

Adamas Pharmaceuticals Inc  
Form 10-Q  
May 13, 2015  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-Q**

---

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

**For the quarterly period ended March 31, 2015**

**or**

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

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

**1900 Powell Street, Suite 750**  
**Emeryville, CA**  
(Address of Principal Executive Offices)

**94608**  
(Zip Code)

**(510) 450-3500**

(Registrant's Telephone Number, Including Area Code)

---

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of May 6, 2015 was 17,823,046.

---

Table of Contents

ADAMAS PHARMACEUTICALS, INC.

INDEX

		<b>Page</b>
<u>PART I.</u>	<u>FINANCIAL INFORMATION (unaudited)</u>	
<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements</u>	
	<u>Condensed Consolidated Balance Sheets at March 31, 2015 and December 31, 2014</u>	3
	<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2015 and 2014</u>	4
	<u>Condensed Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2015 and 2014</u>	5
	<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2015 and 2014</u>	6
	<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
<u>Item 4.</u>	<u>Controls and Procedures</u>	23
<u>PART II.</u>	<u>OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u>	24
<u>Item 1A.</u>	<u>Risk Factors</u>	24
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	52
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	53
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	53
<u>Item 5.</u>	<u>Other Information</u>	53
<u>Item 6.</u>	<u>Exhibits</u>	53
<u>SIGNATURES</u>		54

---

In this report, unless otherwise stated or the context otherwise indicates, references to the company, Adamas, we, us and our refer to Adamas Pharmaceuticals, Inc.

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

	<b>March 31, 2015 (unaudited)</b>	<b>December 31, 2014</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 29,228	\$ 61,446
Marketable securities, current	85,263	60,912
Accounts receivable	485	524
Prepaid expenses and other current assets	540	645
Total current assets	115,516	123,527
Property and equipment, net	1,294	1,228
Marketable securities, non-current	30,495	36,364
Other assets	38	70
Total assets	\$ 147,343	\$ 161,189
<b>Liabilities and stockholders equity</b>		
Current liabilities		
Accounts payable	\$ 3,806	\$ 3,685
Accrued liabilities	4,161	8,595
Other current liabilities	138	265
Total current liabilities	8,105	12,545
Non-current liabilities	1,685	1,570
Total liabilities	9,790	14,115
Commitments and Contingencies (Note 7)		
Stockholders equity		
Common stock, \$0.001 par value - 100,000,000 shares authorized, 17,727,226 and 17,551,375 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	22	22
Additional paid-in capital	160,135	157,581
Accumulated other comprehensive income (loss)	(53)	(180)
Accumulated deficit	(22,551)	(10,349)
Total stockholders equity	137,553	147,074
Total liabilities and stockholders equity	\$ 147,343	\$ 161,189

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



Table of Contents

## ADAMAS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands except per share data)

	Three Months Ended March 31,	
	2015	2014
<b>Revenue</b>	\$ 226	\$ 176
<b>Operating expenses</b>		
Research and development	7,533	2,758
General and administrative	4,919	3,109
Total operating expenses	12,452	5,867
Loss from operations	(12,226)	(5,691)
Interest and other income (expense), net	78	(688)
Loss before income taxes	(12,148)	(6,379)
Income tax expense	(54)	(1)
Net loss	\$ (12,202)	\$ (6,380)
Net loss per share attributable to common stockholders:		
Basic	\$ (0.69)	\$ (0.67)
Diluted	\$ (0.69)	\$ (0.67)
Weighted average number of shares used in computing net loss attributable to common stockholders:		
Basic	17,643	9,525
Diluted	17,643	9,525

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

Table of Contents

**ADAMAS PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(unaudited)**

**(in thousands)**

	<b>Three Months Ended</b>		
	<b>March 31,</b>		
	<b>2015</b>		<b>2014</b>
Net loss	\$	(12,202)	\$ (6,380)
Unrealized gain on available-for-sale securities		127	
Comprehensive loss	\$	(12,075)	\$ (6,380)

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



Table of Contents

## ADAMAS PHARMACUETICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2015	2014
<b>Cash flows from operating activities</b>		
Net loss	\$ (12,202)	\$ (6,380)
Adjustments to reconcile net loss to net cash provided by operating activities		
Depreciation and amortization	70	22
Stock-based compensation	2,142	1,047
Change in preferred stock warrant value		664
Net accretion of discounts and amortization of premiums of marketable securities	194	
Changes in assets and liabilities		
Accrued interest of marketable securities	(114)	
Prepaid expenses and other assets	138	(275)
Accounts receivable	39	(122)
Accounts payable	2	(2,052)
Accrued liabilities and other liabilities	(4,334)	311
Net cash used in operating activities	(14,065)	(6,785)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(18)	(77)
Purchases of investments	(18,435)	
Net cash used in investing activities	(18,453)	(77)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock upon exercise of stock options	300	36
Proceeds from issuance of common and preferred stock upon exercise of warrants		1,013
Net cash provided by financing activities	300	1,049
Net decrease in cash and cash equivalents	(32,218)	(5,813)
Cash and cash equivalents at beginning of period	61,446	85,612
Cash and cash equivalents at end of period	\$ 29,228	\$ 79,799
<b>Supplemental disclosure</b>		
Cash paid for income taxes	\$ 4,691	\$
Accrued deferred offering costs	\$	\$ 1,940

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

Table of Contents

**ADAMAS PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**1. THE COMPANY**

Adamas Pharmaceuticals, Inc. (the Company) is a specialty pharmaceutical company focused on the development and commercialization of therapeutics targeting chronic disorders of the central nervous systems ( CNS ). The Company achieves this by enhancing the pharmacokinetic profiles of approved drugs to create novel therapeutics for use alone and in fixed-dose combination products. The Company's business strategy is twofold. The Company intends to develop and commercialize its wholly owned products directly. In addition, the Company may form partnerships with companies that have an already established CNS market presence. The Company is developing its lead wholly owned product candidate, ADS-5102, for a complication associated with the treatment of Parkinson's disease known as levodopa induced dyskinesia, or LID, and potentially as a treatment for one or more additional CNS indications. The Company successfully completed a Phase 2/3 clinical study in LID in 2013 and has initiated two Phase 3 registration trials and a separate open-label safety study in 2014 in support of the LID indication. Its late-stage therapeutics portfolio includes an approved product, Namenda XR® which Forest Laboratories, Inc. ( Forest ), a subsidiary of Actavis plc, developed and is responsible for marketing in the United States under a license from the Company and also includes a recently approved product, Namzaric™ (formerly MDX-8704), co-developed with Forest, which is expected to launch in the second quarter of 2015.

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ( 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 we believe are necessary for a fair presentation of the periods presented. The condensed consolidated balance sheet at December 31, 2014 was derived from the audited consolidated financial statements, but does not include all disclosures required by GAAP. These interim financial results are not necessarily indicative of results to be expected for the full fiscal year or any other future period and should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2014, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC.

**Liquidity and Financial Condition**

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

Based upon the current status of, and plans for, its product development, the Company believes that the existing cash, cash equivalents and marketable securities of \$145.0 million as of March 31, 2015 will be adequate to satisfy the Company's capital needs through at least the next twelve months. However, the process of developing and commercializing products requires significant research and development, preclinical testing and clinical trials, manufacturing arrangements, as well as regulatory approvals. These activities, together with the Company's general and administrative expenses, are expected to result in significant operating losses until the commercialization of the Company's products or partner collaborations generate sufficient revenue to cover expenses. While the Company had net income during 2014, it has not generated any commercial revenue from sales of its products. Under its license agreement with Forest, the Company received the final milestone payment in 2014, and is not entitled to receive any royalties for sales of Namenda XR and Namzaric until mid-2018 for sales of Namenda XR and five years after the launch of Namzaric. 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.

Table of Contents

**Use of Estimates**

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

**Forward Stock Split**

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

**Revenue Recognition**

The Company recognizes revenue when all four of the following criteria have been met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable and (iv) collectability is reasonably assured. Revenue under license and collaboration 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 collaboration objectives and royalties on sales of commercialized products. The Company's performance obligations under the collaborations 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 collaborators.

On January 1, 2011, the Company adopted an accounting standards update that amends the guidance on accounting for new arrangements, or those materially modified, with multiple deliverables. This guidance eliminates the requirement for objective and reliable evidence of fair value of the undelivered items in order to consider a deliverable a separate unit of accounting. It also changes the allocation method such that the relative-selling-price method must be used to allocate arrangement consideration to the units of accounting in an arrangement. This guidance establishes the following estimation hierarchy that must be used in estimating selling price under the relative-selling-price method: (i) vendor-specific objective evidence of fair value of the deliverable, if it exists, (ii) third-party evidence of selling price, if vendor-specific

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

objective evidence is not available or (iii) vendor's best estimate of selling price, if neither vendor-specific nor third-party evidence is available.

On January 1, 2011, the Company adopted an accounting standards update that provides guidance on revenue recognition using the milestone method. Payments that are contingent upon achievement of a substantive milestone are recognized 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 are recognized as the related services or activities are performed, in accordance with the contract terms. Payments may be made to or by the Company based on the number of full-time equivalent researchers assigned to the collaboration project and the related research and development expenses incurred.

Table of Contents

**Clinical Trial Accruals**

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

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

**Research and Development**

Research and development ( R&D ) expenses include salaries, contractor and consultant fees, external clinical trial expenses performed by contract research organizations ( CRO ), licensing fees, acquired intellectual property with no alternative future use, and facility and administrative expense allocations. In addition, we fund R&D at research institutions under agreements that are generally cancelable at our 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 our 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 our research and development expenses.

We accrue 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 our internal clinical personnel, and we aim to match the accrual to actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities using available information; however, if we underestimate activity levels associated with various studies at a given point in time, we could be required to record significant additional R&D expenses in future periods when the actual activity level becomes known. We charge all such costs to R&D expenses. Non-refundable advance payments are capitalized and expensed as the related goods are delivered or services are performed.

