Adamas Pharmaceuticals Inc
Form 10-Q
August 08, 2017

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 June 30, 2017
or
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File 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)

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

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No
Number of shares outstanding of the issuer's common stock, par value $0.001 per share, as of July 31, 2017 was 22,514,076.

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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)

	June 30, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$33,618	$ 23,735
Available-for-sale securities	94,725	89,917
Accounts receivable	34	794
Prepaid expenses and other current assets	1,814	2,541
Total current assets	130,191	116,987
Property and equipment, net	3,107	3,156
Available-for-sale securities, non-current	16,586	22,292
Other assets	38	38
Total assets	$149,922	$ 142,473
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$4,385	$ 3,589
Accrued liabilities	6,396	5,867
Other current liabilities	268	287
Total current liabilities	11,049	9,743
Long-term debt	33,768	—
Other non-current liabilities	1,201	547
Total liabilities	46,018	10,290
Commitments and Contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.001 par value — 5,000,000 shares authorized, and zero shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, $0.001 par value — 100,000,000 shares authorized, 22,462,838 and 22,013,644 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	27	27
Additional paid-in capital	263,042	254,558
Accumulated other comprehensive loss	(183)	(193)
Accumulated deficit	(158,982)	(122,209)
Total stockholders' equity	103,904	132,183
Total liabilities and stockholders' equity	$149,922	$ 142,473

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	$2	$222	$2	$397
Operating expenses				
Research and development	7,176	9,224	14,264	16,746
General and administrative, net	13,115	8,058	22,259	14,699
Total operating expenses	20,291	17,282	36,523	31,445
Loss from operations	(20,289)	(17,060)	(36,521)	(31,048)
Interest and other income, net	222	184	426	344
Interest expense	(729)	—	(729)	—
Loss before income taxes	(20,796)	(16,876)	(36,824)	(30,704)
Benefit for income taxes	(51)	—	(51)	—
Net loss	$(20,745)	$(16,876)	$(36,773)	$(30,704)
Net loss per share, basic and diluted	$(0.93)	$(0.78)	$(1.65)	$(1.43)
Weighted average shares used in computing net loss per share, basic and diluted	22,392	21,650	22,300	21,452

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$(20,745)	$(16,876)	$(36,773)	$(30,704)
Unrealized gain (loss) on available-for-sale securities	(17)	21	10	190
Comprehensive loss	$(20,762)	$(16,855)	$(36,763)	$(30,514)

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)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities		
Net loss	$(36,773)	$(30,704)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	572	328
Stock-based compensation	6,649	5,184
Non-cash interest expense	729	—
Net accretion of discounts and amortization of premiums of available-for-sale securities	(71)	407
Changes in assets and liabilities		
Accrued interest of available-for-sale securities	(50)	226
Prepaid expenses and other assets	730	(1,227)
Accounts receivable	760	424
Accounts payable	509	1,525
Accrued liabilities and other liabilities	325	(674)
Net cash used in operating activities	(26,620)	(24,511)
Cash flows from investing activities		
Purchases of property and equipment	(621)	(1,244)
Purchases of available-for-sale securities	(40,071)	—
Maturities of available-for-sale securities	41,100	37,653
Net cash provided by investing activities	408	36,409
Cash flows from financing activities		
Proceeds from issuance of long-term debt	34,600	—
Proceeds from public offerings, net of offering costs	—	61,822
Payment of debt issuance costs	(136)	—
Proceeds from issuance of common stock upon exercise of stock options	1,201	2,122
Proceeds from employee stock purchase plan	430	326
Net cash provided by financing activities	36,095	64,270
Net increase in cash and cash equivalents	9,883	76,168
Cash and cash equivalents at beginning of period	23,735	33,104
Cash and cash equivalents at end of period	$33,618	$109,272
Supplemental disclosure of noncash investing and financing activities		
Debt issuance costs in accounts payable and accrued expense	$460	$—
Purchases of property and equipment in accounts payable and accrued expense	$51	$267

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") discovers and develops new medicines to treat chronic neurologic disorders. The Company's portfolio includes:

ADS-5102: a high-dose amantadine therapy taken once-daily at bedtime.

ADS-5102 for Levodopa-Induced Dyskinesia in Patients with Parkinson's Disease

A New Drug Application ("NDA") for the treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson's disease is under review by the Food and Drug Administration ("FDA") with a Prescription Drug User Fee Act ("PDUFA") date, or deadline by which the FDA must review the NDA, of August 24, 2017. Levodopa-induced dyskinesia is a form of dyskinesia (abnormality or impairment of voluntary movement) associated with levodopa therapy, a drug used to treat Parkinson's disease. If approved, the Company plans to initiate access to ADS-5102 for patients in 2017 and execute a full launch of the medicine via the deployment of sales representatives with marketing and promotional support in January 2018.

ADS-5102 for Multiple Sclerosis Walking Impairment

The Company completed a Phase 2, 4-week proof-of-concept study designed to evaluate ADS-5102 in patients with multiple sclerosis (MS) who have walking impairment, with plans to initiate a Phase 3 study in Q1 2018.

ADS-4101: an investigational high-dose lacosamide to be taken once-daily at bedtime.

ADS-4101 for Partial Onset Seizures in Patients with Epilepsy

Lacosamide is an anti-epilepsy active ingredient previously approved by the FDA and currently marketed by UCB SA/NV as VIMPAT® (lacosamide). The Company is currently conducting a multi-dose Phase 1b study designed to evaluate the tolerability and pharmacokinetic profile of three ascending doses of ADS-4101 (up to 600 mg/day) taken once-daily at bedtime compared to ascending doses of twice daily VIMPAT tablets in 24 healthy volunteers.

Namzaric® (memantine hydrochloride extended-release and donepezil hydrochloride) capsules and Namenda XR® (memantine hydrochloride) extended-release capsules.

These two commercially available medicines currently marketed by Forest Laboratories Holdings Limited ("Forest"), an indirect wholly-owned subsidiary of Allergan plc (collectively, "Allergan") in the United States for the treatment of moderate to severe Alzheimer's disease. The Company is eligible to receive royalties on net sales of Namenda XR® and Namzaric® beginning in June of 2018 and May of 2020, respectively.

The Company was incorporated in the State of Delaware on November 15, 2000, and operates as one segment. The Company's headquarters and operations are located in Emeryville, California.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The 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, 2016 was derived from the audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP. These

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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, 2016, included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC.

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 including short-term and long-term classification, embedded derivatives, income taxes, and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results may differ from those estimates.

Liquidity and Financial Condition

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

Based upon the current status of, and plans for, its product development and commercialization, the Company believes that the existing cash, cash equivalents, and investments of $144.9 million as of June 30, 2017 will be adequate to satisfy the Company's capital needs through at least the next twelve months from the issuance of this Quarterly Report on Form 10-Q. 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, 2013, and 2012, it has not generated any commercial revenue from sales of its products. Under its license agreement with Allergan, the Company received the final milestone payment in 2014, and is not entitled to receive any royalties for net sales of Namzaric® until mid-2020 and Namenda XR® until mid-2018. To achieve sustained profitability, the Company, alone or with others, must successfully develop its product candidates, obtain required regulatory approvals, and successfully manufacture and market its products.

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-

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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 equivalent employees assigned to the license agreement are recognized as the related services or activities are performed, in accordance with the contract terms.

Accounts Receivable

The Company's accounts receivable balance consists of amounts due from Allergan, in accordance with the contract terms of the license agreement, for research and development funding and full-time equivalent employees assigned to the Allergan license agreement, as well as for reimbursement of external costs, recorded as contra-expense, associated with supporting prosecution and litigation of intellectual property rights.

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

Research and Development

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

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

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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.

Long-Term Debt

Long-term debt consists of the Company's loan agreement with HealthCare Royalty Partners ("HCRP"). The Company accounted for the loan agreement as a debt financing arrangement. Interest expense is accrued using the effective interest rate method over the estimated period the debt will be repaid. Debt issuance costs have been recorded as a debt discount in the Company's consolidated balance sheets and are being amortized and recorded as interest expense throughout the life of the loan using the effective interest rate method. The Company must make certain assumptions and estimates, including future royalties and net product sales, in determining the expected repayment term and amortization period of the debt discount, as well as the classification between current and long-term portions. The Company periodically assesses these assumptions and estimates, and adjusts the liabilities accordingly.

