory milestones. Under the agreement, external costs incurred related to the prosecution and litigation of intellectual property rights are reimbursable. For the twelve months ended December 31, 2016, reimbursed expenses amounting to \$2.4 million are reflected as a reduction to general and administrative, net. In addition, the Company may earn tiered royalty payments based on future net sales of Namzaric® and Namenda XR®.

The Company identified the following two non-contingent performance deliverables under the license agreement: (i) transfer of intellectual property rights, inclusive of the related technology know-how conveyance ("license and know-how" or "license") and (ii) the obligation to participate on the Joint Development Committee ("JDC"). The Company concluded that the license and the know-how together represent a single deliverable, and therefore the two together have been accounted for as a single unit of accounting. There was no separate consideration identified in the agreement for the deliverables and there was no right of return under the agreement. The Company considered the provisions of the multiple-element arrangement guidance in determining whether the deliverables outlined above have standalone value. The transfer of license and know-how has standalone value separate from the obligation to participate on the JDC, as the agreement allows Allergan to sublicense its rights to the acquired license to a third party. Further, the Company believes that Allergan has research and development expertise with compounds similar to those licensed under the agreement and has the ability to engage other third parties to develop these compounds, allowing Allergan to realize the value of the license and know-how without receiving the JDC participation.

The Company developed its best estimates of selling prices ("BESP") for each deliverable in order to allocate the non-contingent arrangement consideration to the two units of accounting. Based on BESP analysis, value assigned to the obligation to participate on the JDC was a negligible amount. Accordingly, the entire upfront license fee of \$65.0 million was allocated to the transfer of license and technical know-how. Revenue recognition commenced upon delivery of the license and was recognized on a straight-line basis through the period of the transfer of the know-how. Allergan was able to derive value from the license as the know-how was transferred. A straight-line pattern of revenue recognition is only acceptable when a more precise pattern cannot be discerned. The way in which the transfer of know-how occurred did not give rise to a more precise pattern of recognition, and the Company therefore recognized revenue on a straight-line basis over the period of the transfer of the know-how (from November 2012 to February 2013).

In November and December 2013, the Company received a total of \$40.0 million in milestone payments under its license agreement with Allergan. The milestone payments were for the successful completion of studies that supported the New Drug Application ("NDA") filing with the FDA for Namzaric® by Allergan. In May 2014, the Company received an additional \$25.0 million milestone payment under the license agreement. This milestone payment was a result of the FDA's acceptance of the NDA for Namzaric®. In December 2014, the Company received a final \$30.0 million milestone payment in connection with the FDA approval of Namzaric®. These amounts have been recorded as revenue when received in the consolidated statements of operations and comprehensive income during 2013 and 2014, respectively.

The Company is entitled to receive royalties on net sales in the United States by Allergan, its affiliates, or any of its sublicensees of controlled-release versions of memantine products covered by the terms of the license agreement. Beginning in May 2020, the Company will be entitled to receive royalties in the low to mid-teens from Allergan for sales of Namzaric® in the United States. Beginning in June 2018, the Company will be entitled to receive royalties in the low to mid-single digits for sales of Namenda XR® in the United States. Allergan's obligation to pay royalties with respect to fixed-dose memantine-donepezil products, including Namzaric®, continues until the later of (i) 15 years after the commercial launch of the first fixed-dose memantine-donepezil product by Allergan in the United States or (ii) the expiration of the Orange Book listed patents for which Allergan obtained rights from the Company covering such product. Allergan's obligation to pay royalties with respect to Namenda XR® continues until the expiration of the Orange Book listed patents covering such products. However, Allergan's

obligation to pay royalties for any product covered by the license is eliminated in any quarter where there is significant competition from generics.

## 7. WARRANTS TO PURCHASE COMMON OR PREFERRED STOCK

In conjunction with various financings between 2002 and 2012, the Company issued warrants to purchase 758,994 shares of convertible preferred stock and 127,780 shares of common stock. The relative fair value of these warrants was determined using the Black-Scholes model and was amortized to interest expense over the term of each loan, unless subsequently modified.

Immediately prior to the completion of the Company's IPO in 2014, 206,162 of the warrants to purchase common stock were either exercised for cash or automatically net exercised for a total issuance of 199,837 shares of common stock, pursuant to the terms of the warrants. In July 2015, warrants to purchase an aggregate of 7,116 shares of common stock were exercised in a cashless exercise, resulting in the issuance of 3,484 shares of common stock. As of December 31, 2016 and 2015, warrants to purchase zero and 7,116 shares of common stock were outstanding, respectively.

Prior to the IPO in April 2014, the warrants to purchase convertible preferred stock were classified as a liability and remeasured to fair value each reporting period. The Company had estimated the fair value of these liabilities using the Black-Scholes model and assumptions that were based on the individual characteristics of the warrants on the valuation date, as well as the assumptions for expected volatility, expected life, dividends, and risk-free interest rate. The remeasurement of the fair value of the outstanding warrants from December 31, 2013 through the date of the conversion to a common stock warrant and following the exercise resulted in a \$1.0 million expense recorded to other income (expense), net in the Company's consolidated statements of operations and comprehensive income. As of both December 31, 2016 and 2015, there were no warrants to purchase convertible preferred stock outstanding.

## 8. COMMITMENTS AND CONTINGENCIES

### Lease Commitments

The Company leases approximately 18,500 square feet of office space in Emeryville, California under an operating lease that expires April 30, 2020. The lease provides for periods of escalating rent. The total cash payments over the life of the lease are divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period.