**Basic and Diluted Net Income Per Share Attributable to Common Stockholders**

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

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

Table of Contents

**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 and amortizing the fair value of the stock-based awards granted over the applicable vesting period. All stock options awards 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. The measurement of nonemployee stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

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

**Recent Accounting Pronouncements**

In May 2014, the FASB issued Accounting Standards Update (ASU) 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 when it becomes effective January 1, 2017. Early adoption is not permitted. We have not yet selected a transition method nor have we determined the effect of the standard on our consolidated financial position and results of operations.

**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



## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

activity and pricing as of the measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data; and

- Level 3 inputs which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

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

	Total	Fair Value Measurements at March 31, 2015		
		Level 1	Level 2	Level 3
<b>Assets</b>				
Money market	\$ 27,054	\$ 27,054		\$
Corporate debt	96,953		96,953	
U.S. Treasury notes	14,811		14,811	
Commercial paper	3,993		3,993	
Total	\$ 142,811	\$ 27,054	\$ 115,757	\$

Table of Contents

	Total	Fair Value Measurements at December 31, 2014		Level 3
		Level 1	Level 2	
<b>Assets</b>				
Money market	\$ 59,303	\$ 59,303	\$	\$
Corporate debt	85,311		85,311	
U.S. Treasury notes	11,965		11,965	
Total	\$ 156,579	\$ 59,303	\$ 97,276	\$

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. We review trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

There were no transfers between Level 1 and Level 2 during the three months ended March 31, 2015.

**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 income (loss) within stockholders equity. The Company may pay a premium or receive a discount upon the purchase of marketable securities. Interest earned and gains realized on marketable securities and amortization of discounts received and accretion of premiums paid on the purchase of marketable 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 investments (in thousands):

	March 31, 2015			Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	

Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

<b>Investments:</b>								
Corporate debt	\$	97,024	\$	12	\$	(83)	\$	96,953
U.S. Treasury notes		14,793		18				14,811
Commercial paper		3,993						3,993
	\$	115,810	\$	30	\$	(83)	\$	115,757
<b>Reported as:</b>								
Short-term investments	\$	85,308	\$	12	\$	(59)	\$	85,261
Long-term investments		30,502		18		(24)		30,496
Total	\$	115,810	\$	30	\$	(83)	\$	115,757

Table of Contents

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>Investments:</b>				
Corporate debt	\$ 85,474	\$	\$ (163)	\$ 85,311
U.S. Treasury notes	11,982		(17)	11,965
	\$ 97,456	\$	\$ (180)	\$ 97,276
<b>Reported as:</b>				
Short-term investments	\$ 61,014	\$	\$ (104)	\$ 60,910
Long-term investments	36,442		(76)	36,366
Total	\$ 97,456	\$	\$ (180)	\$ 97,276

Short-term and long-term investments includes accrued interest of \$392,000 and \$241,000, respectively, as of March 31, 2015. Short-term and long-term investments includes accrued interest of \$309,000 and \$209,000, respectively, as of December 31, 2014. The Company has not incurred any realized gains or losses on investments for the three months ended March 31, 2015 and 2014. Investments are classified as short-term or long-term depending on the underlying investment's maturity date. Long-term investments have a maturity date range of greater than 12 months and a maximum of 22 months as of March 31, 2015.

## 5. COLLABORATION AND LICENSE AGREEMENTS

In November 2012, the Company granted Forest an exclusive license, with right to sublicense, certain of the Company's intellectual property rights relating to human therapeutics containing memantine in the United States. In connection with these rights, Forest markets Namenda XR and is expected to launch Namzaric in the second quarter of 2015 for the treatment of moderate to severe dementia related to Alzheimer's disease. Pursuant to the agreement, Forest made an upfront payment of \$65.0 million. The Company earned and received additional cash payments totaling \$95.0 million upon achievement by Forest of certain development and regulatory milestones. In addition, the Company may earn tiered royalty payments based on future net sales of Namenda XR and Namzaric.

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

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

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

more precise pattern of recognition, and the Company therefore recognized revenue on a straight-line basis over the period of the transfer of the know-how (from November 2012 to February 2013).

In November and December 2013, the Company received a total of \$40.0 million in milestone payments under its license agreement with Forest. The milestone payments were for the successful completion of studies that support the

Table of Contents

planned New Drug Application ( NDA ) filing with the FDA for Namzaric by Forest. In May 2014, the Company received an additional \$25.0 million milestone payment under the license agreement. This milestone payment was a result of the FDA s acceptance of the NDA for Namzaric. In December 2014, the Company received a final \$30.0 million milestone payment in connection with the FDA approval of Namzaric. These amounts have been recorded as revenue when received in the consolidated statements of operations and comprehensive income during 2013 and 2014, respectively.

Commencing in June 2018, the Company is entitled to receive low to mid-single digit royalties on net sales in the United States by Forest, its affiliates, or any of its sublicensees of controlled-release versions of memantine, such as Namenda XR, or any other product covered by the terms of the license agreement. Forest s obligation to pay royalties with respect to controlled-release versions of memantine covered by the agreement continue until the expiration of the Orange Book listed patents covering such products. In addition, commencing five years after the initial launch of a fixed-dose memantine-donepezil product in the United States, such as Namzaric, which Forest expects to launch in the second quarter of 2015, the Company is entitled to receive royalties at rates ranging from the low double digits to the mid-teens on the net sales by Forest, its affiliates, and any sublicensees of such products in the United States. Forest s obligation to pay royalties with respect to fixed-dose memantine-donepezil products continues until the later of (i) 15 years after the commercial launch of the first fixed-dose memantine-donepezil product by Forest in the United States or (ii) the expiration of the Orange Book listed patents for which Forest obtained rights from us covering such product. However, Forest s obligation to pay royalties for any product covered by the license is eliminated in any quarter where there is significant competition from generics.

**6. WARRANTS TO PURCHASE COMMON STOCK**

In conjunction with various financings between 2002 and 2012, the Company issued warrants to purchase 751,878 shares of convertible preferred stock and 127,780 shares of common stock. The relative fair value of these warrants was determined using the Black-Scholes model and was amortized to interest expense over the term of each loan, unless subsequently modified. As of both March 31, 2015 and December 31, 2014, warrants to purchase 7,116 shares of common stock were outstanding and zero warrants to purchase convertible preferred stock were outstanding, respectively.

Prior to the IPO in April 2014, the warrants were classified as a liability and remeasured to fair value each reporting period. The Company had estimated the fair value of these liabilities using the Black-Scholes model and assumptions that were based on the individual characteristics of the warrants on the valuation date, as well as the assumptions for expected volatility, expected life, dividends, and risk-free interest rate. Immediately prior to the completion of the Company s IPO in 2014, all of the warrants were either exercised for cash or automatically net exercised for a total issuance of 199,837 shares of common stock, pursuant to the terms of the warrants. Just prior to the exercises, all of the outstanding warrants, covering 220,004 shares, were remeasured using the intrinsic value of the warrant computed as the difference between the \$16.00 per share IPO price and the \$3.80 per share exercise price of the warrant. The remeasurement of the fair value of these warrants from December 31, 2013 through the date of the conversion to a common stock warrant and following the exercise resulted in a \$1.0 million expense recorded to other income (expense), net in the Company s consolidated statements of operations and comprehensive income. The resulting fair value of approximately \$27.9 million was reclassified as additional paid-in capital upon completion of the IPO.

The following table summarizes the outstanding warrants as of:

Number of Shares Outstanding	
March 31, 2015	December 31, 2014

Common stock warrants	7,116	7,116
-----------------------	-------	-------

## 7. COMMITMENTS AND CONTINGENCIES

### Lease Commitments

The Company leases approximately 12,500 square feet of office space in Emeryville, California. In May 2014, the Company amended its corporate lease agreement to increase the square footage leased from approximately 12,500 to approximately 18,500 square feet for an additional term of 65 months through April 30, 2020. The Company plans to take occupancy of the additional space by the end of the second quarter of 2015.

Table of Contents

As of March 31, 2015, future minimum lease payments under a non-cancelable facility operating lease including related office equipment were as follows (in thousands):

	<b>March 31,</b>	
	<b>2015</b>	
2015	\$	422
2016		624
2017		624
2018		634
2019		654
Thereafter		223
<b>Total</b>	<b>\$</b>	<b>3,181</b>

The Company's total rent expense for the three months ended March 31, 2015 and 2014 was approximately \$142,000 and \$58,000, respectively.

**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**

Several companies have submitted Abbreviated New Drug applications, or ANDAs, to the FDA requesting permission to manufacture and market generic versions of Namenda XR, on which the Company is entitled to receive royalties from Forest beginning in June 2018. In the notices, these companies allege that the patents associated with Namenda XR, some of which are owned by Forest or licensed by Forest from Merz Pharma GmbH & Co. KGaA and others of which are owned by the Company and licensed by the Company exclusively to Forest in the United States, are invalid, unenforceable and/or will not be infringed by the companies' manufacture, use, or sale of generic versions of Namenda XR. In January, February, and April 2014, the Company, Forest, Forest Laboratories Holdings Ltd., 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



## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

relevant patents against all of these companies. The parties are collectively seeking judgment that (i) the defendants have infringed the patents at issue, (ii) the effective date of any approval of the defendants' ANDAs shall not be earlier than the expiration date of the last to expire of the relevant patents, including any extensions or exclusivities, (iii) the defendants be enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, any products that infringe or induce or contribute to the infringement of the patents at issue prior to the expiration date of the last to expire of the patents, including extensions and exclusivities, and (iv) the Company, Forest, Forest Laboratories Holdings Ltd., and Merz be awarded monetary relief, in addition to any attorneys' fees, costs, and expenses relating to the actions. The trial is scheduled for February 2016. Because these lawsuits were filed within the requisite 45 day period provided in the U.S. Food, Drug and Cosmetic Act, there are stays preventing FDA approval of the ANDAs for 30 months or until a court decision adverse to the patents. The 30 month stays for these ANDAs will begin to expire in June 2016.