Embedded Derivatives Related to Debt Instruments

Embedded derivatives that are required to be bifurcated from their host contract are evaluated and valued separately from the debt instrument. Under the Company's loan agreement with HCRP, upon the occurrence of a default or a change in control, the Company may be required to make mandatory prepayments of the borrowings. The prepayment premium is considered an embedded derivative, as the holder of the loans may exercise the option to require prepayment by the Company. Further, in the event of a regulatory change that results in a material adverse effect on HCRP's rate of return, the Company shall pay directly to HCRP an amount that compensates HCRP for such reduction. The embedded derivative is presented as a component of other non-current liabilities. The Company will remeasure the embedded derivatives each reporting period and report changes in the estimated fair value as gains or losses in interest and other income, net, in the condensed consolidated statement of operations.

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 six months ended June 30, 2017, approximately 6,107,000 and 5,899,000, 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 six months ended June 30, 2016, approximately 5,714,000 and 5,542,000, 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 is recognized and amortized over the applicable vesting period. All stock options awarded to non-employees are accounted for at the fair value of the consideration received or the fair value of the equity instrument issued, as calculated using the Black-Scholes model. Stock options granted to non-employees are subject to periodic revaluation at each reporting date as the underlying equity instruments vest.

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

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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, ASU 2016-12, Narrow-Scope Improvements and Practical Expedients, and ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. The Company plans to adopt the new standard in the first quarter of fiscal year 2018. The Company is currently evaluating the method of adoption and effect the new guidance will have on its consolidated financial statements.

In 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 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.

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718) – Scope of Modification Accounting. The new guidance clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. This guidance is effective for fiscal years beginning after December 15, 2017. Early adoption is permitted. The Company does not expect the adoption of the new guidance to have a material impact 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,

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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):

	June 30, 2017			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market	$19,960	$19,960		$ —
Corporate debt	43,120	—	43,120	—
U.S. Treasury notes	68,191	—	68,191	—
Total assets measured at fair value	$131,271	$19,960	$111,311	$ —
Liabilities:				
Embedded derivative liability	$764	$—	$—	$ 764
Total liabilities measured at fair value	$764	$—	$—	$ 764

	December 31, 2016			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market	$192	$ 192	$—	$ —
Corporate debt	51,233	—	51,233	—
U.S. Treasury notes	60,976	—	60,976	—
Total assets measured at fair value	$112,401	$ 192	$112,209	$ —

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. In certain cases where there is limited activity or less transparency around inputs to valuation, the related assets or liabilities are classified as Level 3. The Company classified an embedded derivative related to the Royalty-Backed Loan as a Level 3 liability.

The fair value of the embedded derivative as a result of a change in control was calculated using a probability-weighted discounted cash flow model. The model used in valuing this embedded derivative requires the use of significant estimates and assumptions including but not limited to: 1) expected cash flows the Company expects to receive on U.S. net sales of ADS-5102 and on royalties from Allergan on U.S. net sales of Namzaric®; 2) the Company's risk adjusted discount rates; 3) the probability of FDA approval and receipt of Orphan Drug exclusivity for ADS-5102 for the treatment of LID; and 4) the probability of a change in control occurring during the term of the note based on the percentage of similar companies that were acquired over the previous five year period. Changes in the estimated fair value of the bifurcated embedded derivative are reported as gains or losses in interest and other income, net, in the condensed consolidated statement of operations. In the periods presented, the embedded derivative value as a result of an event of default and the value as a result of increased costs due to a regulatory change are both not material, but could

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become material in future periods if a specified event of default or regulatory change became more probable than is currently estimated. See Note 7 “Long-Term Debt,” for further description.

There were no transfers between any of the levels of the fair value hierarchy during the three and six months ended June 30, 2017.

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 June 30, 2017 and December 31, 2016 (in thousands):

	June 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Investments:				
Corporate debt	$43,185	$ 1	$ (66)	$43,120
U.S. Treasury notes	68,309	—	(118)	68,191
Total	$111,494	$ 1	$ (184)	$111,311
Reported as:				
Short-term investments	$94,891	$ 1	$ (167)	$94,725
Long-term investments	16,603	—	(17)	16,586
Total	$111,494	$ 1	$ (184)	$111,311

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Investments:				
Corporate debt	$51,354	$ —	$ (121)	$51,233
U.S. Treasury notes	61,048	5	(77)	60,976
Total	$112,402	$ 5	$ (198)	$112,209
Reported as:				
Short-term investments	$90,050	$ 1	$ (134)	$89,917
Long-term investments	22,352	4	(64)	22,292
Total	$112,402	$ 5	$ (198)	$112,209

Short-term and long-term investments include accrued interest of $0.4 million and $0.1 million, respectively, as of June 30, 2017. Short-term and long-term investments includes accrued interest of $0.3 million and $0.1 million, respectively, as of December 31, 2016. The Company has not incurred any realized gains or losses on investments for the three and six months ended June 30, 2017 and 2016. Investments are classified as short-term or long-term depending on

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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 15 months as of June 30, 2017.

5. LICENSE AGREEMENTS

In November 2012, the Company granted Allergan an exclusive license, with right to sublicense, certain of the Company's intellectual property rights relating to human therapeutics containing memantine in the United States. In connection with these rights, Allergan markets and sells Namzaric® and Namenda XR® for the treatment of moderate to severe dementia related to Alzheimer's disease. Pursuant to the agreement, Allergan made an upfront payment of $65.0 million. The Company earned and received additional cash payments totaling $95.0 million upon achievement by Allergan of certain development and regulatory milestones. Under the agreement, external costs incurred related to the prosecution and litigation of intellectual property rights are reimbursable. For the six months ended June 30, 2017 and 2016, reimbursed expenses amounting to zero and $1.2 million, respectively, are reflected as a reduction to general and administrative, net. In addition, the Company may earn tiered royalty payments based on future net sales of Namzaric® and Namenda XR®.

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

6. COMMITMENTS AND CONTINGENCIES

Lease Commitments

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

As of June 30, 2017, future minimum lease payments under the non-cancelable facility operating lease were as follows (in thousands):

	June 30, 2017
2017 (remaining)	$ 307
2018	634
2019	653
2020	224
2021	—
Thereafter	—
Total	$ 1,818

Purchase Commitments

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

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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 and Other Legal Proceedings

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, including one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv) to the FDA requesting approval 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 Company and Forest will continue to enforce the patents associated with Namenda XR®.

The Company and Forest have entered into a series of settlement agreements with all Namenda XR® ANDA filers, except for one recent ANDA filer. 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.

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. If the appeal is unsuccessful, generic entry of Namenda XR® could occur prior to January 31, 2020.

On June 2, 2017, the Company and Forest filed a lawsuit against the remaining ANDA filer in the U.S. District Court for the District of Delaware for infringement of certain patents based on that filer's filing of an ANDA seeking FDA approval to manufacture and market generic versions of Namenda XR® that included one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv). This action is ongoing and in a very early stage.

On July 24, 2017, an ANDA filer that previously entered into a settlement agreement with Forrest and Adamas filed a complaint against the Company and Forest in the Court of Chancery of the State of Delaware alleging that Forest and the Company breached the license agreement and settlement agreement entered into with that filer to settle the litigation related to its ANDA referencing Namenda XR® as the reference listed drug. This action is ongoing and in a very early stage.

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Additionally, as of the date of this filing, a number of companies have submitted ANDAs including one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv) to the FDA requesting approval 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 filed 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 but one of the ANDA filers, including all first filers on all the available dosage forms of Namzaric®. Entry dates for generic Namzaric® are governed by the settlement agreements in those actions. Subject to those agreements, the earliest date on which any of these agreements grants a license to market generic version of Namzaric® is January 1, 2025 or in the alternative, an option to launch an authorized generic version of Namzaric® beginning on January 1, 2026. The Company and Forest intend to continue to enforce the patents associated with Namzaric®.

On June 2, 2017, the Company and Forest filed a lawsuit against the remaining ANDA filer in the U.S. District Court for the District of Delaware for infringement of certain patents based on its filing of an ANDA seeking FDA approval to manufacture and market generic versions of Namzaric® that included one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv). This action is ongoing and in a very early stage.

On April 20, 2017, an opposition was filed against Adamas' European Patent EP 2 506 709 B1, which relates to extended-release compositions comprising amantadine or a pharmaceutically acceptable salt thereof. On May 26, 2017, the Company received a Communication of Notices of Opposition (R. 79(1) EPC) from the European Patent Office that requested the Company file its observations in response to the opposition within a period of four months from May 26, 2017. The Company intends to continue to challenge this opposition.

