Adamas Pharmaceuticals Inc
Form 10-Q
November 03, 2016

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

FORM 10-Q

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

For the quarterly period ended September 30, 2016

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File No. 001-36399

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

Delaware	42-1560076
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1900 Powell Street, Suite 750
Emeryville, CA 94608
(Address of Principal Executive Offices) (Zip Code)

(510) 450-3500
(Registrant's Telephone Number, Including Area Code)

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 (§

232.405 of this chapter) 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

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 Exchange Act). Yes No

Number of shares outstanding of the issuer’s common stock, par value $0.001 per share, as of October 31, 2016 was 21,982,429.

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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
ADAMAS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share data)

	September 30, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 9,776	$ 33,104
Available-for-sale securities	92,409	73,691
Accounts receivable	769	1,284
Prepaid expenses and other current assets	7,433	5,108
Total current assets	110,387	113,187
Property and equipment, net	3,078	2,353
Available-for-sale securities, non-current	43,725	13,165
Other assets	38	38
Total assets	$ 157,228	$ 128,743
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 5,956	$ 3,052
Accrued liabilities	6,306	8,457
Other current liabilities	301	298
Total current liabilities	12,563	11,807
Non-current liabilities	600	749
Total liabilities	13,163	12,556
Commitments and Contingencies (Note 7)		
Stockholders' equity		
Preferred stock, $0.001 par value — 5,000,000 shares authorized, and zero shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value — 100,000,000 shares authorized, 21,982,429 and 18,505,462 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	27	23
Additional paid-in capital	251,351	178,473
Accumulated other comprehensive loss	(64)	(158)
Accumulated deficit	(107,249)	(62,151)
Total stockholders' equity	144,065	116,187
Total liabilities and stockholders' equity	$ 157,228	$ 128,743

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$138	$768	$535	$1,392
Operating expenses				
Research and development	7,437	9,960	24,183	26,198
General and administrative, net	7,344	5,803	22,043	16,568
Total operating expenses	14,781	15,763	46,226	42,766
Loss from operations	(14,643)	(14,995)	(45,691)	(41,374)
Interest and other income, net	249	85	593	265
Loss before income taxes	(14,394)	(14,910)	(45,098)	(41,109)
Provision (benefit) for income taxes	—	(51)	—	3
Net loss	$(14,394)	$(14,859)	$(45,098)	$(41,112)
Net loss per share, basic and diluted	$(0.66)	$(0.81)	$(2.09)	$(2.28)
Weighted average shares used in computing net loss per share, basic and diluted	21,941	18,395	21,616	18,001

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

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ADAMAS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$(14,394)	$(14,859)	$(45,098)	$(41,112)
Unrealized gain (loss) on available-for-sale securities	(96)	68	94	202
Comprehensive loss	$(14,490)	$(14,791)	$(45,004)	$(40,910)

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

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

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$(45,098)	$(41,112)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	562	306
Stock-based compensation	7,782	7,205
Net accretion of discounts and amortization of premiums of available-for-sale securities	(332)	850
Changes in assets and liabilities		
Accrued interest of available-for-sale securities	(119)	(14)
Prepaid expenses and other assets	(2,325)	(393)
Accounts receivable	515	(412)
Accounts payable	3,007	(834)
Accrued liabilities and other liabilities	(2,431)	(469)
Net cash used in operating activities	(38,439)	(34,873)
Cash flows from investing activities		
Purchases of property and equipment	(1,222)	(1,131)
Purchases of available-for-sale securities	(95,528)	(32,578)
Maturities of available-for-sale securities	46,795	33,745
Net cash provided by (used in) investing activities	(49,955)	36
Cash flows from financing activities		
Proceeds from public offerings, net of offering costs	61,822	9,657
Proceeds from issuance of common stock upon exercise of stock options	2,918	671
Proceeds from employee stock purchase plan	326	181
Net cash provided by financing activities	65,066	10,509
Net decrease in cash and cash equivalents	(23,328)	(24,328)
Cash and cash equivalents at beginning of period	33,104	61,446
Cash and cash equivalents at end of period	$9,776	$37,118
Supplemental disclosure of noncash investing and financing activities		
Purchase of property and equipment in accounts payable and accrued expenses	227	88
Disposal of fully depreciated property and equipment	—	20

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

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ADAMAS PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. DESCRIPTION OF BUSINESS

Adamas Pharmaceuticals, Inc. (the "Company") is a pharmaceutical company that is developing new medicines to improve the daily lives of those affected by chronic neurologic disorders. Approximately 36 million people in the United States suffer from chronic neurologic disorders, including Alzheimer's disease, Parkinson's disease (PD), multiple sclerosis, and epilepsy. The Company has pioneered a platform based on an understanding of time dependent biologic effects of disease activity and drug response to achieve symptomatic relief without additional tolerability issues. The Company has developed a portfolio of chrono-synchronous therapies to potentially address chronic neurologic disorders. The Company's first proprietary product candidate is ADS-5102, a chrono-synchronous amantadine therapy, for the treatment of levodopa-induced dyskinesia (LID) in patients with PD. The Company submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for ADS-5102 in October 2016. The FDA has designated that LID in patients with PD is an orphan disease. There are currently no approved drugs in the United States or Europe for the treatment of LID in PD.