From November 2014 through May 2015, we and Forest have entered into a series of settlement agreements on undisclosed terms.

Table of Contents

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

**8. STOCKHOLDERS EQUITY**

**Common Stock**

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

The Company has classified all unvested shares of common stock issued upon the early exercise of stock options as employee deposits (a liability) as these options are not considered to be substantively exercised until vested. At March 31, 2015 and December 31, 2014, 3,000 and 13,000 shares of common stock, respectively, from early exercised options were unvested.

**Shares reserved for Future Issuance**

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

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Common stock options outstanding	5,189,903	4,981,522
Common stock options available for grant	1,901,909	1,584,378
Employee stock purchase plan	425,327	249,887
Warrants to purchase common stock	7,116	7,116
<b>Total</b>	<b>7,524,255</b>	<b>6,822,903</b>

**9. STOCK-BASED COMPENSATION**

**Stock Compensation Plans**

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

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

In February 2014, the Company's board of directors adopted, and in March 2014 the Company's stockholders approved, the 2014 Equity Incentive Plan (the 2014 Plan), which became effective on the completion of the IPO. No further grants were then made under the 2007 Plan. Under the 2014 Plan, 1,993,394 shares of the Company's common stock were made available for issuance, which included all shares that, as of the effective time, were reserved for issuance pursuant to the 2007 Plan, and is subject to further increase for shares that were subject to outstanding options under the 2007 Plan and the 2002 Plan as of the effective time that thereafter expire, terminate, or otherwise are forfeited or reacquired. The number of shares of the Company's common stock reserved for issuance pursuant to the 2014 Plan will automatically increase on the first day of each fiscal year for a period of up to 10 years, commencing on the first day of the fiscal year following 2014, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding fiscal year, or a lesser number of shares as determined by our board of directors. For 2015, the common stock available for issuance under the 2014 Plan increased by 701,763 shares of common stock. As of March 31, 2015, the number of shares available for issuance under the 2014 Plan was 1,901,909.

Options granted under the 2014 Stock Plan may have terms of up to ten years. All options issued to date have had a ten year life. The exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the board of directors. The exercise price of an ISO and NSO granted to a 10% stockholder shall not

Table of Contents

be less than 110% of the estimated fair value of the shares on the date of grant, respectively, as determined by the board of directors. The exercise price of a NSO shall not be less than the par value per share of common stock. The options granted generally vest over four years and vest at a rate of 25% upon the first anniversary of the issuance date and 1/48th per month thereafter.

In February 2014, the Company's board of directors adopted and, in March 2014, the Company's stockholders approved, the 2014 Employee Stock Purchase Plan (the "ESPP"), which became effective on the completion of the Company's IPO. The ESPP authorized the issuance of 262,762 shares. Under the ESPP, employees, subject to certain restrictions, may purchase shares of common stock at 85% of the fair market value at either the beginning of the offering period or the date of purchase, whichever is less. Purchases are limited to the lesser of 15% of each employee's eligible annual compensation or \$25,000. Through March 31, 2015, the Company issued a total of 12,875 shares under the ESPP. The number of shares available for future issuance under the plan were 425,327 at March 31, 2015. Beginning January 1, 2015 and continuing through and including January 1, 2024, the amount of common stock reserved for issuance under the ESPP will increase annually on that date by the lesser of (i) one percent (1%) of the total number of shares of common stock outstanding on such December 31, (ii) 520,000 shares of common stock, or (iii) a number of shares as determined by the Board of Directors prior to the beginning of each year, which shall be the lesser of (i) or (ii) above. For 2015, the common stock available for issuance under the ESPP increased by 175,440 shares of common stock.

The stock option and related activity under all of our stock option plans is summarized as follows:

	Outstanding Options		Weighted-	Remaining Contractual Term (years)	Aggregate Intrinsic Value (thousands)
	Number of Shares	Average Exercise Price	Average		
<b>Stock Options</b>					
Balances, December 31, 2014	4,981,522	\$ 6.10			
Options granted	474,900	17.31			
Options exercised	(175,851)	1.70			
Options forfeited	(90,668)	2.66			
Balances, March 31, 2015	5,189,903	\$ 7.34	7.71	\$	52,867
Vested and expected to vest, March 31, 2015	4,931,769	\$ 7.16	7.65	\$	51,082
Exercisable, March 31, 2015	4,177,896	\$ 5.04	7.23	\$	52,053

The aggregate intrinsic value of options outstanding, vested and expected to vest, and exercisable were calculated as the difference between the exercise price of the options and the fair value of Adamas's common stock of \$17.49.

**Stock-Based Compensation**

The following table reflects stock-based compensation expense recognized for the three months ended March 31, 2015 and 2014, respectively (in thousands):



Table of Contents

As of March 31, 2015, there was total unrecognized compensation cost of approximately \$25.6 million. This cost is expected to be recognized over a period of 3.7 years.

The Company estimated the fair value of each option grant on the date of grant using the Black-Scholes model with the following weighted-average assumptions:

	Three Months Ended			
	2015		March 31, 2014	
Expected price volatility	71% - 73%		94% - 96%	
Risk-free interest rate	1.37% - 1.82%		2.07% - 2.20%	
Expected term (in years)	6.00	6.25	7.00	
Dividend yield				

**Non-employee Stock-Based Compensation**

During the three months ended March 31, 2015, the Company granted options to purchase zero and 158,000 shares of common stock to consultants, respectively. These options are granted in exchange for consulting services to be rendered and vest over the term of the consulting agreement.

The Company estimated the fair value of each option grant on the date of grant using the Black-Scholes model with the following weighted-average assumptions:

	Three Months Ended			
	2015		March 31, 2014	
Expected price volatility	76% - 77%		72% - 98%	
Risk-free interest rate	1.84% - 1.86%		0.81% - 2.75%	
Expected term (in years)	8.75	9.00	3.25	10.00
Dividend yield				

**10. NET INCOME PER SHARE**

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

Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

	Three Months Ended March 31,	
	2015	2014
<b>Historical net income per share</b>		
Numerator:		
Net loss	\$ (12,202)	\$ (6,380)
Denominator:		
Basic common shares outstanding:		
Basic common shares outstanding: weighted average common shares outstanding	17,653	9,527
Less: weighted average unvested common shares subject to repurchase	(10)	(2)
Weighted average number of common shares used in calculating net income per share basic	17,643	9,525
Dilutive securities:		
Common stock option		
Warrants to purchase common stock		
Weighted average number of common shares used in calculating net income per share diluted	17,643	9,525
Net income (loss) per share to attributable to common stockholders:		
Basic	\$ (0.69)	\$ (0.67)
Diluted	\$ (0.69)	\$ (0.67)

Table of Contents

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

	<b>2015</b>	<b>Three Months Ended March 31,</b>	<b>2014</b>
Convertible preferred stock			4,459
Options to purchase common stock	456		5,196
Warrants to purchase convertible preferred stock			200
Warrants to purchase common stock			896
<b>Total</b>	<b>456</b>		<b>10,751</b>



Table of Contents

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

**Overview**

We are a specialty pharmaceutical company driven to improve the lives of those affected by chronic disorders of the central nervous system, or CNS. We achieve this by enhancing the pharmacokinetic profiles of approved drugs to create novel therapeutics for use alone and in fixed-dose combination products. Our business strategy is twofold. We intend to develop and commercialize our wholly owned products directly. In addition, we may form partnerships with companies that have an already established CNS market presence. We are developing our lead wholly owned product candidate, ADS-5102, for a complication associated with the treatment of Parkinson's disease known as levodopa induced dyskinesia, or LID, and potentially as a treatment for one or more additional CNS indications. We have successfully completed a Phase 2/3 clinical trial, in which patients receiving ADS-5102 had a statistically significant 43% reduction in LID compared to their baseline LID experienced prior to taking ADS-5102. In 2014, we initiated the remaining Phase 3 registration trials of ADS-5102 for LID. We plan to commercialize ADS-5102 and potentially other wholly-owned product candidates, if approved, by developing a specialty CNS commercial organization including a sales force to reach high volume prescribing neurologists and movement disorder specialists in the United States and in other markets through distribution agreements and collaborations with CNS-focused pharmaceutical companies. Our late stage therapeutics portfolio includes memantine-based products focused on Alzheimer's disease, which have been exclusively licensed to Forest Laboratories, Inc., or Forest, a subsidiary of Actavis plc, in the United States. The first product, Namenda XR®, which Forest developed and is marketing in the United States under a license from us, is a controlled-release product, and the second product, Namzaric (formerly known as MDX-8704), which we co-developed with Forest, is a fixed-dose combination product, recently approved by the U.S. Food and Drug Administration, or FDA, that Forest is expected to market and launch in the second quarter of 2015.

Our revenue to date has been generated primarily from license, milestone, and development revenue pursuant to our license agreement with Forest. We have not generated any commercial product revenue. As of March 31, 2015, we had an accumulated deficit of \$22.6 million. Although we reported net income in each of the years ending December 31, 2014, 2013, and 2012, this was primarily due to the recognition of revenue pursuant to our license agreement with Forest. There are no further milestone payments to be earned under our license agreement with Forest. We cannot assure you that we will receive additional collaboration revenue in the future. We incurred significant losses prior to 2012 and expect to incur significant and increasing losses in the foreseeable future as we advance our product candidates into later stages of development and, if approved, commercialization.