As of December 31, 2016, future minimum lease payments under the non-cancelable facility operating lease were as follows (in thousands):

	<u>December 31, 2016</u>
2017	\$ 614
2018	634
2019	653
2020	224
2021	—
Thereafter	—
<b>Total</b>	<b>\$ 2,125</b>

The Company's total rent expense was approximately \$625,000, \$628,000, and \$277,000 for the years ended December 31, 2016, 2015, and 2014, respectively.

### Purchase Commitments

The Company enters into contracts in the normal course of business that include, among others, arrangements with clinical research organizations for clinical trials, vendors for pre-clinical research, and vendors for clinical supply manufacturing. These contracts generally provide for termination upon notice, and therefore the Company believes that its obligations under these agreements are not material.



## **Contingencies**

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown, because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

## **Indemnification**

In accordance with the Company's amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

## **Litigation**

In November 2012, the Company granted Forest an exclusive license to certain of the Company's intellectual property rights relating to human therapeutics containing memantine in the United States. Under the terms of that license agreement, Forest has the right to enforce such intellectual property rights which are related to its right to market and sell Namzatic<sup>®</sup> and Namenda XR<sup>®</sup> for the treatment of moderate to severe dementia related to Alzheimer's disease. The Company has a right to participate in, but not control, such enforcement actions by Forest.

As of the date of this filing, several companies have submitted Abbreviated New Drug Applications, or ANDAs, to the FDA requesting permission to manufacture and market generic versions of Namenda XR<sup>®</sup>, on which the Company is entitled to receive royalties from Forest beginning in June 2018. In the notices, these companies allege that the patents associated with Namenda XR<sup>®</sup>, some of which are owned by Forest or licensed by Forest from Merz Pharma GmbH & Co. KGaA, and others of which are owned by the Company and licensed by the Company exclusively to Forest in the United States, are invalid, unenforceable, and/or will not be infringed by the companies' manufacture, use, or sale of generic versions of Namenda XR<sup>®</sup>. The Company, Forest, Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (together Merz) filed lawsuits in the U.S. District Court for the District of Delaware for infringement of the relevant patents against all of these companies.

The Company and Forest have entered into a series of settlement agreements with all Namenda XR<sup>®</sup> ANDA filers, except for one defendant with respect to the certain patents subject to the Markman ruling described below. Entry dates for generic Namenda XR<sup>®</sup> are governed by the settlement agreements in that action. Subject to those agreements, the earliest date on which any of these agreements grants a license to market generic version of Namenda XR<sup>®</sup> is January 31, 2020 or in the alternative, an option to launch an authorized generic version of Namenda XR<sup>®</sup> beginning on January 31, 2021.

In January 2016, the Delaware District Court issued a claim construction (Markman) ruling in the Namenda XR<sup>®</sup> litigation that includes findings of indefiniteness as to certain claim terms in the asserted patents licensed by the Company to Forest. On July 26, 2016, the District Court issued a final judgment of invalidity on those patents based upon the Markman ruling. The Company and Forest filed the notice of appeal of that final judgment to the United States Court of Appeals for the Federal Circuit. The appeal is ongoing. If the appeal is unsuccessful, generic entry of Namenda XR<sup>®</sup> could occur prior to January 31, 2020.

Additionally, as of the date of this filing, a number of companies have submitted ANDAs requesting permission to manufacture and market generic versions of Namzatic<sup>®</sup>, on which the Company is entitled to receive royalties from Forest beginning in May 2020. The Company and Forest have begun to file lawsuits alleging infringement of the relevant patents against Namzatic<sup>®</sup> ANDA filers, who are seeking to launch generic versions of Namzatic<sup>®</sup>, in the same court as heard the Namenda XR<sup>®</sup> litigation. As of the date of this filing, the Company and Forest have settled with all but one active defendants, including the first filers on all the available dosage forms of Namzatic<sup>®</sup>, granting a license to market the first generic versions of Namzatic<sup>®</sup> on January 1, 2025 subject to the settlement agreements. The Company and Forest will continue to enforce the patents associated with Namzatic<sup>®</sup>.

From time to time, the Company may be party to legal proceedings, investigations, and claims in the ordinary course of its business. Other than the matters described above, the Company is not presently a party to any material legal proceedings.

## 9. CONVERTIBLE PREFERRED STOCK

The Company's amended and restated certificate of incorporation filed on April 15, 2014, authorizes 5,000,000 shares of preferred stock, of which there were no shares outstanding as of December 31, 2016 and 2015. Upon close of the IPO in April 2014, all of the Company's outstanding shares of convertible preferred stock were automatically converted into shares of common stock.

At December 31, 2013, the convertible preferred stock consisted of the below (in thousands except share and per share data). The fair value was approximately \$27.9 million upon completion of the IPO.

Series	Shares		Per Share Liquidation Preference	Carrying Value
	Authorized	Outstanding		
Series AA	5,000,000	3,431,620	\$ 3.81	\$ 6,521
Series AA-1	1,700,000	1,287,554	50.00	12,628
	6,700,000	4,719,174		\$ 19,149

## 10. STOCKHOLDERS' EQUITY

### Common Stock

The amended and restated certificate of incorporation authorizes the Company to issue 100,000,000 shares of common stock. Common stockholders are entitled to dividends as and when declared by the board of directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. Each share of common stock is entitled to one vote.

The Company has classified payments received for all unvested shares of common stock issued upon the early exercise of stock options as employee deposits (a liability) as these options are not considered to be substantively exercised until vested. At December 31, 2016 and December 31, 2015, zero and 3,000 shares of common stock, respectively, from early exercised options were unvested.