In addition, the Company contributed to the development of two medicines, which have been exclusively licensed to Forest Laboratories Holdings Limited ("Forest Laboratories" or "Forest"), an indirect wholly-owned subsidiary of Allergan plc: Namzaric® (memantine hydrochloride extended-release and donepezil hydrochloride) capsules; and Namenda XR® (memantine hydrochloride) extended-release capsules.

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 unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the Company believes are necessary for a fair presentation of the periods presented. The condensed consolidated balance sheet at December 31, 2015 was derived from the audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP. These interim financial results are not necessarily indicative of results to be expected for the full fiscal year or any other future period and should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2015, included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC.

Liquidity and Financial Condition

To date, nearly all 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, the Company believes that the existing cash, cash equivalents, and investments of $145.9 million as of September 30, 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 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 and 2013, it has not generated any commercial revenue from sales of its products. Under its license agreement with Forest, the Company received the final milestone payment in 2014, and is not entitled to receive any royalties for sales of Namzaric until mid-2020 and Namenda XR until mid-2018. To

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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.

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.

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.

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.

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.

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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 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, 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 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.

Basic and Diluted Net Loss Per Share

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net 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 and unvested restricted stock units 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. The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. For the three and nine months ended September 30, 2016, approximately 5,523,000 and 5,535,000, respectively, shares of potentially dilutive securities were excluded from the computation of diluted net income per share as their effect would have been anti-dilutive. For the three and nine months ended September 30, 2015, approximately 5,381,000 and 5,206,000, respectively, shares of potentially dilutive securities were excluded

from the computation of diluted net income per share as their effect would have been anti-dilutive.

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

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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 201-16, Narrow-Scope Improvements and Practical Expedients. The Company has not yet selected a transition method nor has it determined the effects of the standards 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 effects of this update on the Company's consolidated financial statements are not expected to be material.
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 effects of this update on the Company's consolidated financial statements are not expected to be material.

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 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

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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. The effects of this update on the Company's consolidated financial statements are not expected to be material.

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. 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 September 30, 2016			
	Total	Level 1	Level 2	Level 3
Assets				
Money market	$21	$ 21	$—	$ —
Corporate debt	65,901	—	65,901	—
U.S. Treasury notes	70,233	—	70,233	—
Total assets measured at fair value	$136,155	$ 21	$136,134	$ —

	Fair Value Measurements at December 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets				
Money market	$23,430	$23,430	$—	$ —
Corporate debt	56,787	—	56,787	—
U.S. Treasury notes	30,069	—	30,069	—

Total assets measured at fair value	$110,286	$23,430	$86,856	$ —

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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.

There were no transfers to or from Level 1 and Level 2 during the three and nine months ended September 30, 2016.

4. 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 loss within stockholders' equity. Realized gains and losses are reclassified from other comprehensive 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 September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Investments:				
Corporate debt	$65,964	$ 3	$ (66)	$65,901
U.S. Treasury notes	70,234	14	(15)	70,233
Total	$136,198	$ 17	$ (81)	$136,134
Reported as:				
Short-term investments	$92,428	$ 16	$ (35)	$92,409
Long-term investments	43,770	1	(46)	43,725
Total	$136,198	$ 17	$ (81)	$136,134

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Investments:				
Corporate debt	$56,892	$ —	$ (105)	$56,787
U.S. Treasury notes	30,122	1	(54)	30,069
Total	$87,014	$ 1	$ (159)	$86,856

Reported as:				
Short-term investments	$73,817	$ 1	$ (127)	$73,691
Long-term investments	13,197	—	(32)	13,165
Total	$87,014	$ 1	$ (159)	$86,856

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Short-term and long-term investments includes accrued interest of $0.3 million and $0.2 million respectively, as of September 30, 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 three and nine months ended September 30, 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 17 months as of September 30, 2016.

5. LICENSE AGREEMENTS

In November 2012, the Company granted Forest 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, Forest markets and sells Namzaric and Namenda XR for the treatment of moderate to severe dementia related to Alzheimer's disease. Pursuant to the agreement, Forest made an upfront payment of $65.0 million. The Company earned and received additional cash payments totaling $95.0 million upon achievement by Forest 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 nine months ended September 30, 2016, reimbursed expenses amounting to $2.4 million are reflected as a reduction to general and administrative, net.