Under our agreement with Forest, 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, \$40.0 million in development milestone fees recognized in 2013, a \$25.0 million milestone payment related to FDA acceptance of Forest's New Drug Application, or NDA, submission for Namzaric recognized in May 2014, and a final \$30.0 million milestone payment recognized in December 2014 upon FDA approval of the NDA. Forest has stated that it expects to launch Namzaric in the second quarter of 2015. Beginning five years after commercial launch, we are entitled to receive tiered royalties in the low double digits to the mid-teens for sales of Namzaric in the United States. In addition, we are also entitled to receive tiered royalties in the low to mid-single digits from Forest for sales of Namenda XR in the United States beginning in 2018, however, we do not expect these will make a significant financial contribution to our business.

We expect our research and development expenses to increase as we continue to advance our product candidates through clinical development. In addition, we plan to commercialize ADS-5102 for LID, if approved, and potentially other wholly-owned product candidates by developing a specialty CNS commercial organization including a sales force to reach high volume prescribing neurologists and movement disorder specialists in the United States. Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of expenses incurred or when, or if, we will be able to achieve sustained profitability.

Prior to our initial public offering of our common stock, or IPO, in April 2014, we had raised an aggregate of

Table of Contents

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 completed our IPO pursuant to which we issued 3,000,000 shares of common stock and received net proceeds of approximately \$41.4 million, after underwriting discounts, commissions and offering expenses. In May 2014, we issued an additional 81,371 shares of common stock pursuant to the underwriters' partial exercise of their option to purchase additional shares, for net proceeds of approximately \$1.2 million, after deducting underwriting discounts and commissions. In connection with the completion of our IPO, all convertible preferred stock converted into common stock.

As of March 31, 2015, we had cash, cash equivalents, and marketable securities of \$145.0 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, and reimbursements for research and development expenses under our license agreement with Forest and to a lesser degree from NIH grants and government contracts. We do not expect to recognize any further milestone payments under our license agreement with Forest, while development funding is expected to remain at modest levels in the current and future periods. Beginning in June 2018, we will be entitled to receive royalties in the low to mid-single digits from Forest for sales of Namenda XR in the United States and beginning five years after commercial launch, royalties in the low double digits to the mid-teens for sales of Namzaric in the United States. We were also awarded a continuation of an NIH grant for \$1.0 million in August 2014, which we will administer, but conduct through subcontractors. The focus of work under this grant is in non-core areas to the Company.

***Research and development expenses***

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our wholly owned product candidates, as well as the development of product candidates pursuant to our agreement with Forest. We recognize all research and development costs as they are incurred. We began tracking our external costs by project beginning January 1, 2006.

Research and development expenses consist of:

- fees paid to clinical consultants, clinical trial sites, and vendors, including clinical research organizations, or CROs, in conjunction with implementing 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;

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

- other consulting fees paid to third parties; and
  
- employee-related expenses, which include salaries, benefits, and stock-based compensation.

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

		2015	March 31,	2014
<b>Product candidates</b>				
ADS-5102	\$	7,115	\$	2,274
Other research and development expenses (1)		418		484
<b>Total research and development expenses</b>	\$	7,533	\$	2,758

---

(1) Other research and development expenses include costs not allocated to a specific program.

The program-specific expenses summarized in the table above include costs directly attributable to our product candidates. We allocate research and development salaries, benefits, and indirect costs to our product candidates on a program-specific basis, and we include these costs in the program-specific expenses.

Table of Contents

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 our research and development expenses will increase as we continue our Phase 3 registration trials for ADS-5102 in LID and initiate clinical-stage programs for ADS-5102 in one or more indications. 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 collaborations with other pharmaceutical companies, CROs, and academic third parties to participate in the development and commercialization of our product candidates, and we may enter into additional 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 collaborations 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***

General and administrative expenses consist primarily of personnel and related benefit costs, and facilities, professional services, insurance, and public company related expenses. We anticipate our general and administrative expenses will increase as we continue to support our clinical and potentially commercial-stage programs. If ADS-5102 for LID or other products are approved by the FDA, we plan to market and sell through our own sales force to reach high volume prescribing neurologists and movement disorder specialists in the United States, which will further increase general and administrative expenses.

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

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

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

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no significant and material changes in our critical accounting policies during the three months ended March 31, 2015, 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, 2014.

Table of Contents**Results of operations***Comparison of the three months ended March 31, 2015 and 2014*

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

	March 31,				Increase/ (Decrease)	% Increase/ (Decrease)
	2015	2014				
Revenue	\$ 226	\$ 176	\$	\$	50	29%
Research and development expenses	7,553	2,758			4,775	173%
General and administrative expenses	4,919	3,109			1,810	58%
Interest and other income (expense), net	78	(688)			766	111%

**Revenue**

Our revenue for the three months ended March 31, 2015 was \$226,000 compared to \$176,000 for the three months ended March 31, 2014. Revenue for both periods is primarily related to reimbursement of certain expenses as provided for in our license agreement with Forest, as well as from government contracts.

**Research and development expenses**

Research and development expenses increased by \$4.8 million, or 173%, to \$7.6 million for the quarter ended March 31, 2015 from \$2.8 million for the three months ended March 31, 2014. The increase in research and development expenses related primarily to manufacturing of clinical supplies, commencement, and continued enrollment of our Phase 3 registration trials in support of ADS-5102 for LID, which increased \$4.8 million, or 213%, to \$7.1 million from \$2.3 million for three months ended March 31, 2015 and 2014, respectively. Other research and development expenses were \$0.4 million for the quarter ended March 31, 2015, which is consistent with the same period in the prior year. Research and development expenses also included stock-based compensation expense of \$0.7 million compared to \$0.4 million for the three months ended March 31, 2015 and 2014, respectively.

**General and administrative expenses**

General and administrative expenses increased by \$1.8 million, or 58%, to \$4.9 million for the three months ended March 31, 2015 from \$3.1 million for the three months ended March 31, 2014. The increase in general and administrative expenses was primarily due to the increase in headcount-related expenses. General and administrative expenses also included stock-based compensation expense of \$1.4 million compared to \$0.6 million for the three months ended March 31, 2015 and 2014, respectively.

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

Interest and other income (expense), net increased by \$0.8 million or 111%, to a net interest income of \$78,000 for the three months ended March 31, 2015 from a net interest expense of \$0.7 million for the three months ended March 31, 2014. Net interest income for the quarter ended March 31, 2015 was primarily due to interest income earned on investments. Net expense for the period ended March 31, 2014, was primarily attributed to the remeasurement of preferred stock warrants and recognition of the change in fair value.

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

We have funded our operations primarily through \$160 million of payments received pursuant to our license agreement with Forest, \$88.2 million of sales of convertible preferred stock and warrants, and \$42.6 million pursuant to sales of our common stock in public offerings, including \$41.4 million in our April 2014 IPO. 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 in 2014, 2013, and 2012, we recognized a profit and positive cash flow as a result of payments received pursuant to our license agreement with Forest, we received our final milestone payment from Forest in December 2014, and we do not currently receive any royalties from Forest, nor do we have other collaborations from which we might expect milestone or royalty revenue. Consequently, we expect to incur substantial and increasing losses for the foreseeable future. As of March 31, 2015, we had cash, cash equivalents and marketable securities of \$145.0 million. We believe our existing cash and cash equivalents will be sufficient to fund our projected operating requirements, including operations related to the continued development of ADS-5102 for LID, for at least the next 12 months based on cash, cash equivalents, and marketable securities on hand as of March 31, 2015.

We expect to increase our spending in connection with the development and commercialization of our product candidates, particularly for ADS-5102 for LID and other indications. In order to continue these activities, we may decide to



Table of Contents

raise additional funds through a combination of equity offerings, debt financings, collaborations, and other strategic alliances. Sufficient additional funding may not be available on acceptable terms, or at all. If adequate funds are not available in the future, we may need to delay, reduce the scope of, or put on hold our clinical studies, research and development programs, or commercialization efforts.

**Comparison of 2015 and 2014**

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
Net cash (used in) provided by:		
Operating activities	\$ (14,065)	\$ (6,785)
Investing activities	(18,453)	(77)
Financing activities	300	1,049
Net increase (decrease) in cash and cash equivalents	\$ (32,218)	\$ (5,813)

Net cash used in operating activities was \$14.1 million for the three months ended March 31, 2015 compared to \$6.8 million for the quarter ended March 31, 2014. Net loss of \$12.2 million for the three months ended March 31, 2015 included net non-cash adjustments of \$2.4 million, which consisted primarily of stock-based compensation of \$2.1 million. Net loss of \$6.4 million for the three months ended March 31, 2014 included non-cash adjustments of \$1.7 million, primarily related to \$1.0 million in stock-based compensation. The primary use of cash was to fund the ongoing clinical studies and product development activities related to ADS-5102 for LID.

Net cash used in investing activities was \$18.5 million for the three months ended March 31, 2015 compared to \$77,000 for the same period in the prior year. The increase in net cash used in investing activities resulted primarily from the purchase of \$18.4 million of marketable securities in the quarter ended March 31, 2015.

Net cash provided by financing activities was \$0.3 million for the three months ended March 31, 2015, compared to \$1.0 million of net cash used by financing activities for the three months ended March 31, 2014. In the quarter ended March 31, 2015, we received net cash proceeds of \$0.3 million related to the exercise of stock options, compared to the same quarter in the prior year, in which we received net cash proceeds of \$1.0 million from the issuance of stock from the exercise of warrants.

**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.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE 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 March 31, 2015, we had cash, cash equivalents, and investments of \$145.0 million, consisting of cash and cash equivalents, as well as short and long-term investment grade marketable securities. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration and our holdings in US government bonds and corporate debt securities mature prior to our expected need for liquidity, we believe that our exposure to interest rate risk is not significant and, as a consequence, a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

**ITEM 4. 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

Table of Contents

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.

**Evaluation of Disclosure 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 March 31, 2015. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of March 31, 2015, our disclosure controls and procedures were effective.