### Public Offering

In April 2014, the Company issued and sold 3,000,000 shares of its common stock in its initial public offering ("IPO") at a public offering price of \$16.00 per share, for net proceeds of approximately \$41.4 million after deducting underwriting discounts and commissions of approximately \$3.4 million and expenses of approximately \$3.2 million. In May 2014, the Company issued and sold 81,371 shares of its common stock pursuant to the underwriters' partial exercise of their option to purchase additional shares, for net proceeds of approximately \$1.2 million after deducting underwriting discounts and commissions of approximately \$91,000. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 4,003,225 shares of common stock. In addition, all of the Company's convertible preferred stock warrants outstanding at the close of the IPO were converted into common stock.

In January 2016, the Company completed a follow-on public offering of 2,875,000 shares of common stock, which includes the exercise in full by the underwriters of their option to purchase 375,000 shares of common stock, at an offering price of \$23.00 per share. Proceeds from the follow-on public offering were approximately \$61.8 million, net of underwriting discounts and offering-related transaction costs.

### Controlled Equity Offering

On June 1, 2015, the Company entered into a Controlled Equity Offering Sales Agreement ("Sales Agreement") with a sales agent, pursuant to which the Company was able to, at its discretion, issue and sell common stock from time to time with a value of up to a maximum of \$25.0 million in an at-the-market offering. The sales agent earned a 3% commission on gross proceeds for any sales of common stock made under the Sales Agreement. During the year ended December 31, 2016, there were no shares sold under the Sales Agreement. The Company sold a total of 509,741 shares under the Sales Agreement in 2015 at prevailing market prices with an average price of \$20.04 for net proceeds of \$9.7 million. The Sales Agreement was terminated in November 2016.

**Shares reserved for Future Issuance**

Shares of Company's common stock reserved for future issuance are as follows:

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Common stock awards issued and outstanding	5,483,557	5,328,378
Authorized for future issuance under 2014 Equity Incentive Plan	1,576,926	1,463,415
Authorized for future issuance under 2016 Inducement Plan	334,062	—
Employee stock purchase plan	532,849	394,148
<b>Total</b>	<u>7,927,394</u>	<u>7,185,941</u>

**11. STOCK-BASED COMPENSATION****Stock Compensation Plans**

In October 2002, the Company established its 2002 Employee, Director, and Consultant Stock Plan and in December 2007, the Company established its 2007 Stock Plan. No further grants were then made under the 2002 Plan.

In February 2014, the Company's board of directors adopted, and in March 2014 the Company's stockholders approved, the 2014 Equity Incentive Plan (the "2014 Plan"), which became effective on the completion of the IPO. No further grants were then made under the 2007 Plan. Under the 2014 Plan, 1,993,394 shares of the Company's common stock were made available for issuance which included all shares that, as of the effective time, were reserved for issuance pursuant to the 2007 Plan, and is subject to further increase for shares that were subject to outstanding options under the 2007 Plan and the 2002 Plan as of the effective time that thereafter expire, terminate, or otherwise are forfeited or reacquired. The number of shares of the Company's common stock reserved for issuance pursuant to the 2014 Plan will automatically increase on the first day of each fiscal year for a period of up to 10 years, commencing on the first day of the fiscal year following 2014, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding fiscal year, or a lesser number of shares as determined by the Company's board of directors. For 2016 and 2015, the common stock available for issuance under the 2014 Plan increased by 739,708 and 701,763 shares of common stock, respectively. As of December 31, 2016, the number of shares available for issuance under the 2014 Plan was 1,576,926.

Options granted under the 2014 Stock Plan may have terms of up to ten years. All options issued to date have had a ten year life. The exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the board of directors. The exercise price of an ISO and NSO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, respectively, as determined by the board of directors. The exercise price of a NSO shall not be less than the par value per share of common stock. The options granted generally vest over four years and vest at a rate of 25% upon the first anniversary of the issuance date and 1/48th per month thereafter. Restricted stock units granted vest at a rate of 25% per year over four years.

In March 2016, the Company's board of directors approved the 2016 Inducement Plan (the "Inducement Plan") under which 450,000 shares of the Company's common stock were made available for issuance. Options granted under the Inducement Plan may have terms of up to ten years. All options issued to date have had a ten year life. Consistent with the 2014 Plan, options granted generally vest over four years and vest at a rate of 25% upon the first anniversary of the issuance date and 1/48th per month thereafter. Restricted stock units granted vest at a rate of 25% per year over four years. The Inducement Plan was adopted by the board of directors without stockholder approval pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules.

## Stock Option Activity

The stock option and related activity under all of the Company's stock compensation plans is summarized as follows:

Stock Options	Outstanding Options		Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (thousands)
	Number of Shares	Weighted Average Exercise Price		
<b>Balances, December 31, 2015</b>	5,328,378	\$ 8.57		
Options granted	1,042,975	14.75		
Options exercised	(586,956)	5.18		
Options forfeited	(436,672)	13.85		
Options expired	(77,529)	17.70		
<b>Balances, December 31, 2016</b>	<u>5,270,196</u>	<u>\$ 9.60</u>	<u>7.06</u>	<u>\$ 39,744</u>
<b>Vested and expected to vest, December 31, 2016</b>	<u>5,123,793</u>	<u>\$ 9.49</u>	<u>7.03</u>	<u>\$ 39,182</u>
<b>Vested, December 31, 2016</b>	<u>3,178,726</u>	<u>\$ 7.12</u>	<u>6.25</u>	<u>\$ 31,719</u>

The aggregate intrinsic value of options outstanding, vested and expected to vest, and vested were calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of December 31, 2016 of \$16.90. During the years ended December 31, 2016, 2015, and 2014, the Company granted stock options to employees to purchase 1,030,375, 917,150, and 2,310,583 shares of common stock, respectively, with a weighted-average grant date fair value of \$9.15, \$11.47, and \$10.77, respectively. As of December 31, 2016, there was total unrecognized compensation cost related to unvested options of approximately \$19.1 million. This cost is expected to be recognized over a period of 2.4 years. The total fair value of employee stock options vested for the years ended December 31, 2016, 2015, and 2014 was \$8.4 million, \$10.0 million and \$0.9 million, respectively.

