Adamas Pharmaceuticals Inc
Form 10-Q
November 04, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2014

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	**42-1560076**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
2200 Powell Street, Suite 220 Emeryville, CA	**94608**
(Address of Principal Executive Offices)	(Zip Code)

(510) 450-3500

(Registrant s Telephone Number, Including Area Code)

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

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 x No o

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 o	Accelerated filer o	Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

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

Number of shares outstanding of the issuer s common stock, par value $0.001 per share, as of October 30, 2014 was 17,125,780.

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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.

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PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Adamas Pharmaceuticals, Inc.

Unaudited Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	September 30, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$ 137,526	$ 85,612
Accounts receivable	120	129
Prepaid expenses and other current assets	1,284	267
Total current assets	138,930	86,008
Property and equipment, net	443	199
Other assets	70	9
Total assets	$ 139,443	$ 86,216
Liabilities, convertible preferred stock and stockholders equity		
Current liabilities		
Accounts payable	$ 3,033	$ 2,097
Accrued liabilities	3,517	2,119
Other current liabilities	146	2
Total current liabilities	6,696	4,218
Warrant liability		6,232
Non-current liabilities		12
Total liabilities	6,696	10,462
Commitments and Contingencies (Note 6)		
Convertible preferred stock, $0.001 par value - 5,000,000 shares and 6,700,000 authorized at September 30, 2014 and December 31, 2013, and zero and 4,719,174 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively; zero and $77,433 liquidation preference at September 30, 2014 and December 31,2013, respectively		19,149
Stockholders equity		
Common stock, $0.001 par value - 100,000,000 shares authorized, 16,971,385 and 9,515,528 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	22	14
Additional paid-in capital	152,805	77,163
Accumulated deficit	(20,080)	(20,572)
Total stockholders equity	132,747	56,605
Total liabilities, convertible preferred stock and stockholders equity	$ 139,443	$ 86,216

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

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Adamas Pharmaceuticals, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Income

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue	$ 215	$ 161	$ 25,545	$ 30,985
Operating expenses				
Research and development	5,412	1,387	13,343	5,037
General and administrative	4,353	1,571	10,724	4,054
Total operating expenses	9,765	2,958	24,067	9,091
Income (loss) from operations	(9,550)	(2,797)	1,478	21,894
Interest and other income (expense), net	(1)	(426)	(801)	(1,414)
Income (loss) before income taxes	(9,551)	(3,223)	677	20,480
Income tax expense	(6)	(216)	(185)	(503)
Net income (loss)	$ (9,557)	$ (3,439)	$ 492	$ 19,977
Net income (loss) attributable to common stockholders				
Basic	$ (9,557)	$ (3,439)	$ 53	$ 12,630
Diluted	$ (9,557)	$ (3,439)	$ 54	$ 13,294
Net income (loss) per share attributable to common stockholders				
Basic	$ (0.57)	$ (0.36)	$ 0.00	$ 1.33
Diluted	$ (0.57)	$ (0.36)	$ 0.00	$ 1.19
Weighted average number of shares used in computing net income (loss) attributable to common stockholders				
Basic	16,787	9,510	13,998	9,506
Diluted	16,787	9,510	16,769	11,194

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

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Adamas Pharmaceuticals, Inc.

Unaudited Consolidated Statements of Cash Flows

(in thousands)

	Nine Months Ended September 30,	
	2014	**2013**
Cash flows from operating activities		
Net income	$ 492	$ 19,977
Adjustments to reconcile net income to net cash used in operating activities		
Depreciation and amortization	99	43
Stock-based compensation	4,907	386
Change in preferred stock warrant value	983	1,073
Provision for employee notes receivable		1
Issuance of common stock and vesting of restricted common stock for services received		75
Write-off of fixed assets	80	
Changes in assets and liabilities		
Prepaid expenses and other assets	(1,077)	(364)
Accounts receivable	9	774
Accounts payable	936	(1,933)
Accrued liabilities and other liabilities	811	(193)
Deferred revenue		(29,611)
Net cash provided by (used in) operating activities	7,240	(9,772)
Cash flows from investing activities		
Purchase of property and equipment	(194)	(162)
Net cash used in investing activities	(194)	(162)
Cash flows from financing activities		
Proceeds from public offering of common stock, net of underwriters discount	45,851	
Payment of public offering costs	(3,219)	
Proceeds from issuance of common stock upon exercise of stock options	250	25
Proceeds from issuance of common and preferred stock upon exercise of warrants	1,986	
Principal payments on convertible promissory notes		(4,000)
Net cash provided by (used in) financing activities	44,868	(3,975)
Net increase (decrease) in cash and cash equivalents	51,914	(13,909)
Cash and cash equivalents at beginning of period	85,612	62,957
Cash and cash equivalents at end of period	$ 137,526	$ 49,048
Supplemental disclosure of noncash items		
Accrued capital expenditures	$ 229	$
Liability assumed in noncash stock transaction	$ 341	$