There has been no change in our internal control over financial reporting that occurred during the quarter ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

Several companies submitted Abbreviated New Drug applications, or ANDAs, to the FDA requesting permission to manufacture and market generic versions of Namenda XR, on which we are entitled to receive royalties from Forest beginning in June 2018. In the notices, these companies allege that the patents associated with Namenda XR, some of which are owned by Forest or licensed by Forest from Merz Pharma GmbH & Co. KGaA and others of which are owned by us and licensed by us exclusively to Forest in the United States, are invalid, unenforceable, and/or will not be infringed by the companies' manufacture, use, or sale of generic versions of Namenda XR. In January, February, and April 2014, we, Forest, Forest Laboratories Holdings Ltd., 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. We are seeking judgment that (i) the defendants have infringed the patents at issue, (ii) the effective date of any approval of the defendants' ANDAs shall not be earlier than the expiration date of the last to expire of the relevant patents, including any extensions or exclusivities, (iii) the defendants be enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States any products that infringe or induce or contribute to the infringement of the patents at issue prior to the expiration date of the last to expire of the patents, including extensions and exclusivities, and (iv) we, Forest, Forest Laboratories Holdings Ltd., and Merz be awarded monetary relief, in addition to any attorneys' fees, costs, and expenses relating to the actions. The trial is scheduled for February 2016. Because these lawsuits were filed within the requisite 45 day period provided in the U.S. Food, Drug and Cosmetic Act, there are stays preventing FDA approval of the ANDAs for 30 months or until a court decision adverse to the patents. The 30 month stays for these ANDAs will begin to expire in June 2016.

From November 2014 through May 2015, we and Forest have entered into a series of settlement agreements on undisclosed terms.

**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.*

Table of Contents

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

*Although we reported net income for the fiscal years ended December 31, 2014, 2013, and 2012, we incurred significant losses in prior years and expect to incur substantial losses in the future.*

We are a clinical-stage specialty pharmaceutical company and do not currently directly market any products. We currently exclusively license U.S. patent rights for two approved products, Namenda XR and Namzaric (formerly known as MDX-8704), to Forest Laboratories, or Forest, a wholly owned subsidiary of Actavis plc, and Forest markets Namenda XR and intends to market Namzaric in the United States, but we do not currently receive royalties on the sales of those products. We continue to incur significant research and development and general and administrative expenses related to our product candidates and our operations. Although we reported net income for the fiscal years ended December 31, 2014, 2013, and 2012, this was almost entirely due to milestone payments we received pursuant to our license agreement with Forest. We incurred significant operating losses in 2011 and prior years and as we received our final milestone payment in 2014 pursuant to our license agreement with Forest, we expect to incur substantial and increasing losses for the foreseeable future. As of March 31, 2015, we had an accumulated deficit of \$22.6 million.

We have financed our operations primarily through our collaboration with Forest, public and private equity offerings, and, to a lesser extent, government grants, venture debt, and benefits from tax credits made available under a federal stimulus program supporting drug development. We have devoted substantially all of our efforts to research and development, including clinical studies, but have not completed development of any product candidates. We anticipate that our expenses will increase substantially as we:

- conduct Phase 3 registration trials of our lead wholly owned product candidate, ADS-5102 in levodopa induced dyskinesia, or LID;
- initiate and conduct clinical trials of ADS-5102 for treatment of other indications in addition to LID;
- seek regulatory approvals for our product candidates that successfully complete clinical studies;
- establish a specialty CNS sales force and distribution and marketing capabilities to commercialize products for which we may obtain regulatory approval;
- 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;
- continue the research, development, and manufacture of our current product candidates; and

- seek to discover or in-license additional product candidates.

To be profitable in the future, we or our current and future potential collaboration partners must succeed in developing and commercializing products with significant market potential. This will require us or our partners to be successful in a range of activities, including advancing product candidates into clinical trials, completing clinical studies, and obtaining regulatory approvals related to those product candidates, and manufacturing, marketing, and selling those products for which regulatory approvals are obtained. We or our partners may not succeed in these activities, and, as a result, we may never generate revenue that is sufficient to be profitable in the future. We will not be entitled to receive any royalty payments with respect to sales of Namenda XR until June 2018, and with respect to sales of our second partnered product, Namzaric, until the second quarter of 2020, five years after its expected launch in the United States.

Even if we attain profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve or sustain profitability would cause cash generated from operations to be inadequate to fund future operations and could depress the value of our stock and impair our ability to raise capital, expand our business, diversify our product candidates, market our product candidates, if approved, or continue our operations.

***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 or our guidance.***

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. We received our final milestone payment under our license agreement with Forest in

Table of Contents

2014. Any future revenue will depend on the establishment of potential future collaboration and license agreements, if any, and the achievement of any upfront or milestone payments provided thereunder and sales of our product candidates, if approved. Accordingly, upfront and milestone payments may vary significantly from period to period, and any such variance could cause a significant fluctuation in our operating results from one period to the next. 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 pre-clinical 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;
- future accounting pronouncements or changes in our accounting policies; and
- changing or volatile U.S., European, and global economic environments.

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

operating results and/or earnings guidance that we may provide.

*We may need additional funds and, if we cannot raise additional capital when needed, we may have to curtail or cease operations.*

We are seeking to advance multiple product candidates through the research and clinical development process. The completion of the development and the potential commercialization of our product candidates, should they receive approval, will require substantial funds. As of March 31, 2015, we had approximately \$145.0 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. Our future financing requirements will depend on many factors, some of which are beyond our control, including:

- the rate of progress and cost of our clinical studies;
  
- the initiation of additional clinical studies or new programs;
  
- the timing of, and costs involved in, seeking and obtaining approvals from the U.S. Food and Drug Administration, or FDA, and potentially other regulatory authorities;
  
- the costs of commercialization activities related to our product candidates should any be approved, including initiating and expanding our sales, marketing, and distribution activities;



Table of Contents

- the degree and rate of market acceptance of any approved products launched by us, Forest, or any future partners;
- the coverage of our products, if approved, by third-party payors and the formulary tier in which health plans and other payors place our products and the rate at which the products are reimbursed;
- our ability to enter into additional collaboration, licensing, commercialization, or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing therapeutic approaches or other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts other than our license agreement with Forest, which may be terminated by Forest upon delivery of notice. Until we can generate sufficient revenue from our own products and from royalties paid to us by Forest pursuant to our license agreement to finance our operations, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, asset sales, and other marketing and distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms. If we raise additional capital through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams, or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, 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.

**Risks related to the development and commercialization of our current and future products**

*Our success depends heavily on the approval and successful commercialization of ADS-5102, the successful U.S. commercialization by Forest of Namzarin and the successful U.S. commercialization by Forest of Namenda XR. If we are unable to successfully commercialize ADS-5102 or Forest is unable to successfully commercialize Namzarin and Namenda XR in the U.S., or if either we or Forest experience significant delays in doing so, our business will be materially harmed.*

We have invested a significant portion of our efforts and financial resources into the development of ADS-5102, an oral once-daily controlled-release version of the FDA-approved drug amantadine, and Namzarin, a fixed-dose combination of the FDA-approved drugs memantine and donepezil. Namzarin has been exclusively licensed to Forest in the United States. In addition, we have granted Forest a royalty-bearing license under certain of our patents to commercialize Namenda XR, a controlled-release version of memantine, in the United States. Our ability to generate product and royalty revenue will depend heavily on the successful development, regulatory approval and eventual commercialization of ADS-5102 and successful commercialization of Namzarin and Namenda XR. Under the terms of our license agreement with Forest, we will not be entitled to receive royalty payments on the sale of Namenda XR until June 2018 and royalty payments on the sale of

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

Namzaric until the second quarter of 2020, five years after its expected launch. The success of these drugs and drug candidates will depend on numerous factors, including:

- successfully completing clinical studies for ADS-5102;
- receiving marketing approval for ADS-5102 from the FDA and, to a lesser extent, similar regulatory authorities outside the United States for our product candidates;
- establishing commercial manufacturing arrangements with third parties;
- launching commercial sales of any of the product candidates that may be approved;
- the medical community and patients accepting any approved product;
- the placement of any approved products on payors' formulary tiers and the reimbursement rates established for the approved products;

Table of Contents

- effectively competing with other therapies;
- any approved products continuing to have an acceptable safety profile following approval; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we or Forest 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.

Forest's ability to successfully commercialize Namzaric and Namenda XR will depend in part on its ability to transition patients currently being prescribed the immediate-release version of memantine, known as Namenda IR, to Namenda XR and subsequently or directly to Namzaric. The Attorney General of the State of New York has filed a lawsuit against Forest and Actavis challenging Forest's announced plan to discontinue sales of Namenda IR in the fall of 2014 and seeking to require Forest and Actavis to, among other things, continue selling Namenda IR until generic memantine is commercially available, expected to occur in the second half of 2015. If this litigation or other factors negatively impact Forest's ability to successfully commercialize Namenda XR and Namzaric, our future royalty income could be materially adversely affected.

***ADS-5102 is our only product candidate in clinical trials, and we cannot give any assurance that the Phase 3 clinical trials or development program will be successful or completed in a timely or effective manner. If clinical studies of ADS-5102 or our other product candidates fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Our failure to successfully complete our Phase 3 registration trials for ADS-5102, or otherwise adequately demonstrate the safety and effectiveness of this product candidate will prevent us from receiving regulatory approval and would have a material and adverse impact on our business.***

ADS-5102 is our only product candidate in clinical trials. Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of our product candidates in humans. Clinical studies are expensive, are difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing. The outcome of preclinical testing and early clinical studies may not be predictive of the success of later clinical studies, and interim results of a clinical study do not necessarily predict final results. For example, the successful results of our Phase 2/3 study of ADS-5102 for the treatment of LID, including the lack of difference from placebo in the incidence of sleep-related adverse events or other safety measures, may not be repeated in our Phase 3 registration trials. Furthermore, as the design of our Phase 3 registration trials differ in a number of respects from our Phase 2/3 study, including longer study periods, and the results, such as the reduction in LID compared to baseline prior to the administration of ADS-5102, may vary. This observed benefit from our Phase 2/3 study may prove to be inconclusive or negative in our Phase 3 results if the duration of response, or other efficacy measure, decreases over time or patients are found to require increasing doses of ADS-5102 to achieve equivalent therapeutic benefits, as may be the case with levodopa in some patients. As the prevalence of Parkinson's disease increases with age, there may also be worsening of Parkinson's disease symptoms of the patients, or other safety issues that arise whether related or unrelated to ADS-5102, that may negatively affect the Phase 3 registration trial results. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing promising results in earlier clinical trials. A 2009 study completed by the Tufts Center for the Study of Drug Development estimated that less than 47% of certain CNS drugs in Phase 3 clinical trials proceeded to regulatory review.