The options outstanding and exercisable by exercise price at December 31, 2016 is summarized as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number of Shares	Weighted-Average Remaining Life (in years)	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	
\$0.00 - 0.99	1,136,066	4.94	\$ 0.67	1,136,066	\$ 0.67	
\$1.00 - 8.99	538,052	5.02	2.71	538,052	2.71	
\$9.00 - 10.99	1,402,600	7.13	9.00	1,402,600	9.00	
\$11.00 - 16.99	1,049,597	8.87	14.45	268,046	14.74	
\$17.00 - 26.22	1,143,881	8.41	17.99	506,035	18.14	
	<u>5,270,196</u>	<u>7.06</u>	<u>\$ 9.60</u>	<u>3,850,799</u>	<u>\$ 7.26</u>	

The weighted average remaining contractual life and aggregated intrinsic value of options exercisable as of December 31, 2016 are 6.40 years and \$37.7 million, respectively. The aggregate intrinsic value of options exercised was approximately \$6.6 million, \$6.6 million, and \$10.0 million for the years ended December 31, 2016, 2015, and 2014, respectively. The aggregate intrinsic value is calculated as the pre-tax difference between the weighted-average exercise price of the underlying awards and the closing price per share of \$16.90 of the Company's common stock on December 31, 2016. The calculation excludes any awards with an exercise price higher than the closing price of the Company's common stock on December 31, 2016.

## Restricted Stock Unit Activity

The restricted stock unit and related activity under all of the Company's stock compensation plans is summarized as follows:

Restricted Stock Units	Outstanding Units	
	Number of Shares	Weighted-Average Grant Date Fair Value
<b>Unvested, December 31, 2015</b>	—	\$ —
Granted	229,561	14.59
Vested	—	—
Forfeited	(16,200)	13.66
<b>Unvested, December 31, 2016</b>	<b>213,361</b>	<b>\$ 14.66</b>

As of December 31, 2016, there was total unrecognized compensation cost related to unvested RSU's of approximately \$2.6 million. This cost is expected to be recognized over a period of 3.4 years.

## Employee Stock Purchase Plan

In February 2014, the Company's board of directors adopted and, in March 2014, the Company's stockholders approved, the 2014 Employee Stock Purchase Plan (the "ESPP"), which became effective on the completion of the Company's IPO. The ESPP authorized the issuance of 262,762 shares. Under the ESPP, employees, subject to certain restrictions, may purchase shares of common stock at 85% of the fair market value at either the beginning of the offering period or the date of purchase, whichever is less. Purchases are limited to the lesser of 15% of each employee's eligible annual compensation or \$25,000. Through the end of 2016, the Company has issued a total of 90,280 shares under the ESPP. The number of shares available for future issuance under the plan were 532,849 at December 31, 2016. Beginning January 1, 2015 and continuing through and including January 1, 2024, the amount of common stock reserved for issuance under the ESPP will increase annually on that date by the lesser of (i) one percent (1%) of the total number of shares of common stock outstanding on such December 31, (ii) 520,000 shares of common stock, or (iii) a number of shares as determined by the board of directors prior to the beginning of each year, which shall be the lesser of (i) or (ii) above. For 2016 and 2015, the common stock available for issuance under the ESPP increased by 184,927 and 175,440 shares of common stock, respectively.

## Stock-Based Compensation Expense

The following table reflects stock-based compensation expense recognized for the years ended December 31, 2016, 2015, and 2014 (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Research and development:			
Employees	\$ 2,645	\$ 2,492	\$ 1,157
Non-employee consultants	210	664	1,331
General and administrative:			
Employees	7,446	6,388	2,887
Non-employee consultants	270	412	1,828
<b>Total expense</b>	<b>\$ 10,571</b>	<b>\$ 9,956</b>	<b>\$ 7,203</b>

The Company's method of valuation for share-based awards is based on the Black-Scholes model. The Company's determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to the Company's expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. A description of the assumptions follows:

- The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers, as well as taking into consideration the Company's own historical volatility since its IPO in 2014.

- The risk-free interest rate is based on the U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.
- The expected term of the options granted represents the average period the stock options are expected to remain outstanding. The Company has elected to use the “simplified method” for estimating the expected term, which is calculated as the mid-point between the vesting period and the contractual term of the options.
- The expected dividend yield assumption was based on the Company’s historical and expectation of dividend payouts.
- Determination of the fair value of the shares of common stock underlying the stock options historically has been the responsibility of the Company’s board of directors. Subsequent to the IPO in April 2014, the fair value of common stock is determined based on the closing price of the NASDAQ Global Market exchange.