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 currently party to any material legal proceedings.

7. LONG-TERM DEBT

Royalty-Backed Loan Agreement

In May 2017, the Company, through a new wholly-owned subsidiary, Adamas Pharma, LLC, entered into a Royalty-Backed Loan with HCRP, whereby the Company borrowed $35.0 million and has the right to receive an additional $65.0 million upon FDA approval and receipt of Orphan Drug exclusivity of ADS-5102 (amantadine) extended-release capsules for the treatment of LID in patients with Parkinson's disease if achieved prior to a specified date. Principal and interest will be payable quarterly from the proceeds of a 12.5% royalty on U.S. net sales of ADS-5102 and up to $15.0 million of the Company's annual royalties from Allergan on U.S. net sales of Namzaric® starting in May 2020, pursuant to the Company's license agreement with Allergan. The royalty rate on net sales of ADS-5102 will drop to 6.25% after the principal amount of the loan has been repaid in full, until the Company has made total payments of 200% of the funded amounts. The Company may elect to voluntarily prepay the loan at any time in which case the amount due will be 200% of the funded amounts, less total payments made to date. Royalty rates are subject to increase to 17.5% and 22.5% if total principal and interest payments have not reached minimum specified levels at measurement dates on December 2021 and December 2022, respectively. Under the terms of the loan, HCRP has recourse to Adamas Pharma, LLC, not the Company. The loan agreement matures in December 2026 but as the repayment of the loan amount is contingent upon the sales volumes of ADS-5102 and royalties from Allergan, the repayment term may be shortened depending on the actual sales of ADS-5102 and actual royalties received from Allergan.

The loans bear interest at an annual rate of 11% on the outstanding principal amount and includes an interest-only period until the interest payment date following the ninth full calendar quarter after the earlier of the $65.0 million additional loan or October 2018. To the extent that royalties are insufficient to pay interest in full, any unpaid portion of the quarterly interest payment will be added to the principal amount of the loans. For the three months ended June 30, 2017, accrued interest in the amount of $0.7 million was added to the principal balance of the loan.

In connection with the Royalty-Backed Loan, the Company paid HCRP a lender expense amount of $0.4 million and incurred additional debt issuance costs totaling $0.8 million. The lender expense and additional debt issuance costs have been recorded as a debt discount and are being amortized and recorded as interest expense over the estimated

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term of the loan using the effective interest method. The Company recorded interest expense, including amortization of the debt discount, related to the Royalty-Backed Loan, of $0.7 million for the three months ended June 30, 2017. The effective interest rate on the amounts borrowed under the Royalty-Backed Loan, including the amortization of the debt discount was 16.6%.

The assumptions used in determining the expected repayment term of the loan and amortization period of the debt discount require that we make estimates that could impact the short and long-term classification of these costs, as well as the period over which these costs will be amortized.

The Company may be required to make mandatory prepayments of the borrowings under the Royalty-Backed Loan, subject to specified prepayment trigger events, including: (1) the occurrence of any event of default or (2) the occurrence of a change in control. Upon the prepayment of all or any of the outstanding principal balance, the Company shall pay in addition to such prepayment, a prepayment premium. As the holder of the loans may exercise the option to require prepayment by the Company, the prepayment premium is considered to be an embedded derivative which is required to be bifurcated from its host contract and accounted for as a separate financial instrument. The embedded derivative is presented together with the debt instrument and the related debt discount on a combined basis. The valuation of the embedded derivative is described further in Note 3.

Long-term debt and unamortized debt discount balances are as follows (in thousands):

	June 30, 2017
Loans payable, gross	$35,000
Less: Unamortized debt discount and issuance costs	(1,888)
Plus: Unpaid portion of quarterly interest payment	656
Carrying value of loans payable	33,768
Less: Current portion of long-term debt	—
Non-current portion of long-term debt	$33,768

The estimated fair value of the long-term debt, as measured using Level 3 inputs, approximates the carrying amounts as presented on the balance sheet as of June 30, 2017. The estimated fair value was calculated in the same manner as the valuation of the embedded derivative as described further in Note 3.

There are no contractual minimum principal payments due until the loan matures in December 2026 as the repayment of the loan amount is contingent upon the sales volumes of ADS-5102 and royalties from Allergan.

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.

Public Offering

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

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Shares Reserved for Future Issuance

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

	June 30, 2017	December 31, 2016
Common stock awards issued and outstanding	6,130,397	5,483,557
Authorized for future issuance under 2014 Equity Incentive Plan	1,623,483	1,576,926
Authorized for future issuance under 2016 Inducement Plan	556,562	334,062
Employee stock purchase plan	718,210	532,849
Total	9,028,652	7,927,394

Sales Agreement

In May 2017, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC ("Cowen"), as sales agent, pursuant to which the Company may, from time to time, issue and sell at its option, shares of the Company's common stock for an aggregate offering price of up to $50.0 million under an at-the-market offering ("ATM Offering"). Sales of the common stock, if any, will be made pursuant to a shelf registration statement that was declared effective by the Securities and Exchange Commission ("SEC") on November 21, 2016. Cowen is acting as sole sales agent for any sales made under the Sales Agreement and the Company will pay Cowen a commission of up to 3% of the gross proceeds. The Company's common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary.

The Company is not obligated to make any sales of shares of common stock under the Sales Agreement. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. As of June 30, 2017, no shares have been sold under the Sales Agreement.

9. STOCK-BASED COMPENSATION

Stock Compensation Plans

In January 2017, the common stock available for issuance under the 2014 Equity Incentive Plan (the "2014 Plan") automatically increased by 4% of the total number of shares of the Company's capital stock outstanding on December 31, 2016, or 880,362 shares.

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. In January 2017, an amendment to the Inducement Plan was approved to increase the number of shares available for issuance an additional 450,000 shares for a total of 900,000 shares.

Employee Stock Purchase Plan

In January 2017, the common stock available for issuance under the 2014 Employee Stock Purchase Plan (the "ESPP") automatically increased by 1% of the total number of shares of the Company's capital stock outstanding on December 31, 2016, or 220,090 shares.

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Stock-Based Compensation Expense

The following table reflects stock-based compensation expense recognized for the three and six months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development:				
Employees	$849	$691	$1,624	$1,276
Non-employee consultants	46	40	92	122
General and administrative:				
Employees	2,870	1,877	4,921	3,710
Non-employee consultants	—	23	12	76
Total expense	$3,765	$2,631	$6,649	$5,184

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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

At Adamas, we believe in the power and the promise of medicines derived from a deep understanding of time-dependent biology. All biological processes, including the body's responses to disease and drug interventions, are governed by complex timing patterns. When the timing of disease and drug responses are out of sync, patient outcomes can be compromised.

Our expertise lies in uncovering and mapping the relationship between disease and drug activity timing patterns. From there, we strive to create medicines with therapeutic profiles that match the pattern of disease to drive a significant and durable clinical effect. As a result, our medicines are designed to provide patients with what they need, when they need it-the right level of drug at the right place and time to enhance efficacy-and then lower levels of drug when they don't need it. Our goal is to develop medicines that are timed for the benefit of patients.

A unique understanding of time-dependent biological processes informs our every innovation, targeting advancement in treatment of chronic neurologic disorders. Our portfolio includes:

ADS-5102: ADS-5102 is a high-dose, extended-release amantadine capsule taken once daily at bedtime.

ADS-5102 for Levodopa-Induced Dyskinesia in Patients with Parkinson's Disease

Parkinson's disease is a chronic neurodegenerative disorder affecting close to 1 million people in the United States. Levodopa, which replaces lost dopamine, is considered the "gold standard" and the most effective therapy for Parkinson's disease. Over time, people with Parkinson's disease require increasingly higher or more frequent doses of levodopa in order to avoid recurrent periods of OFF time - characterized by slowness of movement, rigidity, impaired walking, tremor, and postural instability - when the underlying symptoms of Parkinson's disease return. As Parkinson's disease progresses, nearly all people on levodopa therapy will also experience levodopa-induced dyskinesia, which is characterized by involuntary movements that are non-rhythmic, purposeless, and unpredictable.

In a robust clinical program consisting of three randomized placebo-controlled studies and a two-year, ongoing, open label safety study, ADS-5102 demonstrated a durable reduction in both dyskinesia and OFF time in people with Parkinson's disease.