The Company is entitled to receive royalties on net sales in the United States by Forest, 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 Forest 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. Forest'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 Forest in the United States or (ii) the expiration of the Orange Book listed patents for which Forest obtained rights from the Company covering such product. Forest's obligation to pay royalties with respect to Namenda XR continues until the expiration of the Orange Book listed patents covering such products. However, Forest's obligation to pay royalties for any product covered by the license is eliminated in any quarter where there is significant competition from generics.

6. WARRANTS TO PURCHASE COMMON 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 both September 30, 2016 and December 31, 2015, there were no warrants to purchase common stock outstanding.

7. 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.

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As of September 30, 2016, future minimum lease payments under the non-cancelable facility operating lease were as follows (in thousands):

	September 30, 2016
2016 (remaining)	$ 149
2017	615
2018	634
2019	653
2020	224
Thereafter	—
Total	$ 2,275

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 Namzaric and Namenda XR 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, 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, 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. 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 parties are collectively seeking judgment that (i) the defendants have infringed the patents at issue, (ii) the effective date of any approval of the defendants' ANDAs shall not be earlier than the expiration date of the last to expire of the relevant patents, including any extensions or exclusivities, (iii) the defendants be enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, any products that infringe or induce or contribute to the

infringement of the patents at issue prior to the expiration date of the last to expire of the patents, including extensions and exclusivities, and (iv) the Company, Forest, and Merz be awarded monetary relief, in addition to any attorneys' fees, costs, and expenses relating to the actions.

The Company and Forest have entered into a series of settlement agreements with the Namenda XR 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 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 is January 31, 2020 or in the alternative, an option to launch an authorized generic version of Namenda XR beginning on January 31, 2021.

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In January 2016, the Delaware District Court issued a claim construction (Markman) ruling in the Namenda XR 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.

Additionally, as of the date of this filing, a number of companies have submitted ANDAs requesting permission to manufacture and market generic versions of Namzaric, 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 Namzaric ANDA filers, who are seeking to launch generic versions of Namzaric, in the same court as heard the Namenda XR litigation. As of the date of this filing, the Company and Forest have settled with all active defendants, including the first filers on all the available dosage forms of Namzaric, granting a license to market the first generic versions of Namzaric on January 1, 2025 subject to the settlement agreements. The Company and Forest will continue to enforce the patents associated with Namzaric.

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.

8. 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 September 30, 2016 and December 31, 2015, zero and 3,000 shares of common stock, respectively, from early exercised options were unvested.

Controlled Equity Offering

On June 1, 2015, the Company entered into a Controlled Equity Offering Sales Agreement ("Sales Agreement"), with Cantor Fitzgerald & Co. ("Cantor"), as sales agent, pursuant to which the Company may, 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. All sales of shares have been made pursuant to a shelf registration statement that was declared effective by the Securities and Exchange Commission ("SEC") on June 1, 2015. Cantor has acted as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. The common stock has been sold at prevailing market prices at the time of the sale, and, as a result, prices have varied. Unless otherwise terminated earlier, the Sales Agreement continues to be in effect until all shares available under the Sales Agreement have been sold. During the nine months ended September 30, 2016, there were no additional shares sold under the Sales Agreement. As of September 30, 2016, the Company had sold a total of 509,741 shares of common stock under the Sales Agreement at an average price of $20.04 for net proceeds of $9.7 million.

Public Offering

On January 6, 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.

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Shares reserved for Future Issuance

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

	September 30, 2016	December 31, 2015
Common stock awards issued and outstanding	5,468,650	5,328,378
Authorized for future issuance under 2014 Equity Incentive Plan	1,600,003	1,463,415
Authorized for future issuance under 2016 Inducement Plan	334,062	—
Employee Stock Purchase Plan	555,894	394,148
Total	7,958,609	7,185,941

9. STOCK-BASED COMPENSATION

Stock Compensation Plans

In 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. 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, the common stock available for issuance under the 2014 Plan increased by 739,708 shares of common stock.

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. 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.

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

Stock Options	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances, December 31, 2015	5,328,378	$ 8.57
Granted	978,100	14.78
Exercised	(578,786)	5.04
Forfeited	(422,542)	13.60
Expired	(38,499)	17.26
Balances, September 30, 2016	5,266,651	$ 9.64
Vested and expected to vest, September 30, 2016	5,110,042	$ 9.53
Vested, September 30, 2016	3,029,384	$ 6.98

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

Restricted Stock Units	Outstanding Units	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, December 31, 2015	—	$ —
Granted	215,249	14.61
Vested	—	—
Forfeited	(13,250)	13.66
Unvested, September 30, 2016	201,999	$ 14.67

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. 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, the common stock available for issuance under the ESPP increased by 184,927 shares of common stock.