As stock-based compensation expense recognized in the Consolidated Statement of Operations for fiscal years 2016, 2015, and 2014 is based on awards ultimately expected to vest, each has been reduced for estimated forfeitures, based on historical experience. ASC 718-10 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company estimated the fair value of employee stock options and ESPP shares on the date of grant using the Black-Scholes model with the following weighted-average assumptions:

	Years Ended December 31,		
	2016	2015	2014
<b>Stock Options</b>			
Expected price volatility	69% - 71%	68% - 80%	90% - 96%
Risk-free interest rate	1.23% - 1.81%	1.37% - 1.95%	1.84% - 2.20%
Expected term (in years)	5.50 - 6.25	5.50 - 6.25	6.75 - 7.00
Dividend yield	—	—	—

	Years Ended December 31,		
	2016	2015	2014
<b>Employee Stock Purchase Plan</b>			
Expected price volatility	68% - 73%	56% - 62%	67% - 75%
Risk-free interest rate	0.49% - 0.60%	0.07% - 0.41%	0.02% - 0.05%
Expected term (in years)	0.50	0.50	0.50
Dividend yield	—	—	—

Stock-based compensation expense related to employee stock options for the years ended December 31, 2016, 2015, and 2014 was \$9.3 million, \$8.7 million, and \$4.0 million, respectively. Stock-based compensation expense related to the ESPP plan for the years ended December 31, 2016, 2015, and 2014 was \$0.3 million, \$0.2 million, and \$69,200, respectively. Stock-based compensation expense related to restricted stock units was \$0.5 million for the year ended December 31, 2016, and zero for the years ended December 31, 2015 and 2014.

#### Non-Employee Stock-Based Compensation

During the years ended December 31, 2016, 2015, and 2014, the Company granted options to purchase 12,600, zero, and 199,550 shares of common stock to consultants, respectively. These options are granted in exchange for consulting services to be rendered and are measured and recognized as the stock options are earned. Options issued during the year ended 2016 were granted to a member of the Company’s board of directors. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered.

The Company estimated the fair value of non-employee stock options using the Black-Scholes model with the following weighted-average assumptions:

	Years Ended December 31,		
	2016	2015	2014
Expected price volatility	71% - 77%	76% - 82%	72% - 98%
Risk-free interest rate	1.47% - 2.46%	1.84% - 2.26%	0.81% - 2.75%
Expected term (in years)	7.00 - 9.75	8.00 - 9.00	3.25 - 10.00
Dividend yield	—	—	—

Compensation expense related to non-employee options for years ended December 31, 2016, 2015, and 2014 was approximately \$0.5 million, \$1.1 million, and \$3.2 million, respectively.

## 12. INCOME TAXES

Income (loss) before provision for income tax is summarized as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
United States	\$ (60,147)	\$ (57,074)	\$ 17,599
International	(26)	—	(2)
Total	\$ (60,173)	\$ (57,074)	\$ 17,597

The provision for income taxes is summarized as follows (in thousands):

	December 31,		
	2016	2015	2014
Current:			
Federal	\$ (116)	\$ (5,273)	\$ 7,367
State	1	1	7
Foreign	—	—	—
	(115)	(5,272)	7,374
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
	—	—	—
Provision (benefit) for income taxes	\$ (115)	\$ (5,272)	\$ 7,374

During 2014, the Company reduced its current Federal and state taxes payable by \$1.6 million related to excess tax benefits from stock-based compensation, offsetting additional paid-in capital. There was no reduction related to excess tax benefits from stock-based compensation for the years ended December 31, 2016 and 2015. The provision for income taxes differs from the amount computed by applying the federal income tax rate of 35% to pretax income (loss) from operations as a result of the following:

	December 31,		
	2016	2015	2014
Statutory federal income tax rate	\$ (21,079)	\$ (19,976)	\$ 6,159
State income taxes, net of federal tax benefits	(9)	1	1
Warrants	—	—	344
Foreign rate differential	10	—	1
Tax credits	(3,905)	(8,303)	(168)
Net operating loss carryback	—	4,099	—
Change in statutory rates	624	—	—
Stock compensation	(1,109)	821	302
State net operating losses	1,779	—	—
Other	109	1,330	(70)
Change in valuation allowance	23,465	16,756	805
Income tax provision	<u>\$ (115)</u>	<u>\$ (5,272)</u>	<u>\$ 7,374</u>

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2016	2015
Net operating loss carryforwards	\$ 29,102	\$ 12,665
Research and development tax credits	14,453	8,652
Accruals and reserves	395	345
Stock compensation	6,902	5,341
Depreciation and amortization	1,765	2,149
Total deferred tax assets	52,617	29,152
Less: Valuation allowance	(52,617)	(29,152)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The deferred income tax assets have been fully offset by a valuation allowance, as realization is dependent on future earnings, if any, the timing and amount of which are uncertain. The net valuation allowance increased by \$23.5 million and \$18.9 million for the years ended December 31, 2016 and 2015, respectively.

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood, and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At present, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the accompanying balance sheets.

As of December 31, 2016 and December 31, 2015, the Company had federal net operating loss carryforwards of approximately \$73.0 million and \$25.0 million, respectively, available to reduce future taxable income. The Company also had state net operating loss carryforwards of approximately \$61.8 million as of December 31, 2016 and December 31, 2015. The federal net operating loss carryforward begins expiring in 2025, and the state net operating loss carryforward begins expiring in 2016, if not utilized. In the year ended December 31, 2016, \$7.6 million of California net operating loss carryforwards expired.

The Company has federal research and development tax credit carryforwards of approximately \$3.5 million. If not utilized, the carryforwards will begin expiring in 2024. The Company has state research and development credit carryforwards of approximately \$2.7 million which do not expire. The Company also has orphan drug credit carryforwards of \$9.7 million.

Under federal and similar state tax statutes, changes in the Company's ownership may limit its ability to use its available net operating loss and tax credit carryforwards. The annual limitation, as a result of a change of control, may result in



the expiration of net operating losses and credits before utilization.

The Company's ability to use its remaining net operating loss and tax credit carryforwards may be further limited if the Company experiences a Section 382 ownership change in connection with future changes in its stock ownership.