A new drug application (NDA) for ADS-5102 for the treatment of levodopa-induced dyskinesia in patients with Parkinson's disease is under review by the FDA with a Prescription Drug User Fee Act (PDUFA) action date of August 24, 2017.

If approved, ADS-5102 has the potential to be the first and only FDA-approved medicine for the treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson's disease. In that event, we are planning to initiate access to ADS-5102 for patients in 2017, and execute a full launch of the medicine via the deployment of sales representatives with marketing and promotional support in January 2018.

ADS-5102 for Multiple Sclerosis Walking Impairment

We completed a Phase 2, 4-week proof-of-concept study designed to evaluate ADS-5102 in patients with multiple sclerosis who have walking impairment. A significant benefit in walking speed was observed versus placebo on both mean value and the proportion of participants with a clinically significant ≥20% improvement. The results for timed-up-and-go (TUG) and 2-minute walking test (2MWT) also suggested benefit on other aspects of mobility and walking. We plan to initiate a Phase 3 study in this indication in Q1 2018.

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ADS-4101: ADS-4101 is an investigational high-dose, modified-release lacosamide capsule, taken once-daily at bedtime.

ADS-4101 for Partial Onset Seizures in Patients with Epilepsy

Lacosamide is an anti-epilepsy active ingredient previously approved by the FDA and currently marketed by UCB SA/NV as VIMPAT® (lacosamide). ADS-4101 was designed to temper the initial rate-of-rise in lacosamide concentrations, potentially improving the adverse event profile and dose limitations due to dizziness following administration of VIMPAT. The slow initial rise may enable a higher once-daily dose at bedtime, which results in a higher daytime concentration that may be more effective for patients than VIMPAT.

The data from a Phase 1 study of 24 healthy volunteers showed that a single 400 mg dose of ADS-4101 has improved tolerability compared to the equivalent dose of VIMPAT (lacosamide) immediate-release (IR) tablets. The data also demonstrated that ADS-4101 exhibited the desired pharmacokinetic properties, namely a reduced initial rate-of-rise of lacosamide concentration and prolonged time to maximum drug concentration (Tmax) appropriate for bedtime dosing. We are currently conducting a multi-dose Phase 1b study designed to evaluate the tolerability and pharmacokinetic profile of three ascending doses of ADS-4101 (up to 600 mg/day) taken once-daily at bedtime compared to ascending doses of twice daily VIMPAT tablets in 24 healthy volunteers. We expect to announce topline data for the Phase 1b trial in the third quarter of 2017.

Namzaric® (memantine hydrochloride extended-release and donepezil hydrochloride) capsules and Namenda XR® (memantine hydrochloride) extended-release capsules.

These two commercially available medicines are currently marketed by Forest Laboratories Holdings Limited (“Forest”), an indirect wholly-owned subsidiary of Allergan plc (collectively, “Allergan”), in the United States for the treatment of moderate to severe Alzheimer's disease. We are eligible to receive royalties on sales of Namenda XR® and Namzaric® beginning in June of 2018 and May of 2020, respectively.

Financial operations overview

Summary

Our revenue to date has been generated primarily from license, milestone, and development revenue pursuant to our license agreement with Allergan. We have not generated any commercial product revenue. As of June 30, 2017, we had an accumulated deficit of $159.0 million. Although we reported net income in each of the years ended December 31, 2014, 2013, and 2012, this was primarily due to the recognition of revenue pursuant to our license agreement with Allergan. There are no further milestone payments to be earned under our license agreement with Allergan. We incurred significant losses in the six months ended June 30, 2017, in 2016, 2015, and prior to 2012, and expect to continue to incur significant losses as we advance our product candidates into later stages of development and, if approved, commercialization.

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

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

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cash payments totaling $95.0 million upon achievement by Allergan of certain development and regulatory milestones, which we recognized in 2013 and 2014.

Prior to our initial public offering of our common stock, or IPO, in April 2014, we had raised an aggregate of approximately $87.2 million through the sale of convertible preferred stock and $1.0 million through the exercise of preferred stock warrants. In 2014, we issued and sold 3,081,371 shares of common stock in our IPO and received net proceeds of approximately $42.6 million, which included partial exercise of the underwriters' option to purchase additional shares and after deducting underwriting discounts and offering expenses. In connection with the completion of our IPO, all convertible preferred stock converted into common stock. In June 2015, we entered into a Controlled Equity Offering Sales Agreement, pursuant to which we were able to issue and sell shares of common stock having an aggregate offering value of up to $25.0 million, which was terminated in November 2016. During the term of the agreement, we issued 509,741 shares of common stock and raised net proceeds of $9.7 million. 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. In May 2017, we entered into a sales agreement with Cowen and Company, LLC, pursuant to which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up the $50.0 million. As of June 30, 2017, no shares have been sold under the sales agreement. Also in May 2017, we entered into a royalty-backed loan agreement ("Royalty-Backed Loan") with HealthCare Royalty Partners ("HCRP"), whereby we borrowed $35.0 million and have the right to receive an additional $65.0 million upon FDA approval and receipt of Orphan Drug exclusivity of ADS-5102 (amantadine) extended-release capsules for the treatment of LID in patients with Parkinson's disease if achieved prior to a specified date.

As of June 30, 2017, we had cash, cash equivalents, and available-for-sale securities of $144.9 million.

Revenue

We have not generated any revenue from commercial product sales to date. Our revenue to date has been generated primarily from non-refundable upfront license payments, milestone payments, reimbursements for research and development expenses and full-time equivalents assigned under our license agreement with Allergan, and to a lesser degree reimbursement for research and development expenses from NIH grants and government contracts. We do not expect to recognize any further milestone payments under our license agreement with Allergan, and we expect reimbursements for full-time equivalents assigned to the license agreement to be inconsequential in future periods. Beginning in May 2020, we will be entitled to receive royalties in the low to mid-teens from Allergan for net sales of Namzaric® in the United States, and in June 2018 we will be entitled to receive royalties in the low to mid-single digits for net sales of Namenda XR® in the United States; however, we do not expect the Namenda XR® royalties will make a significant financial contribution to our business. We were also awarded a continuation of an NIH grant for $1.0 million in August 2014 that terminated in July 2016, which we administered, but conducted through subcontractors.

Research and development expenses

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

Research and development expenses consist of:

- fees paid to clinical investigators, clinical trial sites, consultants, and vendors, including contract 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 establishment and validation of manufacturing capabilities for commercial supply, should approval be obtained;
- expenses related to compliance with regulatory requirements;
- other consulting fees paid to third parties; and

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- 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 six months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Increase (Decrease)	Six Months Ended June 30,		Increase (Decrease)
	2017	2016		2017	2016	
ADS-5102	$4,864	$8,053	$ (3,189)	$10,546	$14,237	$ (3,691)
ADS-4101	1,924	—	1,924	2,976	—	2,976
Other research and development expenses	388	1,171	(783)	742	2,509	(1,767)
Total research and development expenses	$7,176	$9,224	$ (2,048)	$14,264	$16,746	$ (2,482)

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

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. We anticipate incurring significant research and development expenses as we continue to support: the FDA's review of ADS-5102 for LID; clinical trials for ADS-5102 in indications beyond LID, including but not limited to walking impairment in multiple sclerosis patients and other Parkinson's disease indications earlier in the Parkinson's disease treatment journey; ADS-4101 for treatment of epilepsy; and potentially additional clinical-stage programs in more indications or for future product candidates. The process of conducting the necessary clinical research to obtain FDA approval is costly and time consuming. We consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each product candidate and clinical program may be affected by a variety of factors, including but not limited to, the quality of the product candidate, early clinical data, investment in the program, competition, manufacturing capability, and commercial viability. Furthermore, in the past we have entered into licensing arrangements with other pharmaceutical companies to develop and commercialize our product candidates, and we may enter into additional licensing arrangements or collaborations in the future. In situations in which third parties have control over the clinical development of a product candidate, the estimated completion dates are largely under the control of such third parties and not under our control. We cannot forecast with any degree of certainty which of our product candidates, if any, will be subject to future licensing or collaboration arrangements or how such arrangements would affect our development plans or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and administrative expenses, net

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

Interest and other income (expense), net

Interest and other income (expense), net, consists primarily of interest received on our investments.

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Interest expense

Interest expense consists of accrued interest pursuant to our Royalty-Based Loan and amortization of debt issuance costs.