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

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Adamas Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

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 proven drugs to create novel therapeutics for use alone and in fixed-dose combination products. The Company is developing its lead wholly owned product candidate, ADS-5102, for a complication of Parkinson s disease known as levodopa induced dyskinesia (LID) and is evaluating other potential CNS indications for which ADS-5102 may have applicability, including hyperkinetic and hypokinetic movement disorders. 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 also includes an NDA-submitted product candidate, MDX-8704, being co-developed with Forest Laboratories, Inc. (Forest), a subsidiary of Actavis plc, (Actavis), and an approved product, Namenda XR®, which Forest developed and is marketing in the United States under a license from the Company.

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 two subsidiaries: Adamas Pharmaceuticals Asia Pte Limited (inactive) and Adamas India Pharmaceuticals Private Limited, which ceased operations in August 2013.

Initial Public Offering

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

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 (U.S. GAAP), and following the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company s annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of the Company s financial information. The results of operations for the three and nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014 or any future interim period. The condensed consolidated balance sheet as of December 31, 2013 has been derived from audited financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. Accordingly, the unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2013 included in the Company s prospectus (Registration No. 333-194342) filed pursuant to Rule 424(b) on April 10, 2014 with the U.S. Securities and Exchange Commission.

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Forward Stock Split

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

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in the condensed 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.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less at time of purchase to be cash equivalents.

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

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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.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents. Substantially all the Company s cash and cash equivalents are held at one financial institution that management believes is of high credit quality. Such deposits generally exceed federally insured limits.

Risk and Uncertainties

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

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

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

Convertible Preferred Stock

The Company classifies the convertible preferred stock as temporary equity on the balance sheets due to certain change in control events that are outside the Company s control, including liquidation, sale or transfer of the Company, as holders of the convertible preferred stock can cause redemption of the shares. Shares of convertible preferred stock were converted to common stock upon close of the IPO in April 2014.

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Convertible Preferred Stock Warrants

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

Fair Value of Financial Instruments

The carrying value of the Company s cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, other assets, accounts payable, accrued liabilities, and convertible notes payable approximate fair value due to the short-term nature of these items. The convertible preferred stock warrant liability was carried at fair value and was zero as of September 30, 2014.

Foreign Currency Translation

For non U.S. operations, the U.S. dollar is the functional currency. Monetary assets and liabilities of the foreign subsidiary are translated into U.S. dollars at current exchange rates. Nonmonetary assets such as property and equipment are translated at historical rates. Income and expense items are translated at average rates of exchange prevailing during the period of the related transactions, except that depreciation charged to operations is translated at historical rates.

Income Taxes

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

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

benefit might change as new information becomes available.

Net Income (Loss) Per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net income per share calculation, stock options and convertible preferred stock warrants are considered to be potentially dilutive securities.

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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 determines whether it has net income attributable to common stockholders, which includes the results of operations less current period convertible preferred stock non-cumulative dividends. If it is determined that the Company does have net income attributable to common stockholders during a period, the related undistributed earnings are 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.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers . The amendment in this ASU provide 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 provide guidance to recognize revenue when (or as) the entity satisfies a performance obligation. The Company is evaluating the impact of this standard.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy has three levels that prioritize the inputs used in fair value measurements:

Level 1	Unadjusted quoted prices in active markets for identical assets or liabilities;
Level 2	Inputs other than quoted prices included within Level 1 that are observable, unadjusted quoted prices 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 related assets or liabilities; and
Level 3	Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company s financial instruments consist of Level 1 assets and Level 3 liabilities. Level 1 securities include highly liquid money market funds. Level 3 liabilities that are measured at fair value on a recurring basis consist of the convertible preferred stock warrant liability.