#### **Uncertain Tax Positions**

The total amounts of unrecognized tax benefits for the years ended December 31, 2016, 2015, and 2014 were \$3.2 million, \$1.8 million, and \$2.6 million, respectively. If recognized, none of the unrecognized tax benefits would affect the effective tax rate.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	December 31,		
	2016	2015	2014
<b>Balance at the beginning of the year</b>	\$ 1,820	\$ 2,608	\$ 2,270
Additions based on prior period tax positions	93	980	348
Additions based on current period tax positions	1,275	—	—
Reductions based on prior period tax positions	—	(1,768)	(10)
<b>Balance at the end of the year</b>	<u>\$ 3,188</u>	<u>\$ 1,820</u>	<u>\$ 2,608</u>

The Company's policy is to account for interest and penalties as income tax expense. The Company accrued \$11,000 of interest related to unrecognized tax benefits during the year ended December 31, 2014. The Company accrued no interest related to unrecognized tax benefits during the years ended December 31, 2016 and 2015. Additionally, the interest accrued in 2014 of \$11,000 was reversed due to the 2015 net operating loss carryback claim and refund.

The Company files income tax returns in the U.S. federal jurisdiction, California, Virginia, New York, and India. The Company is subject to U.S. federal income tax examination for the calendar years ending 2001 through 2016 due to net operating losses that have been carried forward for tax purposes. Additionally, the Company is subject to state income tax examinations for the 2005 through 2016 calendar years due to net operating losses that are being carried forward for tax purposes. The Company is subject to audit by the Indian tax authorities from 2013 onward. The Company is not currently under audit in any major tax jurisdiction.

### 13. NET INCOME PER SHARE

A reconciliation of the numerator and denominator used in the calculation of the basic and diluted net income per share is as follows (in thousands, except per share data):

	December 31,		
	2016	2015	2014
<b>Historical net income (loss) per share</b>			
Numerator:			
Net income (loss)	\$ (60,058)	\$ (51,802)	\$ 10,223
Noncumulative dividend on preferred stock	—	—	(432)
Undistributed earnings allocated to preferred stockholders	—	—	(823)
Basic net income (loss) attributable to common stockholders	(60,058)	(51,802)	8,968
Adjustment to net income (loss) for dilutive securities	—	—	101
Diluted net income (loss) attributable to common stockholders	<u>\$ (60,058)</u>	<u>\$ (51,802)</u>	<u>\$ 9,069</u>
Denominator:			
Basic common shares outstanding:			
Basic common shares outstanding: weighted average common shares outstanding	21,711	18,116	14,849
Less: weighted average unvested common shares subject to repurchase	—	(5)	(12)
Weighted average number of common shares used in calculating net income (loss) per share—basic	<u>21,711</u>	<u>18,111</u>	<u>14,837</u>
Dilutive securities:			
Common stock options	—	—	2,148
Warrants to purchase common stock	—	—	122
Weighted average number of common shares used in calculating net income (loss) per share—diluted	<u>21,711</u>	<u>18,111</u>	<u>17,107</u>
Net income (loss) per share attributable to common stockholders			
Basic	<u>\$ (2.77)</u>	<u>\$ (2.86)</u>	<u>\$ 0.60</u>
Diluted	<u>\$ (2.77)</u>	<u>\$ (2.86)</u>	<u>\$ 0.53</u>

The following shares of potentially dilutive securities were excluded from the computation of diluted net income (loss) per share of common stock for the periods presented, because including them would have been anti-dilutive (in thousands):

	December 31,		
	2016	2015	2014
Options to purchase common stock	5,523	5,249	441
Total	<u>5,523</u>	<u>5,249</u>	<u>441</u>

**14. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

The following table represents certain unaudited quarterly information for the eight quarters ended December 31, 2016. This data has been derived from unaudited consolidated financial statements that, in the opinion of the Company's management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of such information when read in conjunction with the Company's annual audited consolidated financial statements and notes thereto appearing elsewhere in this report. These operating results are not necessarily indicative of results for any future period (in thousands, except per share data):

	Year Ended December 31, 2016			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	\$ 175	\$ 222	\$ 138	\$ 37
Operating expenses	14,163	17,282	14,781	15,330
Net loss	(13,828)	(16,876)	(14,394)	(14,960)
Net loss per share, basic and diluted	(0.65)	(0.78)	(0.66)	(0.68)
	Year Ended December 31, 2015			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	\$ 226	\$ 398	\$ 768	\$ 524
Operating expenses	12,452	14,551	15,763	16,587
Net loss	(12,202)	(14,051)	(14,859)	(10,690) (1)
Net loss per share, basic and diluted	(0.69)	(0.78)	(0.81)	(0.58)

- (1) In the fourth quarter of 2015 the Company recorded an out-of-period correcting adjustment of \$2.9 million to record an income tax benefit related to the carryback of a portion of the current year loss to obtain a tax refund from the prior year which was not properly accounted for in the interim periods of 2015. The Company has determined that the adjustment is not material to any current or interim periods.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2016. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of December 31, 2016, our disclosure controls and procedures were effective.

### **Management's Annual 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 defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in conformity with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- 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
- 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. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, management used 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 believes that, as of December 31, 2016, our internal control over financial reporting is effective based on those criteria.

### *Attestation Report on Internal Control over Financial Reporting*

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to the deferral allowed under the JOBS Act for emerging growth companies.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

### **PART III**

Certain information required by Part III is omitted from this annual report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our 2016 Annual Meeting of Stockholders, or the Proxy Statement, which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2016.