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. Refer to "Note 2 - Summary of Significant Accounting Policies" in the accompanying "Notes to Condensed Consolidated Financial Statements (unaudited)," which information is incorporated by reference here, for changes to our critical accounting policies during the six months ended June 30, 2017, 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, 2016.

Results of operations

Comparison of the three and six months ended June 30, 2017 and 2016

The following table summarizes our results of operations for the three and six months ended June 30, 2017 and 2016 (in thousands, except percentages):

	Three Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2017	2016			2017	2016		
Revenue	$2	$222	$ (220)	(99)%	$2	$397	$ (395)	(99)%
Research and development expenses	7,176	9,224	(2,048)	(22)%	14,284	16,746	(2,482)	(15)%
General and administrative expenses, net	13,115	8,058	5,057	63 %	22,259	14,699	7,560	51 %
Interest and other income, net	222	184	38	21 %	426	344	82	24 %
Interest expense	729	—	729	100 %	729	—	729	100 %

Revenue

Revenue for both the three and six months ended June 30, 2017 was $2,000, compared to $0.2 million and $0.4 million for the three and six months ended June 30, 2016. Revenue for all periods presented was primarily related to reimbursement of certain expenses as provided for in our license agreement with Allergan, as well as from government contracts.

Research and development expenses

Research and development expenses decreased by $2.0 million, or 22%, to $7.2 million for the three months ended June 30, 2017 from $9.2 million for the three months ended June 30, 2016. The decrease in research and development expenses was mainly attributable to costs associated with the clinical development of ADS-5102, due to the conclusion of two Phase 3 clinical trials assessing ADS-5102 for the treatment of LID, in addition to decreased costs associated with the ongoing open-label safety study and decreased volume of pre-commercial manufacturing activities. The decrease was offset in part by increased activity related to clinical work associated with ADS-4101 for the treatment of partial onset seizures in patients with epilepsy. Included in research and development expenses was stock-based

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compensation expense, which was $0.9 million compared to $0.7 million for the three months ended June 30, 2017 and 2016, respectively.

Research and development expenses decreased by $2.5 million, or 15%, to $14.3 million for the six months ended June 30, 2017 from $16.7 million for the six months ended June 30, 2016. The decrease in research and development expenses was mainly attributable to costs associated with the clinical development of ADS-5102, due to the conclusion of two Phase 3 clinical trials assessing ADS-5102 for the treatment of LID, in addition to costs associated with the ongoing open-label safety study which also decreased from the prior year. The decrease was offset by increased activity related to clinical work associated with ADS-4101 for the treatment of partial onset seizures in patients with epilepsy. Included in research and development expenses was stock-based compensation expense, which was $1.7 million compared to $1.4 million for the six months ended June 30, 2017 and 2016, respectively.

General and administrative expenses, net

General and administrative expenses, net, increased by $5.1 million, or 63%, to $13.1 million for the three months ended June 30, 2017 from $8.1 million for the three months ended June 30, 2016. The increase in general and administrative expenses was primarily due to increased costs associated with establishing commercial capabilities in anticipation of the commercialization of ADS-5102 for the treatment of LID, pending regulatory approval, including an increase in headcount-related expenses and commercial activities. General and administrative expenses also included stock-based compensation expense of $2.9 million compared to $1.9 million for the three months ended June 30, 2017 and 2016, respectively.

General and administrative expenses, net, increased by $7.6 million, or 51%, to $22.3 million for the six months ended June 30, 2017 from $14.7 million for the six months ended June 30, 2016. The increase in general and administrative expenses was primarily due to increased costs associated with establishing commercial capabilities in anticipation of the commercialization of ADS-5102 for the treatment of LID, pending regulatory approval, including an increase in headcount-related expenses and commercial activities. General and administrative expenses also included stock-based compensation expense of $4.9 million compared to $3.8 million for the six months ended June 30, 2017 and 2016, respectively.

Interest and other income, net

Interest and other income, net, was essentially unchanged at $0.2 million for the three months ended June 30, 2017 and 2016, and $0.4 million compared to $0.3 million for the six months ended June 30, 2017 and 2016, respectively. Net interest income is primarily due to interest income earned on investments.

Interest expense

The increase in interest expense to $0.7 million for the three and six months ended June 30, 2017 compared to the three and six months ended June 30, 2016 was due to the new Royalty-Backed Loan entered into in May 2017.

Liquidity, capital resources and plan of operation

We have funded our operations primarily through $160.0 million of payments received pursuant to our license agreement with Allergan, $88.2 million sales of convertible preferred stock and warrants, $114.1 million pursuant to sales of our common stock, and $35.0 million pursuant to our Royalty-Backed Loan with HCRP. 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. In June 2015, we entered into a Controlled Equity Offering Sales Agreement, pursuant to which we were able to, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $25.0 million, which was terminated in November 2016. During the term of the agreement we issued 509,741 shares of common stock and raised net proceeds of $9.7 million. In January 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. In May 2017, we entered into a Royalty-Backed Loan with HCRP, whereby we borrowed $35.0 million and have the right to receive an additional $65.0 million upon FDA approval and receipt of Orphan Drug exclusivity of ADS-5102 (amantadine) extended-release capsules for the treatment of LID in patients with Parkinson's disease.

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We have not generated any revenue from the sale of products. We incurred losses and generated negative cash flows from operations since inception through the year ended December 31, 2011. Although we recognized a profit and positive cash flow in 2014, 2013, and 2012 as a result of payments received pursuant to our license agreement with Allergan, we received our final milestone payment from Allergan in December 2014. We do not currently receive any royalties from Allergan, nor do we have other license agreements or collaborations from which we might expect milestone or royalty revenue. Consequently, we expect to continue to incur substantial and increasing losses for the foreseeable future. Our principal sources of liquidity were our cash, cash equivalents, and investments, which totaled $144.9 million as of June 30, 2017, compared to $135.9 million at December 31, 2016.

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

We expect to continue significant spending in connection with the development and commercialization of our product candidates, particularly for ADS-5102 for the treatment of LID, as well as other indications, and also for ADS-4101 for indications in epilepsy, for which Phase 3 clinical trials may be initiated in 2018. In order to continue these activities, we may decide to raise additional funds through a combination of public or private equity offerings, debt financings, royalty financings, collaborations, strategic alliances, licensing arrangements, asset sales, and other marketing and distribution arrangements. Sufficient additional funding may not be available on acceptable terms, or at all. If adequate funds are not available in the future, we may need to delay, reduce the scope of, or put on hold our clinical studies, research and development programs, or commercialization efforts.

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

	Six Months Ended June 30,	
	2017	2016
Net cash (used in) provided by:		
Operating activities	$(26,620)	$(24,511)
Investing activities	408	36,409
Financing activities	36,095	64,270
Net increase in cash and cash equivalents	$9,883	$76,168

Net cash used in operating activities was $26.6 million for the six months ended June 30, 2017 compared to $24.5 million for the same period in the prior year. Net loss of $36.8 million for the six months ended June 30, 2017 included net non-cash adjustments of $7.9 million, which consisted primarily of stock-based compensation of $6.6 million. Net loss of $30.7 million for the six months ended June 30, 2016 included non-cash adjustments of $5.9 million, primarily related to $5.2 million in stock-based compensation. The primary use of cash for the six months ended June 30, 2017 was to fund activities in support of the NDA and pre-commercial activities in preparation for the commercialization for ADS-5102 for the treatment of LID, if approved. Additionally, cash was used to fund development of ADS-4101 for indications in epilepsy.

Net cash provided by investing activities was $0.4 million for the six months ended June 30, 2017, compared to $36.4 million for the same period in the prior year. In the six months ended June 30, 2017, we received $1.0 million as a result of net maturities of available-for-sale securities, offset by $0.6 million in purchases of property and equipment. In the six months ended June 30, 2016 we received $37.7 million as a result of maturities of available-for-sale securities, offset by $1.2 million in purchases of property and equipment.

Net cash provided by financing activities was $36.1 million for the six months ended June 30, 2017, compared to $64.3 million for the six months ended June 30, 2016. In the period ended June 30, 2017, we received net proceeds of $34.6 million from long-term debt and received cash proceeds of $1.6 million related to the exercise of stock options and purchases of common stock under the Employee Stock Purchase Plan. In the six months ended June 30, 2016, we

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received net cash proceeds of $61.8 million related to the sale of common stock under a follow-on public offering, coupled with $2.4 million related to the exercise of stock options and purchases of common stock under the Employee Stock Purchase Plan.

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 June 30, 2017, were not materially different than at December 31, 2016.