Stock-Based Compensation

The following table reflects stock-based compensation expense recognized for the three and nine months ended September 30, 2016 and 2015, respectively (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development:				
Employees	$695	$703	$1,971	$1,799
Nonemployee consultants	43	79	165	491
General and administrative:				
Employees	1,822	1,793	5,532	4,617
Nonemployee consultants	38	48	114	298
Total expense	$2,598	$2,623	$7,782	$7,205

As of September 30, 2016, there was total unrecognized compensation cost related to unvested options of approximately $21.0 million. This cost is expected to be recognized over a period of 2.6 years. As of September 30, 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 3.6 years.

Non-employee Stock-Based Compensation

During the three and nine months ended September 30, 2016, the Company granted options to purchase 12,600 shares of common stock to a member of the Company's board of directors in exchange for consulting services to be rendered. During the three and nine months ended September 30, 2015, the Company did not grant options to purchase common stock to consultants.

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ITEM 2. 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 our condensed consolidated 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 is developing new medicines to improve the daily lives of those affected by chronic neurologic disorders. Approximately 36 million people in the United States suffer from chronic neurologic disorders, including Alzheimer's disease, Parkinson's disease (PD), multiple sclerosis, and epilepsy. We have pioneered a platform based on an understanding of time dependent biologic effects of disease activity and drug response to achieve symptomatic relief without additional tolerability issues. We have developed a portfolio of chrono-synchronous therapies to potentially address chronic neurologic disorders. Our first proprietary product candidate is ADS-5102, a chrono-synchronous amantadine therapy, for the treatment of levodopa-induced dyskinesia (LID) in patients with PD. We submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for ADS-5102 in October 2016. The FDA has designated that LID in patients with PD is an orphan disease. There are currently no approved drugs in the United States or Europe for the treatment of LID in PD.

The ADS-5102 LID NDA is supported by efficacy and safety data compiled from our comprehensive registration program, which was designed to evaluate ADS-5102 for the treatment of LID in patients with PD. The Phase 3 clinical program included three placebo-controlled trials: EASED, EASE LID and EASE LID 3. The three trials enrolled a total of 286 patients, of whom 121 patients received a 340 mg dose of ADS-5102 once daily at bedtime. Both Phase 3 trials met their primary and key secondary endpoints. In addition, the NDA is supported by data from an open-label safety study known as EASE LID 2 for 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.

We are also exploring the utility of ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis. We have completed a positive Phase 2 proof-of-concept study in these patients. The Phase 2 study evaluated ADS-5102 dosed at 340 mg once daily at bedtime and enrolled MS patients with impaired walking speed. A key walking assessment was the timed 25-foot walk (T25FW) test, a well-established outcome measure that has been used as a basis for product approval in the United States and Europe. Key secondary outcome measures included assessments of walking performance. Other outcome measures included assessments of other MS-related symptoms. We plan to pursue a pivotal registration program for this indication.

The second product candidate is ADS-4101, an extended-release version of an FDA-approved single-agent compound for the treatment of epilepsy (partial onset seizures). We anticipate initiating a Phase 1 clinical study of ADS-4101 for partial onset seizures in patients with epilepsy in 2016.

Additionally, through our license to Forest Laboratories Holdings Limited ("Forest Laboratories" or "Forest"), an indirect wholly-owned subsidiary of Allergan plc, our portfolio includes two medicines commercially available in the United States for indications relating to Alzheimer's disease: Namzaric® (memantine hydrochloride extended-release and donepezil hydrochloride) capsules and Namenda XR® (memantine hydrochloride) extended-release capsules. Adamas is eligible to receive royalties on sales of Namenda XR® and Namzaric® beginning in June of 2018 and May of 2020,

respectively.

Our business strategy is to continue to discover, develop and commercialize new treatment solutions for patients independently or in collaboration with partners.

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Financial operations overview

Summary

Our revenue to date has been generated primarily from license, milestone, and development revenue pursuant to our license agreement with Forest. We have not generated any commercial product revenue. As of September 30, 2016, we had an accumulated deficit of $107.2 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 Forest. There are no further milestone payments to be earned under our license agreement with Forest. We cannot assure you that we will receive additional license revenue in the future. We incurred significant losses in the nine months ended September 30, 2016, in 2015, and prior to 2012, and expect to incur significant and increasing losses in the foreseeable future as we advance our product candidates into later stages of development and, if approved, commercialization.

We expect to continue to incur significant research and development expenses as we continue to advance our product candidates through clinical development. In addition, we plan to commercialize ADS-5102, 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 ("CSO"), targeting neurologists and movement disorder specialists in the United States, or possibly through partnership agreements with pharmaceutical companies. 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 sustained profitability.