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this item concerning our directors is incorporated by reference to the information set forth in the section titled “Election of Directors” and “Corporate Governance” in our Proxy Statement. Information required by this item concerning our executive officers is incorporated by reference to the information set forth in the section entitled “Executive Officers and Key Employees” in our Proxy Statement. Information regarding Section 16 reporting compliance is incorporated by reference to the information set forth in the section entitled “Section 16(a) Beneficial Ownership Reporting Compliance” in our Proxy Statement.

Our written Code of Conduct and Ethics applies to all of our directors and employees, including our executive officers, including without limitation our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Conduct and Ethics is available on our website at <http://www.adamaspharma.com> in the Investors section under “Corporate Governance”. Changes to or waivers of the Code of Conduct and Ethics will be disclosed on the same website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver of, any provision of the Code of Conduct and Ethics in the future by disclosing such information on our website.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled “Executive Compensation” and “Compensation Committee Interlocks and Insider Participation” in our Proxy Statement.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our Proxy Statement.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item regarding certain relationships and related transactions and director independence is incorporated by reference to the information set forth in the sections titled “Certain Relationships and Related Persons Transactions” and “Corporate Governance”, respectively, in our Proxy Statement.

#### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section titled “Principal Accountant Fees and Services” in our Proxy Statement.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

**(a)(1) Financial Statements**

Consolidated Financial Statements are listed in the “Index to Consolidated Financial Statements” under Part II, Item 8 of this Annual Report on Form 10-K.

**(a)(2) Financial Statement Schedules**

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.

**(a)(3) Exhibits**

See the Exhibit Index which follows the signature page of this Annual Report on Form 10-K, which is incorporated herein by reference.

**ITEM 16. FORM 10-K SUMMARY**

None.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**Adamas Pharmaceuticals, Inc.**  
(Registrant)

Date: February 28, 2017

/s/ Gregory T. Went, Ph.D.

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Gregory T. Went, Ph.D.  
*Chief Executive Officer*  
(Principal Executive Officer)

Date: February 28, 2017

/s/ William J. Dawson

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William J. Dawson  
*Chief Financial Officer*  
(Principal Financial and Accounting Officer)

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Gregory T. Went, Ph.D. and William J. Dawson, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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



<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Gregory T. Went</u> Gregory T. Went, Ph.D.	Chief Executive Officer and Chairman (Principal Executive Officer)	February 28, 2017
<u>/s/ William J. Dawson</u> William J. Dawson	Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2017
<u>/s/ Michael Bigham</u> Michael Bigham	Director	February 28, 2017
<u>/s/ Richard Booth</u> Richard Booth	Director	February 28, 2017
<u>/s/ Martha J. Demski</u> Martha J. Demski	Director	February 28, 2017
<u>/s/ William Ericson</u> William Ericson	Director	February 28, 2017
<u>/s/ Ivan Lieberburg</u> Ivan Lieberburg, M.D., Ph.D.	Director	February 28, 2017
<u>/s/ David L. Mahoney</u> David L. Mahoney	Director	February 28, 2017
<u>/s/ John MacPhee</u> John MacPhee	Director	February 28, 2017

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporation By Reference</b>				
		<b>Form</b>	<b>SEC File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed Herewith</b>
3.1	Amended and Restated Certificate of Incorporation of Adamas Pharmaceuticals, Inc.	8-K	001-36399	3.1	4/15/2014	
3.2	Amended and Restated Bylaws of Adamas Pharmaceuticals, Inc.	S-1	333-194342	3.4	3/5/2014	
4.1	Reference is made to Exhibits 3.1 through 3.2.					
4.2	Form of Common Stock Certificate of Adamas Pharmaceuticals, Inc.	S-1	333-194342	4.1	3/26/2014	
4.3	Fourth Amended and Restated Investor Rights Agreement, dated as of September 30, 2011, by and among the registrant and certain of its stockholders.	S-1	333-194342	10.5	3/5/2014	
10.1*	Adamas Pharmaceuticals, Inc. 2002 Employee, Director and Consultant Stock Plan, as amended, and Form of Stock Option Grant Notice, Option Agreement and Form of Notice of Exercise.	S-1	333-194342	10.1	3/5/2014	
10.2*	Adamas Pharmaceuticals, Inc. 2007 Stock Plan, as amended, and Form of Stock Option Grant Notice, Option Agreement and Form of Notice of Exercise.	S-1	333-194342	10.2	3/5/2014	
10.3*	Adamas Pharmaceuticals, Inc. 2014 Equity Incentive Plan and Form of Stock Option Grant Notice and Option Agreement.	S-1	333-194342	10.3	4/7/2014	
10.4*	Adamas Pharmaceuticals, Inc. Form of Stock Option Grant Notice and Option Agreement.	10-Q	001-36399	10.24	8/11/2015	
10.5*	Adamas Pharmaceuticals, Inc. 2014 Employee Stock Purchase Plan.	S-1	333-194342	10.4	3/26/2014	
10.6*	Adamas Pharmaceuticals, Inc. Form of Restricted Stock Unit Grant Notice and Award Agreement.	10-K	001-36399	10.24	2/23/2016	
10.7*	2016 Inducement Plan.	S-8	333-194342	99.5	3/17/2016	
10.8*	Form of Restricted Stock Unit Grant Notice and Award Agreement under the Adamas Pharmaceuticals, Inc. 2016 Inducement Plan.	S-8	333-194342	99.6	3/17/2016	
10.9*	Form of Stock Option Grant Notice and Option Agreement under the Adamas Pharmaceuticals, Inc. 2016 Inducement Plan.	S-8	333-194342	99.7	3/17/2016	
10.10*	Office Lease Agreement by and between the registrant and CA-Emeryville Properties Limited Partnership, dated as of October 25, 2006.	S-1	333-194342	10.7	3/5/2014	
10.11	First Amendment to Lease by and between the registrant and NOP Watergate LLC (as successor in interest to CA-Emeryville Properties Limited Partnership), dated as of April 29, 2009.	S-1	333-194342	10.8	3/5/2014	
10.12	Second Amendment to Office lease Agreement by and between the registrant and Emeryville Office, L.L.C. (as successor to NOP Watergate, LLC), dated as of January 18, 2011.	S-1	333-194342	10.9	3/5/2014	
10.13	Third Amendment to Lease by and between the registrant and Emeryville Office, L.L.C., dated as of June 17, 2011.	S-1	333-194342	10.10	3/5/2014	
10.14	Fourth Amendment to Lease by and between the registrant and Emeryville Office, L.L.C., dated as of January 31, 2013.	S-1	333-194342	10.11	3/5/2014	