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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 June 30, 2017, we had cash, cash equivalents, and investments of $144.9 million, compared to $135.9 million at December 31, 2016, consisting of cash and cash equivalents, as well as short and long-term investment grade available-for-sale securities. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration and our holdings in US government bonds and corporate debt securities mature prior to our expected need for liquidity, we believe that our exposure to interest rate risk is not significant and, as a consequence, a one percentage point movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

ITEM 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 June 30, 2017. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2017, 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 June 30, 2017 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

For information regarding legal proceedings, refer to Litigation in “Note 6 - Commitments and Contingencies” in the accompanying “Notes to Condensed Consolidated Financial Statements (unaudited),” which information is incorporated by reference here.

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, regulatory approval, and commercialization of our current and future product candidates, including ADS-5102

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

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

- successfully completing the development program for ADS-5102 and other product candidates in a timely manner;
- receiving marketing approval for ADS-5102 and other product candidates from the FDA in a timely manner;
- successfully establishing and maintaining commercial manufacturing with third parties;
- commercializing ADS-5102 and other product candidates, if approved, including marketing, sales, and distribution of the product independently or in partnership with another company;
- acceptance by the medical community and patients of the approved product;
- the pricing and placement of ADS-5102 on payers’ formulary tiers and the reimbursement rates established for the approved products;
- effectively competing with other approved or used medicines and future compounds in development;
- 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.

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

Our new drug application ("NDA") for ADS-5102 for the treatment of LID in patients with Parkinson's disease was accepted for filing by the FDA in January 2017 and has a Prescription Drug User Fee Act ("PDUFA") date of August 24, 2017. We cannot give any assurance that our NDA for ADS-5102 for the treatment of LID will be approved by regulatory authorities and even if approved, the prescribing information may not reflect the clinical claims needed to successfully promote the product and we may be subject to post-marketing requirements or commitments. Although we have substantially completed the clinical trial program for ADS-5102 for the treatment of LID, except for the long-term open-label safety study of ADS-5102 for the treatment of LID, we do not know if the clinical package for ADS-5102 for the treatment of LID will adequately demonstrate sufficient safety and efficacy to the satisfaction of the FDA to achieve regulatory approval.

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

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

Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. Generally, if a drug product with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the drug product is entitled to a period of marketing exclusivity, which may preclude the FDA from approving another marketing application for the same drug product for the same therapeutic indication. The applicable period of exclusivity is up to seven (7) years in the United States. Even though we have orphan drug designation for ADS-5102 for the treatment of LID, we may not receive orphan designation upon approval due to changes in our application or because we may not be the first to obtain marketing approval. If we do not receive orphan exclusivity at approval, we will also not be eligible to receive additional funds under our Royalty-Backed Loan agreement with HCRP.

With respect to LID, both ADS-5102 and a competitor, Osmotica Pharmaceutical LLC, amantadine product candidate for the treatment of LID have been granted orphan drug designation. If Osmotica were to obtain regulatory approval for its product candidate prior to ADS-5102, it would obtain orphan drug exclusivity for their product candidate and the approval of our marketing application for ADS-5102 could be delayed for so long as Osmotica has exclusivity for its product. The NDA for ADS-5102 for LID is currently under review by the FDA with a PDUFA date of August 24, 2017. We are unaware of the status of Osmotica's clinical development program in LID.

Even if we are first to obtain marketing approval for ADS-5102 for the treatment of LID, the FDA could still subsequently approve the same drug with the same active moiety for the same condition, if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. If we are unable to obtain or maintain orphan exclusivity for ADS-5102 for the treatment of LID, our business would be substantially harmed.

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:

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- 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 effectiveness of marketing, promotion, selling, and distribution support; and
- the availability of third-party insurance coverage or reimbursement.

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

We currently have only limited commercial experience and capabilities with no sales personnel. If we are unable to develop or obtain commercial capabilities, including sales, marketing and market access personnel, we will not be successful in commercializing ADS-5102.

We have only a limited commercial infrastructure and have limited experience in the commercialization, sale, marketing, or distribution of pharmaceutical products, like ADS-5102, if approved. To achieve commercial success for any approved product, including ADS-5102, we must either develop a commercial organization, including sales, marketing and market access personnel 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 through our own sales force personnel with support from a contract sales organization ("CSO") in certain functions. 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 relying on third parties to perform these services. For example, recruiting and building a marketing organization and/or field sales representatives are expensive and time-consuming, and if our product candidates are not commercially successful, our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Also, 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 ADS-5102 or any other of our future product candidates. If we are unable to effectively build, train and equip our sales force, our ability to successfully commercialize ADS-5102 will be harmed.

If approved, ADS-5102 will be a newly-marketed drug and, therefore, none of the members of our sales force will have ever promoted ADS-5102 prior to its launch. In addition, ADS-5102 would be the first drug approved by the FDA for the treatment of LID. As a result, we will be required to expend significant time and resources to train our sales force to be credible, persuasive, and compliant with applicable laws in marketing ADS-5102 to neurologists, movement disorder specialists, and pharmacists. In addition, we must train our sales force to ensure that we deliver a consistent and appropriate message about ADS-5102 to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of ADS-5102 and its proper administration, our efforts to successfully commercialize ADS-5102 could be put in jeopardy, which would negatively impact our ability to generate product revenues.

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Failure to successfully obtain coverage and reimbursement of our products, including ADS-5102, or if coverage and reimbursement is only available at limited levels in the United States, our ability to generate product revenue will be diminished.

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. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. 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.

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, e.g., the federal 340B Drug Pricing Program, or private third-party payers and by any future relaxation of laws that currently 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.

Also, even if we obtain coverage for ADS-5102, the resulting reimbursement payment rates might not be adequate or may require co-payments or co-insurance payments that patients find unacceptably high. Patients may not use ADS-5102 if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost. 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 for which we receive marketing approval, including ADS-5102.

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

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

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

ADS-5102 will face competition from generic versions of immediate-release amantadine and potentially from other extended-release versions of amantadine that may be in development. For example, while immediate-release amantadine is not approved for use in Parkinson's disease for the treatment of LID, some physicians may still prescribe it for such conditions. In addition, a competitor has registered two Phase 3 clinical trials of extended-release amantadine for LID on clinicaltrials.gov.

The NDA for ADS-5102 for the treatment of LID is still under review and there is an ongoing open label safety study with ADS-5102 in LID; therefore, there could be new safety findings regarding ADS-5102 or the FDA may have a different interpretation of our previously reported positive clinical results at approval.

The NDA for ADS-5102 for LID is still under review and we have an ongoing safety study. If any new safety concerns emerging from the FDA's review or our ongoing clinical study, we may:

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

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

If ADS-5102 is approved and commercialized for patients with LID, unforeseen safety issues could emerge thereafter that could require us to change the prescribing information in the future to adding warnings, limit use of the product, and/or result in litigation. Any of these events could have a negative impact on our business.

Discovery of unforeseen safety problems, or increased focus on a known problem, with an approved product could impact our ability to commercialize ADS-5102 and could 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;

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- 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.

Further, 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.

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.

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

There are risks associated with pursuing clinical trials in other indications for ADS-5102, as we may experience numerous unforeseen events during, or as a result of, clinical studies that could harm our ability to commercialize ADS-5102 or to receive regulatory approval for other indications of 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;

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- our third-party vendors, including our Contract Research Organizations ("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.

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®) and in the ADS-5102 clinical trial data in the LID population, there can be no assurance that our program for ADS-5102 for walking impairment associated with multiple sclerosis or future studies in other indications, will not reveal additional safety or tolerability issues. In such an event, our ability to commercialize ADS-5102 for LID and/or expand our business could be compromised.

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.

The marketing and promotion of ADS-5102, if approved, will be limited to the approved indication for use and the information and clinical data included in or consistent with the approved prescribing information. If we want to expand the marketing and promotion of ADS-5102 beyond the approved indication or with information not consistent with the approved prescribing information, we will need to obtain additional regulatory approvals, which may not be granted.

In October 2016, we submitted an NDA seeking regulatory approval of ADS-5102 for the treatment of LID. If this product candidate is approved, we will be permitted to market or promote it only for the treatment of LID and not for other uses. We are developing ADS-5102 for at least one additional indication, treatment of walking impairment in patients with multiple sclerosis, and potentially others. In order to market and promote ADS-5102 for these additional indications, we will need to conduct additional clinical trials that will likely be time-consuming and expensive, and to obtain regulatory approval for such uses. Additionally, our marketing and promotional efforts will be limited to the use of information included in or deemed to be consistent with the approved prescribing information for ADS-5102 for the treatment of LID, including the clinical data and results reflected in the prescribing information. To use information not consistent with the approved prescribing information, will require additional regulatory approvals.