Under our agreement with Forest, beginning in May 2020, we are entitled to receive tiered royalties in the low to mid-teens for 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 Forest for 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 Forest 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. On June 1, 2015, we entered into a Controlled Equity Offering Sales Agreement, pursuant to which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $25.0 million. As of September 30, 2016, we had 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 September 30, 2016, we had cash, cash equivalents, and available-for-sale securities of $145.9 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 Forest, and to a lesser degree reimbursement for research and development expenses from NIH grants and government contracts. We do not expect to recognize any further milestone payments under our license agreement with Forest, while reimbursements

for full-time equivalents assigned to the license agreement are expected 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 Forest for 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 sales of Namenda XR in the United States. 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.

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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, as well as the development of product candidates pursuant to our agreement with Forest. 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 three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Increase/(Decrease)	Nine Months Ended September 30,		Increase/(Decrease)
	2016	2015		2016	2015	
ADS-5102	$5,748	$8,585	$ (2,837)	$19,985	$24,356	$ (4,371)
Other research and development expenses	1,689	1,375	314	4,198	1,842	2,356
Total research and development expenses	$7,437	$9,960	$ (2,523)	$24,183	$26,198	$ (2,015)

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 have reallocated certain other research and development expenses to program-specific expenses for the three and nine months ended September 30, 2015 in order to consistently classify our product candidate expenses between periods.

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 our clinical trials for ADS-5102 for the treatment of LID and walking impairment associated with MS, ADS-4101 for treatment of epilepsy, and potentially initiate 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.

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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, reduced by reimbursement from Forest 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 as we continue to establish our commercial capabilities and support our potentially 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 CSO, targeting neurologists and movement disorder specialists in the United States, or possibly through distribution agreements 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.

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. There have been no significant and material changes in our critical accounting policies during the nine months ended September 30, 2016, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations," in our Annual Report on Form 10-K for the year ended December 31, 2015.

Results of operations

Comparison of the three and nine months ended September 30, 2016 and 2015

The following table summarizes our results of operations for the three and nine months ended September 30, 2016 and 2015 (in thousands, except percentages):

	Three Months Ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2016	2015			2016	2015		
Revenue	$138	$768	$ (630)	(82)%	$535	$1,392	$ (857)	(62)%
Research and development expenses	7,437	9,960	(2,523)	(25)%	24,183	26,198	(2,015)	(8)%
General and administrative expenses, net	7,344	5,803	1,541	27 %	22,043	16,568	5,475	33 %
Interest and other income, net	249	85	164	193 %	593	265	328	124 %

Revenue

Revenue for the three and nine months ended September 30, 2016 was $0.1 million and $0.5 million, respectively, compared to $0.8 million and $1.4 million, respectively, for the same periods in the prior year. Revenue for both periods in 2016 and 2015 was primarily related to reimbursement of certain expenses as provided for in our license agreement with Forest, as well as from government contracts.

Research and development expenses

Research and development expenses decreased by $2.5 million, or 25% to $7.4 million for the three months ended September 30, 2016, compared to the three months ended September 30, 2015. The decrease in research and development expenses was primarily due to the conclusion of two Phase 3 clinical trials for ADS-5102 for the treatment of LID. The decrease due to the conclusion of the two Phase 3 clinical trials was partially offset by increased expenses to support the preparation of the new drug application for ADS-5102 for the treatment of LID, in addition to increased expenses related to

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preclinical work associated with ADS-4101 for the treatment of epilepsy (partial onset seizures). Included in research and development expenses was stock-based compensation expense, which was $0.7 million and $0.8 million for the three months ended September 30, 2016 and 2015, respectively.

Research and development expenses decreased by $2.0 million, or 8% to $24.2 million for the nine months ended September 30, 2016 from $26.2 million for the nine months ended September 30, 2015. The decrease in research and development expenses was due to the conclusion of two Phase 3 clinical trials for the treatment of LID. The decrease was offset 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 work associated with ADS-4101 for the treatment of epilepsy (partial onset seizures) in the first nine months of 2016 as compared to the same period in the prior year. Included in research and development expenses was stock-based compensation expense, which was $2.1 million and $2.3 million for the nine months ended September 30, 2016 and 2015, respectively.

General and administrative expenses, net

General and administrative expenses, net, increased by $1.5 million, or 27%, to $7.3 million for the three months ended September 30, 2016 from $5.8 million for the three months ended September 30, 2015. The increase in general and administrative expenses was due primarily 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. We anticipate general and administrative expenses will increase through the remaining quarter of 2016, reflecting increased investment in pre-commercial activities. General and administrative expenses also included stock-based compensation expense of $1.9 million and $1.8 million for the three months ended September 30, 2016 and 2015, respectively.

General and administrative expenses, net, increased by $5.5 million, or 33%, to $22.0 million for the nine months ended September 30, 2016 from $16.6 million for the nine months ended September 30, 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 $5.6 million and $4.9 million for the nine months ended September 30, 2016 and 2015, respectively.

Interest and other income, net

Interest and other income, net, for the three and nine months ended September 30, 2016 was $0.2 million and $0.6 million, respectively, compared to $0.1 million and $0.3 million for the three and nine months ended September 30, 2015. Net interest income is primarily due to interest income earned on investments.