Exhibit Number	Exhibit Description	Incorporation By Reference				
		Form	SEC File No.	Exhibit	Filing Date	Filed Herewith
10.15	Fifth Amendment to Lease by and between the registrant and Emeryville Office, L.L.C., dated as of May 23, 2014.	10-Q	001-36399	10.3	8/7/2014	
10.16	Sixth Amendment to Lease by and between the registrant and KBSIII Towers At Emeryville, LLC, dated as of October 27, 2015.	10-K	001-36399	10.23	2/23/2016	
10.17	License Agreement by and between the registrant and Forest Laboratories Holdings Limited, dated as of November 13, 2012.	S-1/A	333-194342	10.6	4/7/2014	
10.18*	Adamas Pharmaceuticals, Inc. Executive Severance Plan.	S-1	333-194342	10.19	3/5/2014	
10.19*	Offer Letter by and between Adamas Pharmaceuticals, Inc. and Gregory Went, dated as of March 8, 2006.	S-1	333-194342	10.12	3/5/2014	
10.20*	Offer Letter by and between registrant and William J. Dawson, dated as of August 12, 2014.	8-K	001-36399	10.8	8/13/2014	
10.21*	Offer letter by and between the registrant and Rajiv Patni, MD, dated April 17, 2015.	10-Q	001-36399	10.23	8/11/2015	
10.22*	Offer letter by and between the registrant and Jennifer Rhodes, dated March 25, 2016.	10-Q	001-36399	10.1	5/10/2016	
10.23*	Form of Indemnity Agreement between the registrant and its directors and officers.	S-1	333-194342	10.17	3/5/2014	
10.24*	Adamas Pharmaceuticals, Inc. Transaction Bonus Plan.	S-1	333-194342	10.18	3/5/2014	
10.25*	2016 Executive Cash Bonus Award Program.	10-Q	001-36399	10.2	5/10/2016	
10.26*	Consulting Services Agreement by and between the registrant and John MacPhee, M.P.H., dated February 1, 2016, and as amended dated August 5, 2016.	10-Q	001-36399	10.1	11/3/2016	
10.27*	Compensatory Arrangements with Non-Employee Directors.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (included on the signature page hereto).					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(1).					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X

Exhibit Number	Exhibit Description	Incorporation By Reference				
		Form	SEC File No.	Exhibit	Filing Date	Filed Herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

(1) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

\* Management compensatory contract or arrangement.

**Compensatory Arrangements with Non-Employee Directors****Cash Compensation:**

Annual cash retainer - \$35,000

Lead independent director additional annual cash payment - \$15,000

Annual committee fees:

Committee	Annual Chair Fee	Annual Member Fee
Audit Committee	\$ 15,000	\$ 7,500
Compensation Committee	\$ 10,000	\$ 5,000
Nominating and Corporate Governance Committee	\$ 7,000	\$ 3,500
Development Committee	\$ 7,500	\$ 5,000

**Equity Compensation:**

Initial equity award upon commencement of service as a board member: non-qualified stock option to purchase 30,000 shares of Adamas common stock that vests annually over three years of service.

Annual equity award: non-qualified stock option to purchase 15,000 shares that vests after one year of service.

Additionally, upon the closing of a change of control, the vesting of all outstanding equity awards held by our non-employee directors will accelerate in full.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-214409) and Form S-8 (Nos. 333-210255, 333-202467 and 333-195384) of Adamas Pharmaceuticals, Inc. of our report dated February 28, 2017 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California  
February 28, 2017

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER**  
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Gregory T. Went, Ph.D., hereby certify that:

1. I have reviewed this annual report on Form 10-K of Adamas 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 registrant's most recent fiscal quarter (the registrant's fourth 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.
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 registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weakness 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.

Dated: February 28, 2017

/s/ Gregory T. Went, Ph.D.

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Gregory T. Went, Ph.D.

*Chief Executive Officer*

*(Principal Executive Officer)*

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER**  
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, William J. Dawson, hereby certify that:

1. I have reviewed this annual report on Form 10-K of Adamas 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 registrant's most recent fiscal quarter (the registrant's fourth 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.
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 registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weakness 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.

Dated: February 28, 2017

/s/ William J. Dawson

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William J. Dawson

*Chief Financial Officer*

*(Principal Financial and Accounting Officer)*



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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Gregory T. Went, Ph.D., Chief Executive Officer of Adamas Pharmaceuticals, Inc. (the “Company”), and William J. Dawson, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Annual Report on Form 10-K for the period ended December 31, 2016, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 28<sup>th</sup> day of February, 2017.

/s/ Gregory T. Went, Ph.D.

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Gregory T. Went, Ph.D.

*Chief Executive Officer*

*(Principal Executive Officer)*

/s/ William J. Dawson

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William J. Dawson

*Chief Financial Officer*

*(Principal Financial and Accounting Officer)*

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.