The following table summarizes, for financial assets and liabilities recorded at fair value, the respective fair value and the classification by level of input within the fair value hierarchy defined above (in thousands):

	Fair Value Measurements at September 30, 2014			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$ 134,693	$ 134,693	$	$

	Fair Value Measurements at December 31, 2013			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$ 83,700	$ 83,700	$	$
Liabilities				
Preferred stock warrant liability	$ 6,232	$	$	$ 6,232

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

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

Fair Value Using Level 3 Inputs	**Amounts**
Balance at December 31, 2012	$ 1,706
Change in fair value recorded in Other (income)/expense, net	4,526
Balance at December 31, 2013	6,232
Change in fair value recorded in Other (income)/expense, net	983
Exercise of warrants	(7,215)
Balance at September 30, 2014	$

4. Collaboration and License Agreements

In November 2012, the Company entered into a license agreement with a wholly owned subsidiary of Forest, which granted Forest an exclusive license with right to sublicense certain of the Company s intellectual property rights in the United States in connection with the development and commercialization of MDX-8704 and marketing of Forest s approved product Namenda XR for the treatment of moderate to severe dementia related to Alzheimer s disease. Pursuant to the agreement, Forest made an upfront payment of $65.0 million. The Company was eligible to receive additional cash payments totaling up to $95.0 million upon achievement by Forest of certain development and regulatory milestones in addition to tiered royalty payments based on future net sales of the product upon commercialization.

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 (BESP) for each deliverable in order to allocate the non-contingent arrangement consideration to the two units of accounting. Based on BESP analysis, value assigned to the obligation to participate on the JDC was a negligible amount. Accordingly, the entire upfront license fee of $65.0 million was allocated to the transfer of license and technical know-how. Revenue recognition commenced upon delivery of the license and was recognized on a straight-line basis through the period of the transfer of

the know-how. 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 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 (November 2012 to February 2013).

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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 planned New Drug Application (NDA) filing with the FDA for MDX-8704 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 MDX-8704. These amounts have been recorded as revenue in the condensed consolidated statement of operations and comprehensive income during 2013 and 2014, respectively.

5. Warrants to Purchase Common or Preferred Stock

Common stock warrants

In conjunction with the sale of convertible promissory notes issued in November 2002 and September 2003, the Company issued warrants to purchase 22,220 shares and 88,884 shares, respectively, of the Company s Series A convertible preferred stock. The warrants expire ten years from issuance. The relative fair value of these warrants was determined to be approximately $49,000 and $205,000, respectively, and was amortized to interest expense over the term of each loan. These preferred stock warrants converted to warrants to purchase common stock as part of the Company s recapitalization transaction during 2011. The warrants to purchase 22,220 shares of common stock expired in November 2012 while the warrants to purchase 88,884 shares were scheduled to expire in September 2013, but were subsequently modified to extend their term by one additional year. As such, the Company recorded an additional expense of $52,000. In June 2014, a portion of these warrants were exercised for 3,556 shares of common stock. In September 2014, the remaining warrants were exercised for 85,328 shares of common stock. As of September 30, 2014 and December 31, 2013, warrants to purchase zero and 88,884 shares of common stock were outstanding, respectively.

In conjunction with the convertible promissory notes issued in November 2004, the Company issued warrants to purchase 114,448 shares of common stock at $0.53 per share. The warrants expire on November 26, 2014. The relative fair value of these warrants was determined to be $53,496 and is being amortized to interest expense over the term of the convertible note. To induce payment of the note in cash rather than the holder exercising their conversion option, the warrant holder relinquished the right to purchase 28,616 shares of the Company s common stock provided for under the original warrant. Upon modification of the warrants, the Company recorded a gain of $29,149 during the year ended December 31, 2006 which was equal to the fair market value of the relinquished share purchase right. The gain was recorded in interest and other income and as a reduction in additional paid-in capital. In September 2014, the warrants were exercised for 85,832 shares of common stock. As of September 30, 2014 and December 31, 2013, warrants to purchase zero and 85,832 shares of common stock were outstanding, respectively.