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

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

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

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

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

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price, or AMP, and best price, or BP, for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payers. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

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

Our product candidates, including ADS-5102, include extended-release versions of existing drugs. The manufacture of extended-release versions of drugs is more complex than the manufacture of the immediate-release versions of drugs. Notwithstanding the fact that we have validated our process, 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.

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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.

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

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

The FDCA requires that an applicant for approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon receipt of the paragraph IV notice, the owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. The discovery, trial, and appeals process in such suits can take several years. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. This type of litigation is often time-consuming and costly and may result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. Such litigation has been commenced by Forest Laboratories Holdings Limited ("Forest"), an indirect wholly-owned subsidiary of Allergan plc (collectively, "Allergan") and us to enforce certain patents related to Namenda XR® and Namzaric®. See Litigation in "Note 6 - Commitments and Contingencies" in the accompanying "Notes to Condensed Consolidated Financial Statements (unaudited)" 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.

Risks related to our financial condition and need for additional capital

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

While we are a clinical-stage pharmaceutical company and do not currently market any products, if approved, we expect to begin commercialization of ADS-5102 in 2017. The completion of the development and the potential commercialization of our product candidates, including ADS-5102, should they receive approval, will require substantial funds. In addition, funds are required for the continued operation of our business, as we seek to advance additional product candidates through the research and clinical development to regulatory approval and commercialization. As of June 30, 2017, we had approximately $144.9 million in cash, cash equivalents, and investments. We believe that our available cash, cash equivalents, and investments will be sufficient to fund our anticipated level of operations for at least the next 12 months, but there can be no assurance that this will be the case.

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We have financed our operations primarily through proceeds from our license agreement with Allergan, public and private equity offerings, and, to a lesser extent, our Royalty-Backed Loan with HCRP, 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 cash requirements will increase substantially as we:

- enhance operational, financial, and information management systems and hire more personnel, including personnel to support development of our product candidates and, if a product candidate is approved, our commercial operations;
- commercialize ADS-5102, if it is approved by the FDA, including establishing distribution, marketing, and sales capabilities;
- manufacture ADS-5102 for commercial use, if approved by the FDA;
- investigate ADS-5102 in preclinical and clinical trials for the treatment of walking impairment in patients with MS, and potentially other indications;
- conduct preclinical and clinical trials of ADS-4101 for the treatment of epilepsy (partial onset seizures);
- seek regulatory approvals for our product candidates that successfully complete clinical studies;
- continue the research, development, and manufacture of our current product candidates; and
- seek to discover or in-license additional product candidates.

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

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

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

We have outstanding debt backed by two of our principal assets, ADS-5102 and royalties we may receive on Namzaric, and failure by us or our royalty subsidiary to fulfill our obligations under the applicable loan agreements may cause the repayment obligations to accelerate.

In May 2017, we, through a newly formed wholly-owned subsidiary, entered into a royalty-backed note arrangement with HealthCare Royalty Partners III, L.P. ("HCRP") pursuant to which we initially borrowed $35 million and have the potential to borrow an additional $65 million upon FDA approval and receipt of Orphan Drug exclusivity of

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ADS-5102 (amantadine) extended-release capsules for the treatment of levodopa-induced dyskinesia in patients with Parkinson's disease if achieved prior to a specified date. Interest and principal on the loan will be payable from the proceeds of royalty on U.S. net sales of ADS-5102 and up to $15 million of the Company's annual royalties from Allergan on U.S. net sales of Namzaric® starting in May 2020. The HCRP notes mature in December 2026, if not earlier prepaid.

We secured the loan with rights to ADS-5102 and rights to certain payment amounts on Namzaric and the loan documents further provide for assignment into our subsidiary holding these rights to any future intellectual property, licenses, assets and agreements with respect to the manufacture, development, supply, distribution, sale and commercialization of ADS-5102. The loan documents contain customary events of default permitting HCRP to accelerate and require mandatory prepayment of outstanding principal and interest, including: failure to timely pay principal and interest when due and payable; failure to perform specified covenants with respect to maintenance of the collateral and prohibitions on liens with respect to the collateral; limitations on payments of dividends, additional loans, acquisition or merger transactions not in accordance with the arrangement. Upon the occurrence, an event of default under the loan documents, we could be required to prepay the entire loan and, if we are not able to do so, we may lose control over certain rights and payments to ADS-5102 and royalty payments with respect to Namzaric, either of which would seriously harm our business.

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Any future revenue will depend on the successful commercialization and sales of our product candidates, including ADS-5102 for the treatment of LID, if approved, the payment of royalties to us from Allergan under terms of our licensing agreement regarding Namenda XR® 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, 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

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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, serialize 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 and qualify them. 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, serialize and supply drug product for our clinical studies and, upon regulatory approval, to meet potential future commercial demand. The manufacture of pharmaceutical products in compliance with the FDA's current Good Manufacturing Practices, or cGMPs, requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements, and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to gain approval of the NDA for ADS-5102 or to provide study drugs in our clinical trials and future commercial supply would be jeopardized. Any delay or interruption in the supply of clinical study materials or commercial product could cause delays in our clinical programs, harm our ability to gain approval from regulatory authorities, and potentially disrupt patient access to our future approved products. These events would substantially harm our business, reputation and stock price.

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

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

We currently rely on single source suppliers for our drug substances and drug product candidates, including ADS-5102, and continue to seek additional long-term supply agreements and supplier qualifications. A failure of our single source manufacturer or drug substance supplier or our failure to qualify at least one other manufacturer organization on a timely basis and validate the manufacturing process employed at that manufacturer or supplier 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 and obtain regulatory approvals and qualifications, 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

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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 manufacturing organizations were not able to manufacture our drug substance or drug product or provide the requisite services, our business and financial condition would be materially adversely affected.

In our existing or any future potential collaborations or partnerships, we will likely not be able to control all aspects of the development and commercialization of our product candidates. This lack of control could subject us to additional risks that could harm our business.

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

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

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- 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 Allergan, if Allergan fails to successfully commercialize Namenda XR® and Namzaric® for any reason or if the license agreement with Allergan is terminated, the potential royalties we are eligible to receive under our license agreement with Allergan may not occur or be minimal, and would have a negative impact on our revenue potential and harm our business.

In November 2012, we entered into a license agreement with Allergan pursuant to which we granted Allergan a right to develop and commercialize Namenda XR® and Namzaric® in the United States. Under that agreement, we expect to receive future royalties from Allergan on the net sales of Namenda XR® and Namzaric®, starting in 2018 and 2020, respectively. If Allergan 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 Allergan to commercialize Namenda XR® and Namzaric® and in that capacity Allergan has the discretion to:

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

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

We and Allergan are currently involved in ANDA litigation to enforce our intellectual property rights against generic manufacturers, who are seeking to bring generic versions of Namenda XR® and Namzaric® to the market. See

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Litigation in “Note 6 - Commitments and Contingencies” in the accompanying “Notes to Condensed Consolidated Financial Statements (unaudited)”. Under the terms of that license agreement, Allergan has the right to enforce such intellectual property rights and control such litigation. Specifically, Allergan has the discretion to:

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

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

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

The post-marketing safety risks relating to Namzaric® and Namenda XR® are the same as those facing ADS-5102, which are described in the risk factor captioned “The NDA for ADS-5102 for the treatment of LID is still under review and there is an ongoing open label safety study with ADS-5102 in LID; therefore, there could be new safety findings regarding ADS-5102 or the FDA may have a different interpretation of our previously reported positive clinical results at approval.” These things could lead us to experience failure to receive regulatory approval or receive approval with unexpected safety information in the prescribing information that could limit physician and patient acceptance of the product. Additionally, if ADS-5102 is approved and commercialized for patients with LID, unforeseen safety issues could emerge thereafter that could require us to change the prescribing information in the future to adding warnings or limit use. Any of these events could have a negative impact on our business.