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 Forest, $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 with Cantor Fitzgerald & Co., pursuant to which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $25.0 million. As of September 30, 2016, we had issued 509,741 shares of common stock and raised net proceeds of $9.7 million under the Sales Agreement. 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 Forest, we received our final milestone payment from Forest in December 2014. We do not currently receive any royalties from Forest, 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 $145.9 million as of September 30, 2016.

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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 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.

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, 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.

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

	Nine Months Ended September 30,	
	2016	2015
Net cash (used in) provided by:		
Operating activities	$(38,439)	$(34,873)
Investing activities	(49,955)	36
Financing activities	65,066	10,509
Net increase (decrease) in cash and cash equivalents	$(23,328)	$(24,328)

Net cash used in operating activities was $38.4 million for the nine months ended September 30, 2016 compared to $34.9 million for the same period in the prior year. Net loss of $45.1 million for the nine months ended September 30, 2016 included net non-cash adjustments of $8.0 million, which consisted primarily of stock-based compensation of $7.8 million. Net loss of $41.1 million for the nine months ended September 30, 2015 included non-cash adjustments of $8.4 million, primarily related to $7.2 million in stock-based compensation. The primary use of cash from operating activities for the nine months ended September 30, 2016 was to fund the ongoing clinical studies, product development activities, and NDA preparation activities related to ADS-5102 for the treatment of LID.

Net cash used in investing activities was $50.0 million for the nine months ended September 30, 2016 compared to net cash provided by investing activities of $36,000 for the same period in the prior year. Net cash used in investing activities for the nine months ended September 30, 2016 was a result of $48.7 million in net purchases of available-for-sale securities as a result of investing the cash from our follow-on public offering that occurred in January 2016, and $1.2 million in purchases of property and equipment. Net cash provided by investing activities for the nine months ended September 30, 2015 was a result of $1.2 million in net maturities of available-for-sale securities, offset by $1.1 million in purchases of property and equipment.

Net cash provided by financing activities was $65.1 million for the nine months ended September 30, 2016, compared to $10.5 million for the nine months ended September 30, 2015. In the period ended September 30, 2016, we received net cash proceeds of $61.8 million related to the sale of common stock under a follow-on public offering, compared to the same period in the prior year in which we received $9.7 million in net cash proceeds related to the sale of common stock under a controlled equity offering. In the nine months ended September 30, 2016, we received cash proceeds of $3.2 million related to the exercise of stock options and purchases of common stock under the Employee Stock Purchase Plan, compared to $0.9 million in the same period in the prior year.

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 September 30, 2016, were not materially different than at December 31, 2015.

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ITEM 3. 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 September 30, 2016, we had cash, cash equivalents, and investments of $145.9 million, compared to $120.0 million as of December 31, 2015, consisting of cash and cash equivalents, as well as investments in 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 U.S. 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 one percentage point movement in market interest rates would not have a significant impact on the total realized value of our portfolio. We actively monitor changes in interest rates.

ITEM 4. 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 September 30, 2016. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2016, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control 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 quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In November 2012, we granted Forest Laboratories Holdings Limited ("Forest Laboratories" or "Forest"), an indirect wholly-owned subsidiary of Allergan plc, an exclusive license to certain of our 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 Namzaric and Namenda XR for the treatment of moderate to severe dementia related to Alzheimer's disease. We have 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, on which we are entitled to receive royalties from Forest beginning in June 2018. In the notices, these companies allege that the patents associated with Namenda XR, some of which are owned by Forest or licensed by Forest from Merz Pharma GmbH & Co. KGaA, and others of which are owned by us and licensed by us 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. We, 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 parties are collectively seeking judgment that (i) the defendants have infringed the patents at issue, (ii) the effective date of any approval of the defendants' ANDAs shall not be earlier than the expiration date of the last to expire of the relevant patents, including any extensions or exclusivities, (iii) the defendants be enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, any products that infringe or induce or contribute to the infringement of the patents at issue prior to the expiration date of the last to expire of the patents, including extensions and exclusivities, and (iv) we, Forest, and Merz be awarded monetary relief, in addition to any attorneys' fees, costs, and expenses relating to the actions.

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

In January 2016, the Delaware District Court issued a claim construction (Markman) ruling in the Namenda XR litigation that includes findings of indefiniteness as to certain claim terms in the asserted patents licensed by us to Forest. On July 26, 2016, the District Court issued a final judgment of invalidity on those patents based upon the Markman ruling. We 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.

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

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

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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 Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes.

Risks related to the development 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 of our product candidates, including ADS-5102, an oral once daily controlled-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 ("MS"), 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 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 sales and distribution of the product;
- commercializing ADS-5102 independently or in partnership with another company;
- acceptance by the medical community and patients of the approved product;
- the placement of ADS-5102 approved products 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.