In 2006, the Company issued a warrant to purchase 13,332 shares of common stock at an exercise price of $1.88 per share to a consultant in consideration for the provision of third-party consulting services. The common stock warrant was exercisable for a period of 10 years. The Company recorded $13,000 in additional paid in capital at the time of issuance. In March 2014 the warrant was exercised for 13,332 shares of common stock. As of September 30, 2014 and December 31, 2013, warrants to purchase zero and 13,332 shares of common stock were outstanding, respectively.

In connection with the first two draw-downs pertaining to the 2006 term loan, both made in 2006 for a total of $1.5 million, the Company issued warrants to purchase a total of 13,586 shares of the Company s Series B preferred stock. Using the Black-Scholes model with a volatility of 84%, a term of ten years, and a risk-free interest rate of 4.72%, the fair value of the warrants was determined to be $121,000 and was recorded as warrant liability and discount against the borrowings and is being amortized to interest expense over the term of the loan. These preferred stock warrants converted to warrants to purchase common stock as part of the Company s recapitalization transaction during 2011. In May 2014 the

warrants were exercised for 13,586 shares of common stock. As of September 30, 2014 and December 31, 2013, warrants to purchase zero and 13,586 shares of common stock were outstanding, respectively.

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In connection with the third draw-down pertaining to the 2006 term loan, made in 2007 for $500,000, the Company issued a warrant to purchase 4,528 shares of the Company s Series B preferred stock. Using the Black-Scholes model with a volatility of 73%, a term of ten years, and a risk free interest rate of 4.72%, the fair value of the warrant was determined to be $47,000 and was recorded as warrant liability and discount against the borrowings and is being amortized to interest expense over the term of the loan. This preferred stock warrant converted into a warrant to purchase common stock as part of the Company s recapitalization transaction during 2011. In May 2014 the warrant was exercised for 4,528 shares of common stock. As of September 30, 2014 and December 31, 2013, a warrant to purchase zero and 4,528 shares of common stock was outstanding, respectively.

Convertible preferred stock warrants

In connection with the issuance of convertible promissory notes pursuant to the Note and Warrant Purchase Agreement in April 2011, the Company issued warrants to purchase 55,848 shares of Series AA preferred stock. Using the Black-Scholes model with a volatility of 90%, an expected term of 3 years, and a risk-free interest rate of 0.82%, the fair value of the warrant liability was determined to be $13,000 and was recorded as a debt discount and amortized in 2011. In March 2014 warrants were exercised for 26,284 shares of Series AA preferred stock. In April 2014 and in connection with the IPO, the remaining warrants were exercised for 29,564 of Series AA preferred stock. As of September 30, 2014 and December 31, 2013, warrants to purchase zero and 55,848 shares of Series AA preferred stock were outstanding, respectively.

In connection with the issuance of Series AA preferred stock in June 2011, the Company issued warrants to purchase 462,762 shares of Series AA preferred stock. Using the Black-Scholes model with a volatility of 90%, an expected term of 3 years and a risk-free interest rate of 0.82%, the fair value of the warrant liability was determined to be $65,000 and was recorded as a reduction against the value of Series AA preferred stock. In March 2014 warrants were exercised for 211,012 shares of Series AA preferred stock. In April 2014 and in connection with our IPO, the remaining warrants were exercised for 251,750 shares of Series AA preferred stock. As of September 30, 2014 and December 31, 2013, warrants to purchase zero and 462,762 shares of Series AA preferred stock were outstanding, respectively.

In conjunction with the issuance of convertible promissory notes pursuant to a Series AA Preferred Stock and Secured Note and Warrant Purchase Agreement, or the 2012 Notes, the Company issued warrants to purchase equity securities (the 2012 Warrants). The 2012 Warrants become exercisable on the date the 2012 Notes are converted into the Company s equity securities (or upon cash settlement of the strategic financing put option) and expire on March 22, 2019, or, if there is a Corporate Transaction prior to the date the 2012 Notes are converted, the 2012 Warrants will be automatically net exercised immediately prior to the closing of a Corporate Transaction.