Risks related to government regulation

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

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

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

FDA approval of an NDA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense we invest, failure can

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occur at any stage, and we could encounter problems that require us to repeat clinical studies, perform additional preclinical studies and clinical studies, or abandon development and commercialization of a product candidate altogether. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on, among other factors, the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. The FDA can delay, limit, or deny approval of a product candidate for many reasons, including, but not limited to:

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

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

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

We are developing our current and future product candidates, including ADS-5102, with the expectation that they will be eligible for approval through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the FDCA allows an NDA to rely in part on the FDA's prior conclusions regarding the safety and effectiveness of an approved drug product, or reference listed drug (RLD). Use of the Section 505(b)(2) regulatory pathway could reduce the time required for the development programs of our product candidates by, for example, potentially decreasing the amount of preclinical and/or clinical data specific to a product candidate that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for product approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and the complications and risks associated with regulatory approval would likely substantially increase. Moreover, our inability to pursue the Section 505(b)(2) regulatory pathway may result in competitive products reaching the market more quickly than our product candidates, which would adversely impact our competitive position and prospects. Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee that utilizing this pathway will ultimately lead to faster product development or earlier approval for ADS-5102 or any other product candidate that we may attempt to develop and commercialize.

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

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the approved competing product, then approval of the 505(b)(2) NDA for our product candidate in the target indication may be delayed for as long as the competitor has exclusivity.

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

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

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

- warning letters or untitled letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension, variation, or withdrawal of regulatory approval;
- suspension of ongoing clinical studies;
- voluntary or mandatory product recalls;
- requirements for dissemination of corrective information or modifications to promotional materials;
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications filed by us;
- refusal to permit import or export of our products;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products.

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

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

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, the PPACA was passed, which has substantially changed how healthcare is financed by both governmental and private insurers, and has significantly impacted the U.S. pharmaceutical industry. Details of changes under the PPACA are discussed in the business heading "Other healthcare regulations" in Part I, Item 1, of our 2016 Annual Report on Form 10-K.

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

The continuing efforts of the government, insurance companies, managed care organizations, other payers of healthcare services, and patient and political groups 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;
- the reputation of our Company;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Our ability to commercialize our products successfully, and to attract commercialization partners for our products, will depend in significant part on the availability of adequate financial coverage and reimbursement from third party payers, including, in the U.S., governmental payers such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Details of these considerations are discussed in the business heading "Other healthcare regulations" in Part I, Item 1, of our 2016 Annual Report on Form 10-K.

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

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

Under the Medicaid Drug Rebate program, a manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis

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to the Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

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

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The PPACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's final regulations implementing those changes also could affect the 340B ceiling price calculations for any of our product candidates that we successfully commercialize and could negatively impact our results of operations.

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

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by the reporting manufacturer, governmental or regulatory agencies and the courts. In the case of Medicaid pricing data, if we join the Medicaid Drug Rebate Program and become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we will be obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations would increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in

an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we would be required to offer any of our product candidates that we successfully commercialize under the 340B drug discount program.

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

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

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

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

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

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, lease, arrangement or recommendation of, any good, facility, item, or service for which payment may

be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs. Liability under the Anti-Kickback Statute may be established without a person or entity having actual knowledge of the statute or specific intent to violate it. In addition, the

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government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;

- the federal civil False Claims Act, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds, or knowingly using false records or statements, to obtain payment from the federal government. In recent years, several pharmaceutical and other health care companies have faced enforcement actions under the False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government healthcare programs, providing free product to customers with the expectation that the customers would bill federal programs, product and patient assistance programs, including reimbursement services, and marketing products for off-label or unapproved uses;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. HIPAA also imposes obligations on certain entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, also governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the federal government information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations, such as anti-kickback, and false claims laws, which may be broader in scope and apply to items or services reimbursed by any third-party payer, including commercial insurers. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-relating activities, including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and/or administrative penalties, damages, fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these or other laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, and fraud laws may prove costly.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. Moreover, the requirements governing drug pricing and reimbursement vary widely from country to country. For example, in the European Union the sole legal instrument at the European Union level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC (the Price Transparency Directive). The aim of the Price Transparency Directive is to ensure that pricing and reimbursement mechanisms

established in European Union member states are transparent and objective, do not hinder the free movement and trade of medicinal products in the European Union, and do not hinder, prevent or distort competition on the market. The Price Transparency Directive

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does not, however, provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual European Union member states. The national authorities of the individual European Union member states are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some individual European Union member states adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other European Union member states adopt a system of reference pricing, basing the price or reimbursement level in their territory either, on the pricing and reimbursement levels in other countries, or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Furthermore, some European Union member states impose direct or indirect controls on the profitability of the company placing the medicinal product on the market.

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

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

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

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

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"). Although we are not directly subject to HIPAA—other than potentially with respect to providing certain employee benefits—we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and

our research efforts could be delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

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

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

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

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

We may decide to seek marketing authorizations to commercialize ADS-5102, ADS-4101, and other future product candidates outside of the United States. To market our future products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically, in the EU, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

Before granting an MA, the European Medicines Agency or the competent authorities of the member states of the EU make an assessment of the risk-benefit balance of the product on the basis of a Common Technical Document including, among other information, scientific criteria concerning its quality, safety, and efficacy.

Similar to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU member states both before and after grant of the manufacturing and Marketing Authorizations. This includes control of compliance with

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

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

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

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 and sales and marketing capabilities, and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of June 30, 2017, we had 72 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

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significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

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

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

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

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

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- difficulties in assuring compliance with foreign corrupt practices laws;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

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- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes or typhoons, floods, and fires.

Our internal computer systems, or those of our CROs, CMOs, CSO, 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 are not aware of 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 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 implemented a new ERP system in addition to a new human resource information system (“HRIS”). These projects required and may continue to require investment of capital and human resources 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 and HRIS 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

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cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies.

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

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

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

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of our owned or licensed patents being narrowed, invalidated, or held unenforceable, which could limit our ability to stop or prevent us from stopping others

from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are

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commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

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

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

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

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

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

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we or our licensees may be required to file infringement claims, which can be expensive and time-consuming. For example, we, Forest, Forest Laboratories, Inc., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH filed patent infringement lawsuits under Forest's patents and patents owned by us and licensed to Forest, against several manufacturers of generic pharmaceuticals that have filed ANDAs with the FDA seeking approval to manufacture and sell generic versions of Namzaric® 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,

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opposition, or similar proceedings before the USPTO and its foreign counterparts. The costs of these proceedings could be substantial, and the proceedings may result in a loss of such intellectual property rights. Some of our competitors may be able to sustain the costs of complex patent disputes and litigation more effectively than we can, because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any disputes or litigation could adversely affect our ability to raise the funds necessary to continue our operations. Third parties may assert infringement claims against us or our partners based on existing patents or patents that may be granted in the future. Under our license agreement with Allergan we are obliged to indemnify Allergan under certain circumstances and our royalty entitlements may also be reduced. Our indemnification obligation to Allergan, while subject to customary limitations, has no monetary cap, and our right to receive royalties from Allergan may be eliminated in any calendar quarter in which certain third party generic competition exists. If we or our partners are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

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

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

Risks related to 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;
-

our success in commercializing ADS-5102 for the treatment of LID in patients with Parkinson's disease, if approved by the FDA;

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- the availability of reimbursement by payers at acceptable levels, or at all, for ADS-5102;
- 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;
- our revenue performance, both in absolute terms and relative to analyst and shareholder expectations;
- 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 revenue forecasts, 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

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through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

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

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

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

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

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

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

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

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

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

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

- our board of directors is divided into three classes with staggered three-year terms, which may delay or prevent a change of our management or a change in control;

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

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

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

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

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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 is incorporated here 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: August 8, 2017 /s/ Gregory T. Went, Ph.D.
Gregory T. Went, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2017 /s/ Alfred G. Merriweather
Alfred G. Merriweather
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	Filed/Furnished Herewith
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	Offer Letter by and between the registrant and Richard A. King, dated April 17, 2017.					X
10.2	Offer Letter by and between the registrant and Alfred G. Merriweather, dated June 26, 2017.					X
10.3	Separation Agreement by and between the registrant and William Dawson, dated June 27, 2017.					X
10.4*	Loan Agreement dated May 11, 2017 between Adamas Pharma, LLC and Healthcare Royalty Partners III, L.P.					X
10.5	Secured Promissory Note dated May 11, 2017 between Adamas Pharma, LLC and Healthcare Royalty Partners III, L.P.					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X

32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(1)	X
101.INS	XBRL Instance Document	
101.SCH	XBRL Taxonomy Extension Schema Document	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	

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101.LAB XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

* Confidential Treatment Requested
(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.