In October 2016, we submitted our new drug application ("NDA") for ADS-5102 for the treatment of LID in patients with Parkinson's disease. We cannot give any assurance that the NDA will be accepted for filing by the FDA or that the Phase 3 clinical program for the treatment of LID will adequately demonstrate the safety and effectiveness to receive regulatory approval or 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 LID will adequately demonstrate sufficient safety and efficacy to the

satisfaction of the FDA to achieve regulatory approval. Refusal to file of our NDA by the FDA could delay approval and harm our business.

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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 may be subject to pre-approval 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 and we have not yet had an NDA approved previously. 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.

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 other indications and 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.

If we are required by the FDA to conduct additional 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

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- 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 our other product candidates similar to those we face with ADS-5102.

The risks relating to the development of our other product candidates are the same as, or similar to, the risks relating to the development of ADS-5102.

Our product candidates, including ADS-5102, have not been manufactured in a commercially validated process, nor at a scale that may be required to meet future market demand. There are risks associated with developing and validating manufacturing and packaging processes and scaling up on a timely basis.

Our product candidates, including ADS-5102, have not been manufactured in a commercially validated process, nor at a scale that may be required to meet possible future market demand. There are risks associated with developing and validating manufacturing and packaging processes and scaling up including, among others, delaying submission of an 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 and packaging of extended-release versions of drugs are substantially more complex than the manufacture and packaging 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.

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.

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

We have only a limited commercial infrastructure and have no 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 ("CSO"), or through partnership agreements with pharmaceutical companies. 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

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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), and Duopa (Abbvie). 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, Neurolixis, Amarantus 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 also 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 regarding its conduct of two Phase 3 clinical trials of extended-release amantadine for LID.

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. For example, in July 2015, the FDA granted Osmotica orphan drug designation for its amantadine hydrochloride product candidate for the treatment of LID, for which it has recently announced plans to submit an NDA in 2016. 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. If Osmotica or any of our other competitors obtain orphan drug exclusivity for their product candidate in one of our target indications using the same active moiety as in our product candidate, the marketing application for our drug product in that target indication could be delayed for so long as the competitor has orphan drug exclusivity for its product.

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.

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

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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 and us to enforce certain patents related to Namenda XR and Namzaric. See "Part II. Item 1. Legal Proceedings" 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 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 MS 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.

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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. 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.

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, additional

regulatory approvals will need to be obtained and may not be granted.

In October 2016, we submitted an NDA seeking regulatory approval of ADS-5102 for the treatment of LID. If this medicine is approved, we will be restricted in our ability to market or promote the product 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 MS, and potentially others. In order to market and promote ADS-5102 for these additional indications, we will

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need to conduct additional time-consuming and expensive clinical trials and 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 off-label uses, or if physicians misuse our products, we may become subject to prohibitions 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 strictly regulate the marketing and promotional claims that are made about drug products, such as ADS-5102, if approved. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. 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 using our ADS-5102 products on their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses prior to FDA approval for an additional indication, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. 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. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

Physicians may also misuse our products, potentially leading to adverse results, side effects, or injury, which may lead to product liability claims. If our products are misused, we may become subject to costly 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. Furthermore, the use of our products for indications other than those cleared by the FDA 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.

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.

We are a clinical-stage pharmaceutical company and do not currently market any products. We continue to incur significant research and development and general and administrative expenses related to our product candidates and our operations. We are seeking to advance product candidates through the research and clinical development to regulatory approval and commercialization. The completion of the development and the potential commercialization of our product candidates, including ADS-5102, should they receive approval, will require substantial funds. As of September 30, 2016, we had approximately $145.9 million in cash, cash equivalents, and investments. We believe that our available cash, cash equivalents,

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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 Forest, 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 out 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 Forest, which may be terminated by Forest upon delivery of notice. We expect to finance future cash needs through a combination of public or private equity offerings, debt 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 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 Forest under terms of our licensing agreement regarding Namenda XR and Namzaric, or the establishment of potential future collaboration and license agreements, if any, and the achievement of any upfront or milestone payments provided thereunder. Furthermore,

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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 products 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,

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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 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;
- Forest 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;

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- Forest and future partners may not aggressively or adequately pursue litigation against ANDA filers or may settle such litigation on unfavorable terms, and as Forest substantially controls the current ANDA litigation and terms of settlement and has different economic interests than ours, Forest may grant licenses to generic manufacturers that permit them to make and sell generic versions of Namenda XR, which would negatively impact the royalties we receive under our license with Forest;
- 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 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 and Namzaric

Under our license agreement with Forest, if Forest fails to successfully commercialize Namenda XR and Namzaric for any reason or if the license agreement with Forest is terminated, the potential royalties we expect to receive under our license agreement with Forest 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 Forest pursuant to which we granted Forest a right to develop and commercialize Namenda XR and Namzaric in the United States. Under that agreement, we expect to receive future royalties from Forest on the net sales of Namenda XR and Namzaric, starting in 2018 and 2020,

respectively. If Forest fails to successfully commercialize Namenda XR and, more importantly, Namzaric, 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 Forest to commercialize Namenda XR and Namzaric and in that capacity Forest has as the discretion to:

- determine the efforts and resources that they apply towards commercialization;

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- 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, Forest 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, Forest may manage the litigation and settlements on terms which may have a material and negative impact on our business.