We expect to announce top line results from the first of our Phase 3 registration trials, EASE LID, by the first quarter of 2016, with the results from the remaining trials later in 2016. If the data from any of our Phase 3 registration trials fail to adequately demonstrate the safety and effectiveness of ADS-5102, we may not be able to pursue or obtain regulatory approval, which would have a material and adverse impact on our business.

We may experience numerous unforeseen events during, or as a result of, clinical studies that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including that:

- clinical studies of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;

Table of Contents

- the number of patients required for clinical studies of our product candidates may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, or patients may drop out of these clinical studies at a higher rate than we anticipate;
  
- the cost of clinical studies of our product candidates may be greater than we anticipate;
  
- the conduct of the Phase 3 registration trials for ADS-5102 for LID may require more resources than we anticipate, as these trials require the initiation and training of a large number of sites in the United States and Europe, compliance with a variety of foreign and domestic governmental regulations and new initiatives and processes for which we do not have prior experience implementing;
  
- our clinical sites and clinical investigators may fail to comply with, or inconsistently apply, the trial protocols, regulatory requirements including Good Clinical Practices, contractual obligations and the rating assessments;
  
- our patients or their caregivers may fail to comply with their treatment instructions or home diaries;
  
- our third-party contractors 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 of our product candidates 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 may not approve our proposed clinical development plans or may require costly modifications to such plans;
  
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
  
- 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

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

- the supply or quality of our product candidates or other materials necessary to conduct clinical studies of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical studies or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical studies or other testing of our product candidates, if the results of these studies or tests are not positive or are only modestly positive, or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- 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.

Our product development costs will increase if we experience delays in testing or approvals. Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to commercialize our product candidates and harm our business and results of operations.

Table of Contents

***Even if clinical studies demonstrate statistically significant efficacy and acceptable safety for a product, the FDA or similar regulatory authorities outside the United States may not approve it for marketing.***

In 2014, we initiated our remaining Phase 3 registration trials including a separate open-label safety study of ADS-5102 for LID. If these trials are successful, we intend to submit an NDA for ADS-5102 in that indication. It is possible that the FDA may not consider the results of these studies to be sufficient for approval of the product candidates in their proposed indications. If the FDA were to require us to conduct additional studies of ADS-5102 to support the NDA for approval for the product candidate in its currently contemplated indication, our business and financial results would be materially adversely affected.

***Our product candidates have never been manufactured on a commercial scale, and there are risks associated with developing manufacturing and packaging processes and scaling them up to commercial scale.***

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with developing manufacturing and packaging processes and scaling them up to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of raw materials or equipment. Furthermore, we have no long-term contracts with any CMOs for ADS-5102, and there is no assurance we will be able to negotiate contracts with one or more of these CMOs on acceptable terms or on a timely basis. These risks could delay an NDA for ADS-5102 and adversely affect regulatory approval of a product candidate. In addition, even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that CMOs with which we contract will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities or to produce it in sufficient quantities to meet the requirements for the potential launch of the product to meet potential future demand. If our CMOs are unable to produce sufficient quantities of the approved product, our regulatory approval or commercialization efforts would be significantly impaired, which would have an adverse effect on our business, financial condition, results of operations, and growth prospects.

***Our product candidates, including ADS-5102, Namzaric, and Namenda XR are complex to manufacture, and manufacturing disruptions may occur.***

Our product candidates, including ADS-5102, Namzaric, and Namenda XR all include controlled-released versions of existing drugs, and some are combinations of existing drugs. The manufacture and packaging of controlled-release versions of existing drugs or combinations of existing drugs are substantially more complex than the manufacture and packaging of the immediate-release versions of drugs alone. Even after the manufacturing process for a controlled-release or combination product has been scaled to commercial levels and numerous commercial lots have been produced, manufacturing disruptions may occur. Such problems may prevent the production of lots that meet the specifications required for sale of the product and may be difficult and expensive to resolve. For example, in November 2013, Forest recalled three packaged lots of Namenda XR because Forest's dissolution testing revealed a failure to meet specification throughout shelf life. Namenda XR is one of the components of Namzaric, Forest's fixed-dose combination product for treatment of moderate to severe Alzheimer's disease. If any such issues were to arise with respect to our product candidates or future products, if any, or if Forest's sales of Namzaric or Namenda XR were to be negatively impacted by such issues, our business, financial results or stock price could be adversely affected.

***If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of products on which our future revenue depends, our business will suffer.***

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

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. 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) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

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



Table of Contents

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. 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.

For example, as of August 6, 2014, we had received notice that several companies had submitted ANDAs to the FDA requesting permission to manufacture and market generic versions of Namenda XR, on which we are entitled to receive royalties from Forest beginning in June 2018. In the notices, these companies allege that the patents associated with Namenda XR, one of which is owned by Forest, one of which is exclusively licensed to Forest by Merz Pharma GmbH & Co. KGaA, and others of which are owned by us and licensed by us exclusively to Forest in the United States, are invalid, unenforceable, or will not be infringed by the companies' manufacture, use or sale of generic versions of Namenda XR. In January, February, April, May, and July 2014, we, Forest, Forest Laboratories Holdings Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (together Merz) filed lawsuits for infringement of the relevant patents against several of these companies that had then submitted ANDAs. The trial is scheduled for February 2016. Because these lawsuits were filed within the requisite 45-day period provided in the FDCA, there are stays preventing FDA approval of the ANDAs for 30 months or until a court decision adverse to the patents. The 30-month stay for these ANDAs will expire beginning in June 2016. From November 2014 through May 2015, we and Forest have entered into a series of settlement agreements on undisclosed terms.

For various strategic and commercial reasons, manufacturers of generic medications frequently file ANDAs shortly after FDA approval of a branded drug regardless of the perceived strength and validity of the patents associated with such product. Based on these past practices, we believe it is likely that one or more such generic manufacturers will file ANDAs with respect to Namzaric and ADS-5102, if approved by the FDA, prior to the expiration of the patents related to those compounds.

The filing of an ANDA as described above with respect to any of our products could have an adverse impact on our stock price. Moreover, if any such ANDAs were to be approved and the patents covering the relevant products were not upheld in litigation, or if a generic competitor is found not to infringe these patents, the resulting generic competition would negatively affect our business, financial condition and results of operations.

***Any product candidate that we are able to commercialize may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, thereby harming our business.***

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. In particular, in many countries, including many major European markets, therapies that are based on existing generic drugs, such as Namenda XR (memantine) and ADS-5102 (amantadine), or combinations of existing generic drugs, such as Namzaric, generally are not well-reimbursed. As a result, we anticipate that the commercial success of Namzaric, Namenda XR, and ADS-5102, will be largely dependent on their success in the U.S. market.

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 payors, including government health administration authorities, such as

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

those that administer the Medicare and Medicaid programs, and private health insurers. Third-party payors decide which medications they will cover by placement on their formularies and at what reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot assure you that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to

Table of Contents

successfully commercialize any product candidate that we successfully develop and Forest may be unable to successfully market Namzaric or Namenda XR.

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 and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the United States, private third-party payors 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 payors for new products that we develop, or products developed or marketed by Forest under our license agreement, could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

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

Our product candidate ADS-5102, along with our other earlier stage product candidates, are still in clinical or pre-clinical development. The risk of failure during development is high. It is impossible to predict when or if any of our product candidates will prove safe and tolerable enough to receive regulatory approval. For example, amantadine, the active pharmaceutical ingredient in ADS-5102, carries the risk of blurred vision, dizziness, lightheadedness, faintness, trouble sleeping, depression or anxiety, hallucinations, swelling of the hands, legs, or feet, difficulty urinating, shortness of breath, and rash. These side effects may be the cause of the relatively low rate of acceptance of amantadine by physicians and patients. Although we believe our controlled-release version of amantadine has reduced the risks of these side effects, thereby enabling higher doses, there can be no assurance that our Phase 3 registration trials or future studies in other indications will not fail due to safety or tolerability issues. In such an event, we might need to abandon development of ADS-5102 entirely or for certain indications. If we are forced to abandon development of our product candidates, our business, results of operations, and financial condition will be materially and adversely harmed.

***Safety issues with Namenda XR, Namzaric, or ADS-5102, or the parent drugs or other components of Namenda XR, Namzaric, or ADS-5102, or with approved products of third parties that are similar to Namenda XR, Namzaric, or ADS-5102, could decrease the potential sales of Namenda XR, Namzaric, or ADS-5102 or give rise to delays in the regulatory approval process, restrictions on labeling, or product withdrawal.***

Discovery of previously unknown problems, or increased focus on a known problem, with an approved product may result in restrictions on its permissible uses, including withdrawal of the medicine from the market. The labels for Namenda XR and Namzaric both list potential side effects, such as headache, diarrhea, and dizziness. Side effects have been observed in clinical trial subjects taking ADS-5102, such as constipation, dizziness, hallucination, dry mouth, fall, confusion, headache, nausea, and weakness.

If we or others identify additional undesirable side effects caused by Namenda XR and Namzaric or 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 Forest or us to take our approved drugs off the market;
- Forest or 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;
- Forest or we may have limitations on how we promote our drugs;

Table of Contents

- third-party payors may limit coverage or reimbursement for Forest's or our drugs;
- sales of products may decrease significantly;
- Forest or we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent Forest or 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.

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

In addition, problems with approved products marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as memantine, amantadine, or donepezil could adversely affect the commercialization of Namenda XR, Namzaric, and ADS-5102. For example, the product withdrawals of Vioxx from Merck and Bextra from Pfizer due to safety issues have caused other drugs that have the same therapeutic target, such as Celebrex from Pfizer, to receive additional scrutiny from regulatory authorities.

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

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

We are currently seeking regulatory approval of ADS-5102 for the treatment of LID. If this product candidate is approved, the FDA will restrict our ability to market or advertise the product for other indications, which could limit physician and patient adoption. We may attempt to develop, promote, and commercialize new treatment indications and protocols for ADS-5102 in the future, but we cannot predict when or if the clearances required to do so will be received. In addition, we would be required to conduct additional clinical trials or studies to support approvals for additional indications for ADS-5102, which would be time consuming and expensive, and may produce results that do not support regulatory approvals. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

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

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products, such as ADS-5102, if approved. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, if we receive marketing approval for ADS-5102 for the treatment of LID, the first indication we are pursuing, we cannot

Table of Contents

prevent physicians from using our ADS-5102 products on their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses prior to FDA approval for an additional indication, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

Physicians may also misuse our products, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our products are misused, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Furthermore, the use of our products for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Any of these events could harm our business and results of operations and cause our stock price to decline.

***We currently have no sales or distribution personnel and only limited marketing capabilities. If we are unable to develop a sales and marketing and distribution capability, we will not be successful in commercializing ADS-5102 or other future approved products.***

We do not have a significant sales or marketing infrastructure and have no experience in the sale, marketing, or distribution of therapeutic products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We expect that the primary focus of our commercialization efforts will be the United States, and we intend to develop our own sales force to commercialize ADS-5102 and our other wholly owned future approved products in the United States. Commercialization of ADS-5102 and other future approved products 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 sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

In addition, our existing arrangements for the commercialization of Namenda XR and Namzaric may not be successful and we also may not be successful entering into new arrangements with third parties to sell and market our future approved products or may be unable to do so on terms that are favorable to us. We have and will in the future be likely to have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and could damage our reputation. If we fail to appropriately estimate the size of sales force required to market our products, our commercialization efforts will be adversely affected. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our future approved products.

*Our future products may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.*

Our future products may fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payors, and others in the medical community. The degree of market acceptance of our products, after being approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;



Table of Contents

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

For example, the absence of approved therapeutics to treat LID may require us to educate healthcare providers and patients about LID.

***Delays in the establishment of clinical study sites and enrollment of patients in any of our clinical trials could increase our development costs and delay completion of the study. Failure to timely enroll our Phase 3 registration trials for ADS-5102 and timely file our NDA for the treatment of LID would severely harm our business.***

We may not be able to initiate or continue clinical studies for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these studies as required by the FDA or other regulatory authorities. For example, location and enrollment of eligible patients may be adversely affected by our inability to locate and activate clinical study sites at a satisfactory pace to meet our planned timetables. As part of EASE LID 3, we have recently begun and are continuing to initiate clinical study sites in several countries in Europe for which we have no prior experience. The conduct of studies in foreign countries raise additional issues and complexities and could significantly delay our trials. Even if we are able to enroll a sufficient number of patients in our clinical studies, if the pace of enrollment is slower than we expect for any reason, the development costs for our product candidates may increase, the completion of our studies may be delayed, or our studies could become too expensive to complete. Enrollment of all of the Phase 3 registration trials for ADS-5102 is planned to be completed in 2015; however, we cannot give assurance that we will be successful in meeting that timeline. The study design for our Phase 3 trials of ADS-5102 for the treatment of LID is placebo controlled, meaning that a portion of patients will not receive treatment that may help control the symptoms of their Parkinson's disease. Because these symptoms are uncomfortable, a relatively long study period may make it more difficult to enroll and retain patients in the trial. Failure to timely enroll our Phase 3 registration trials for ADS-5102 would in turn delay our ability to obtain data from these studies. Even if successful, significant delays in the submission of the NDA, currently planned for 2016, may severely

harm our business.

*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 therapeutic products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. For example, in the market for Alzheimer's disease treatments Namenda XR and Namzaric compete or will compete with generic products, such as galatamine, rivastigmine, and donepezil, as well as branded products, such as the Exelon patch (Novartis Pharmaceuticals Corp.) and Aricept 23 mg (Eisai Inc.). ADS-5102, if approved, may face competition from various drugs approved for treatment of Parkinson's disease, though not LID, such as Azilect (Teva Pharmaceuticals Industries, Ltd.), Requip XL (GlaxoSmithKline plc.), Mirapex ER (Boehringer Ingelheim Pharmaceuticals Inc.), Neupro Patch (UCB, Inc.), Comtan (Novartis Pharmaceuticals Corp.), Sinemet (Merck & Co., Inc.), Parcopa (Jazz Pharmaceuticals, Inc.), Apokyn (Bertek), Bromocriptine (Mylan Laboratories, Inc.), Zelapar (Valeant Pharmaceuticals International), Eldepryl (Somerset Pharmaceuticals Inc.), Tasmar (Valeant Pharmaceuticals International), Cogentin (Oaks Pharma Akorn), Exelon (Novartis Pharmaceuticals Corp.), Stalevo (Novartis Pharmaceuticals Corp.), Rytary (Impax), and Duopa (Abbvie). ADS-5102 may also face competition from drugs currently in development for LID from a number of pharmaceutical companies, such as Merck, Novartis, Osmotica Pharmaceuticals, Avanir Pharmaceuticals, Newron Pharmaceuticals S.p.A, Neurolix Inc, Amaranthus BioScience, Adnex Pharma, and Neurim Pharmaceuticals Ltd. Other

Table of Contents

products in late stage development for Parkinson's disease includes product candidates from Kyowa Hakko, Acorda, Neuroderm, Acadia, Bial-Portela CSA, Biotie Therapies Corp, Genervon Biopharmaceuticals, Pharma Two B, and Depomed.

ADS-5102 may also face competition from generic versions of amantadine and from other controlled-release versions of amantadine that may be in development. One such competitor has posted a notice on [clinicaltrials.gov](http://clinicaltrials.gov) regarding conduct of two Phase 3 clinical trials of extended release amantadine for LID. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications. In addition, 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 payors.

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, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing and selling approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties 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.

***Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical studies and will face an even greater risk upon commercial sale of any products that are ultimately approved. 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.

***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 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 spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

Table of Contents

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

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

*We have entered into a license agreement with Forest with respect to Namzaric and Namenda XR, and may enter into additional license or collaboration agreements. These arrangements may place the development of these product candidates and commercialization of any approved products outside our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us, and if our collaborations are not successful, these product candidates or approved products may not reach their full market potential. As Forest substantially controls the intellectual property rights subject to the license agreement and accordingly, the current ANDA litigation and settlement thereof, and has economic interests different from ours, Forest may manage the litigation and settlements on terms which may have a material and negative impact on our business.*

In November 2012, we entered into a license agreement with Forest pursuant to which we granted Forest a co-exclusive right to develop and an exclusive right to commercialize fixed-dose memantine-donepezil products, such as Namzaric, in the United States, and granted Forest a license covering controlled-release versions of memantine, such as Namenda XR. Under the terms of the license agreement, Forest substantially controls the commercialization of these products and the intellectual property rights subject to the license agreement, including the prosecution, maintenance and enforcement of such rights. Collaborations involving our current or future products, such as our agreement with Forest, are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators 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;
- collaborators 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;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator 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 collaborators that would prevent us from collaborating with others;
- Forest and future collaborators 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;
- Forest and future collaborators may not aggressively or adequately pursue litigation against ANDA filers or may settle such litigation on unfavorable terms, and as Forest substantially controls the current ANDA litigation and terms of settlement and has different economic interests than ours, Forest may grant licenses to generic manufacturers that permit them to make and sell generic versions of Namenda XR, which would negatively impact the royalties we receive under our license with Forest;
- disputes may arise between us and a collaborator 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;

Table of Contents

- collaborations may be terminated, sometimes at-will, without penalty, such as with Forest, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

In July 2014, Actavis and Forest announced the completion of the previously announced acquisition of Forest by Actavis. We cannot predict whether this acquisition and subsequent acquisitions, including of Allergan, Inc. by Actavis, which closed in March 2015, will have a negative impact on our business, the pursuit of the ANDA litigation and potential settlements thereof, or on the license agreement with Forest or the intellectual property rights subject thereto.

***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.

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.

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

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

We currently have limited experience in, and we do not own facilities for, clinical-scale manufacturing of our product candidates and we rely upon third-party contract manufacturing organizations to manufacture and supply drug product for our clinical studies. 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 provide study drugs in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical study materials could delay the completion of our clinical studies, increase the costs associated with maintaining our clinical study programs and, depending upon the period of delay, require us to commence new studies at significant additional expense or terminate the studies completely.

All manufacturers of our product candidates 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



Table of Contents

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 or commercialization of our product candidates, entail higher costs, or impair our reputation.

We currently rely on single source suppliers for each of our product candidates under a development agreement. We do not have long-term supply agreements in place. We are currently seeking to qualify and to enter into long-term contracts with at least one manufacturer to include in our anticipated NDA for ADS-5102. Although we believe alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange and negotiate acceptable long-term contracts, which would adversely affect our business. New suppliers of any product candidate would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs, which may be passed on to us. Qualifying and negotiating long term contracts with manufacturers and providers of packaging services is a lengthy process. If at any time, one or more of our qualified contract organizations were not able to manufacture our drug substance or provide the requisite services, our business and financial condition would be materially adversely affected.