We and Forest 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 and Namzaric to the market. See “Part II. Item 1. Legal Proceedings”. Under the terms of that license agreement, Forest has the right to enforce such intellectual property rights and control such litigation. Specifically, Forest 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 Forest substantially controls the current ANDA litigation and terms of settlement and has different economic interests than ours, Forest may grant licenses to generic manufacturers that permit them to make and sell generic versions of Namenda XR, which would negatively impact the royalties we receive under our license with Forest.

We have a right to participate in, but not control, such litigations. If Forest 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 and Namzaric. 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 September 30, 2016, we had 71 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

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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;

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- 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.

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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 Forest, 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,

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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 Holdings Ltd., 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 and Namenda XR. 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 Forest we are obliged to indemnify Forest under certain circumstances and our royalty entitlements may also be reduced. Our indemnification obligation to Forest, while subject to customary limitations, has no monetary cap, and our right to receive royalties from Forest 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

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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 until we receive FDA approval of an NDA. We have not submitted an application or received marketing approval for any of our product candidates. Obtaining approval of an NDA 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:

- 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;

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- insufficient data from preclinical and clinical studies to support an application;
- 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 does not conclude our product candidates 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.

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 for 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 new 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 HCl) 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. The 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 approved product and its manufacturer are subject to continual review by the FDA and/or applicable non-U.S. regulatory authorities. Any regulatory approval that we or our collaboration partners receive for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed, or contain 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 applicable 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, manufacturers of our drug products are required to comply with cGMP regulations,

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which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Additionally, regulatory authorities must approve these 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. 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, the manufacturer or us, including 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 judicially imposed sanctions, including:

- warning letters or untitled letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension 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 government 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 commercialize ADS-5102, ADS-4101, and other future product candidates outside of the United States. To market our future products in the European Economic Area, or EEA, and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically, in the EEA 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 EEA make an assessment of the risk-benefit balance of the product on the basis of a Common Technical Document including, among other things, scientific criteria concerning its quality, safety, and efficacy.

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

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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.

Healthcare reform measures 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, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or, collectively, the PPACA, was enacted in 2010.

The PPACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes, and fraud and abuse measures, all of which impact government healthcare programs. The PPACA, among other things:

- imposes a non-deductible annual fee on entities that manufacture or import certain branded prescription drugs;
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires collection of rebates for drugs paid by Medicaid managed care organizations; and
- provides 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.

These changes impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. We can provide no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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.

The pricing and reimbursement environment for our products may change in the future and become more challenging due to, among other reasons, policies advanced by the new presidential administration, federal agencies, new healthcare legislation passed by Congress or fiscal challenges faced by all levels of government health administration authorities. Among policy makers and payors 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 expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

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

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will become applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation

by both the federal government and the states in which we conduct our business. 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),

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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;

- the federal civil False Claims Act which prohibits, among other things, individuals or entities from 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) 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, 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, 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 U.S. Department of Health and Human Services, or HHS, 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, 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.

The PPACA, among other things, clarified the intent standard of the federal Anti-Kickback Statute such that a person or entity can be found to have violated the statute even without having actual knowledge of the statute or specific intent to violate it. In addition, the PPACA codified case law that a claim for items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

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.

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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 (which could include civil and/or criminal penalties), private litigation and/or adverse publicity and 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 the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA"). 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 EEA to the U.S., a recent decision of the European Court of Justice that invalidated one such mechanism has increased uncertainty around compliance with EU restrictions on cross-border data transfers. 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 to, is anticipated to be adopted in 2016 and will be applicable two years after the date of its publication in the Official Journal for the European Union. The EU Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process and 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 EU 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 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 EEA 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;

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- 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.

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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;

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- 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which are incorporated herein by reference.

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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: November 3, 2016
/s/ Gregory T. Went, Ph.D.
Gregory T. Went, Ph.D.
Chief Executive Officer
(Principal Executive Officer)
Date: November 3, 2016
/s/ William J. Dawson
William J. Dawson
Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation By Reference Form	SEC File No.	Exhibit	Filing Date
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 June 30, 2011, by and among the registrant and certain of its stockholders.	S-1	333-194342	10.5	3/5/2014
10.1	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.				
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.				
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.				
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)				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

(1) This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.