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

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

As of March 31, 2015, we had 46 full-time 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, and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth

Table of Contents

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, typhoons, 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 in California 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;

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

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

Table of Contents

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

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs or commercialization efforts. For example, the loss of clinical study data from completed or ongoing clinical studies for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. While we back-up our internal computer systems periodically and store such data off-site, 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 related to intellectual property**

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

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

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

The patent position of specialty 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

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

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 recently enacted 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

Table of Contents

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. In December 2014, one of the parties involved in the pending Delaware litigation also filed an *inter partes* review petition with the Patent Trial and Appeal Board of the Patent and Trademark Office requesting cancellation of claims of one of our patents covering Namenda XR. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us or Forest, without payment to us.

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

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

Filing, prosecuting, and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our product candidates in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, 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.



Table of Contents

***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, in January, February, April, and May 2014, we, Forest, Forest Laboratories Holdings Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH filed patent infringement lawsuits under Forest's patents and patents owned by us and licensed to Forest, against several manufacturers of generic pharmaceuticals that have filed ANDAs with the FDA seeking approval to manufacture and sell generic versions of 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 the Forest litigation 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.

From November 2014 through May 2015, we and Forest have entered into a series of settlement agreements on undisclosed terms.

***Third parties may initiate legal proceedings alleging that we or our collaborators 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 collaborators 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 collaborators may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, re-examination, *inter partes* review, post-grant review, opposition, or similar proceedings before the USPTO and its foreign counterparts. The costs of these proceedings could be substantial, and the proceedings may result in a loss of such intellectual property rights. Some of our competitors may be able to sustain the costs of complex patent disputes and litigation more effectively than we can, because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any disputes or litigation could adversely affect our ability to raise the funds necessary to continue our operations. Third parties may assert infringement claims against us or our collaborators based on existing patents or patents that may be granted in the future. For example, in December 2013 Teva Pharmaceuticals USA and Mayne Pharma International jointly initiated a lawsuit against Forest alleging that the manufacture and commercialization of Namenda XR by Forest infringes the plaintiffs' U.S. patent. Under our license agreement with Forest we are obliged to indemnify Forest under certain circumstances and our royalty entitlements may also be reduced. Our indemnification obligation to Forest, while subject to customary limitations, has no monetary cap, and our right to receive royalties from Forest may be eliminated in any calendar quarter in which certain third party generic competition exists. If we or our collaborators 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.



Table of Contents

*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 collaborators, 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 collaborators 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.

*We may be subject to claims that our employees have wrongfully used or disclosed intellectual property of their former employers. Intellectual property litigation or proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.*

Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, and we have no knowledge of any instances of wrongful use or disclosure by our employees to date, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of an employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation, or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

**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, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaboration partners are permitted to market our product candidates in the United States until we receive FDA

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

approval of an NDA. We have not submitted an application or received marketing approval for any of our product candidates. Obtaining approval of an NDA can be a lengthy, expensive, and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;

Table of Contents

- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we and our collaboration partners must demonstrate with substantial evidence from well-controlled clinical studies, and to the satisfaction of the FDA and other regulatory authorities abroad, 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 and other regulatory authorities. 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 FDA or other regulatory authorities denying 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 exerted, failure can occur at any stage, and we could encounter problems that cause 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 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 that:

- a product candidate may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical studies sufficient;
- the FDA might not approve our or our third-party manufacturer's processes or facilities; or

- the FDA may change its approval policies or adopt new 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.

***Our competitors could obtain orphan drug exclusivity for their drug products in certain of our target indications, which could delay any marketing approval of our drug product candidates in those target indications.***

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 subsequently 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 years in the United States. Even though we have orphan drug designation for ADS-5102 for the treatment of LID, we may not be the first to obtain marketing approval. If any of our competitors obtain orphan drug exclusivity for their product candidate in one of our target indications, the marketing application for our drug product in that target indication could be delayed for so long as the competitor has orphan drug exclusivity for its product.

Even if we are first to obtain marketing approval for ADS-5102 for the treatment of LID, the FDA could still subsequently approve the same drug with the same active moiety for the same condition, if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor does orphan drug designation give the drug any advantage in the regulatory review or approval process.

Table of Contents

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

We are developing our current and future product candidates, including ADS-5102, with the expectation that they will be eligible for approval through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the FDCA allows an NDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of an approved drug product. Consequently, use of the Section 505(b)(2) regulatory pathway could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that would need to be generated 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 complications and risks associated with regulatory approval of would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway may result in new competitive products reaching the market more quickly than our product candidates, which would adversely impact our competitive position and prospects. Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee that utilizing this pathway will ultimately lead to accelerated product development or earlier approval for ADS-5102 or any other product candidate that we may attempt to develop and commercialize.

In addition, a company obtaining an approved NDA through the Section 505(b)(2) regulatory pathway for a drug product whose active moiety is the same active moiety as that in a previously approved drug (e.g. amantadine HCl) is entitled to three years of market exclusivity if clinical data (other than a bioavailability or bioequivalence study) is required by the FDA to support its findings of safety and efficacy of the approved product. If a competing product were to be approved in our target indication through the Section 505(b)(2) regulatory pathway and granted three years of market exclusivity, and if the FDA were to find that our product candidate (e.g. ADS-5102) does not differ with respect to active moiety, dosage form and strength, route of administration, and indicated use from the approved competing product, then approval of the marketing application for ADS-5102 in the target indication under Section 505(b)(2) may be delayed for as long as a competitor has exclusivity.

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

Once regulatory approval has been granted for a particular product candidate, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that we or our collaboration partners receive for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our product candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion, tracking, and recordkeeping for our products. Further, manufacturers of our drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Additionally, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters;
- civil or criminal penalties and fines;



Table of Contents

- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted for which we may also be required to comply. 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 our future products and our business may suffer.

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

We may decide to commercialize ADS-5102, ADS-8704, and other future product candidates outside of the United States. To market our future products in the European Economic Area, or EEA, and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically, in the EEA medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

Before granting an MA, the European Medicines Agency or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

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 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. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for 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.

*Healthcare reform measures could hinder or prevent our product candidates' commercial success.*

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or, collectively, the PPACA, was enacted in 2010.

Table of Contents

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

- imposes a non-deductible annual fee on entities that manufacture or import certain branded prescription drugs;
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires collection of rebates for drugs paid by Medicaid managed care organizations; and
- provides for a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety. We can provide no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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

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

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

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits knowingly and willfully offering, soliciting, receiving, or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, order, lease, or recommendation of, any good, facility, item, or service for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the

Table of Contents

physician or a member of the physician's family has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;

- the federal transparency requirements under the PPACA require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services, or HHS, information related to physician 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, and transparency laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers.

The PPACA, among other things, amended the intent standard of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to a stricter standard such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and/or administrative penalties, damages, fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, 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.

**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 specialty 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.

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

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:

- 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;

Table of Contents

- the success of our efforts to acquire or in-license additional products or product candidates;
  
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing and our commercialization partners;
  
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
  
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our current or future products;
  
- our ability or inability to raise additional capital and the terms on which we raise it;
  
- the recruitment or departure of key personnel;
  
- changes in the structure of healthcare reimbursement systems;
  
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our current or future products;
  
- market conditions in the pharmaceutical and biotechnology sectors;
  
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
  
- trading volume of our common stock;
  
- sales of our common stock by us or our stockholders;

- general economic, industry, and market conditions; and
- the other risks described in this Risk Factors section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Additionally, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations, and growth prospects.

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

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

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

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



Table of Contents

***We are incurring significant increased costs as a result of operating as a public company, and our management is now required to devote substantial time to new compliance initiatives.***

As a public company, we are incurring significant legal, accounting, and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules of the SEC and those of NASDAQ Global Market, or NASDAQ, have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel now need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to maintain our director and officer liability insurance. We estimate the additional costs we expect to incur as a result of being a public company to be approximately \$2 million annually.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning with this annual report on Form 10-K for the fiscal year ending December 31, 2014. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC, or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial 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 and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock and could adversely affect our ability to access the capital markets.

***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. 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.***

## Edgar Filing: Adamas Pharmaceuticals Inc - Form 10-Q

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

Table of Contents

pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include that:

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

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

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

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

## **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

### *Use of Proceeds*

On April 15, 2014, we issued and sold 3,000,000 shares of our common stock in the IPO at a public offering price of \$16.00 per share, for net proceeds of approximately \$41.4 million, after deducting underwriting discounts and commissions of approximately \$3.4 million and expenses of approximately \$3.2 million. On May 6, 2014, we issued and sold 81,371 shares of common stock pursuant to the underwriters' partial exercise of their option to purchase additional shares, for net proceeds of approximately \$1.2 million, after deducting underwriting discounts and commissions of approximately \$91,000. All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-194342), which was declared effective by the SEC on April 9, 2014.

None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates.

Table of Contents

There has been no material change in the planned use of proceeds from our IPO as described in our prospectus effective April 9, 2014, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

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

Table of Contents

**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: May 13, 2015

/s/ Gregory Went  
Gregory Went, Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 13, 2015

/s/ William Dawson  
William Dawson  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Table of Contents**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>Incorporation By Reference</b>		
			<b>SEC File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>
3.1	Amended and Restated Certificate of Incorporation of Adamas Pharmaceuticals, Inc.	8-K	001-36399	3.1	4/15/2014
3.2	Amended and Restated Bylaws of Adamas Pharmaceuticals, Inc.	S-1	333-194342	3.4	3/5/2014
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate of Adamas Pharmaceuticals, Inc.	S-1	333-194342	4.1	3/26/2014
4.3	Fourth Amended and Restated Investor Rights Agreement, dated as of June 30, 2011, by and among the registrant and certain of its stockholders.	S-1	333-194342	10.5	3/5/2014
10.22	Offer Letter by and between the registrant and Grace Shin, dated November 17, 2014.				
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.				
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.				
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(1)				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				





Table of Contents

101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
---------	--

---

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