The number and class of shares into which the 2012 Warrants are exercisable were determined as follows:

- *Number of shares*

- If the 2012 Notes convert into shares of the Company s equity securities through the financing put options, then the 2012 Warrants are exercisable into a number of shares equal to: (1) 10% of the principal amount of the 2012 Notes issued to the warrant holder divided by (2) the Conversion Price, which is the greater of (a) $3.81 and (b) 80% of the price paid by subsequent investors.

- Upon a Corporate Transaction or in the event the Company elects to settle the strategic financing put option in cash, then the 2012 warrants are exercisable into a number of shares of Series AA preferred stock equal to: (1) 10% of the principal of the 2012 Notes issued to the warrant holder divided by (2) $3.81.

- *Class of shares*

- If the conversion price is equal to $3.81, the 2012 Warrants become exercisable into shares of Series AA preferred stock.

- If the conversion price is greater than $3.81, the 2012 Warrants convert into the class of equity securities issued through the exercise of the financing put options.

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In order to determine a fair value for the 2012 Warrants upon issuance of the 2012 Notes, the Company evaluated multiple potential outcomes using the option pricing model value depending on the scenario while applying estimated probabilities to each scenario value. These scenarios included potential subsequent financing, strategic financing and corporate transaction at different times during 2012. Accordingly, the Company determined the fair value of the warrants to be $269,000, which was recorded as a convertible preferred stock warrant liability and a debt discount. Upon repayment of the 2012 Notes in 2013, the warrants became exercisable to purchase 104,050 shares of Series AA convertible preferred stock at $3.81 per share.

The Company remeasured the value of its preferred stock warrants at each reporting period and recorded the change in fair value in the condensed consolidated statement of operations and comprehensive income. The Company remeasured the value of their preferred warrants at April 9, 2014 and December 31, 2013 and recorded a change in fair value of $1.8 million and $4.5 million, respectively, in the consolidated statement of operations and comprehensive income under interest and other income (expense), net. In March 2014, warrants were exercised for 22,382 shares of Series AA convertible preferred stock. In April 2014, in connection with our IPO, the remaining warrants were exercised for 81,668 shares of Series AA preferred stock. As of September 30, 2014 and December 31, 2013, warrants to purchase zero and 104,050 shares of Series AA preferred stock were outstanding, respectively.

The following table summarizes the outstanding warrants as of:

	Number of shares outstanding	
	September 30, 2014	December 31, 2013
Series AA convertible preferred stock warrants issued in 2011		518,610
Series AA convertible preferred stock warrants issued in 2012		104,050
Common stock warrants	7,116	213,278

6. Commitments and Contingencies

Lease Commitments

In June 2014, the Company amended its facility lease agreement to increase the square footage to 12,492 square feet for a term of 65 months.

As of September 30, 2014, future minimum lease payments under a non-cancelable facility operating lease were as follows (in thousands):

	September 30, 2014
Remainder of 2014	$ 84
2015	550
2016	599

2017		617
2018 and thereafter		1,456
Total	$	3,306

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.

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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 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. 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.

In early November 2014, we, Forest, and Merz entered into a Settlement Agreement with Wockhardt Limited, one of the parties sued by us and Forest for infringement of our patents. Pursuant to this agreement, Worckhardt received a non-exclusive license to make and sell its generic versions of Namenda XR starting March 23, 2026, which is two months prior to the expiration of the last to expire of our relevant patents.

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.

7. Convertible Preferred Stock

The Company s amended and restated certificate of incorporation filed on April 15, 2014, authorizes 5,000,000 shares of convertible preferred stock, of which there were zero shares outstanding as of September 30, 2014.

At December 31, 2013, the convertible preferred stock consisted of the following (in thousands except share and per share data):

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

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8. Shareholders 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 September 30, 2014 and December 31, 2013, 13,000 and zero 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:

	September 30, 2014	December 31, 2013
Conversion of convertible preferred stock		3,432,908
Common stock options outstanding	5,394,880	3,567,858
Common stock options available for grant	1,931,398	1,771,212
Warrants to purchase common stock	7,116	213,290
Warrants to purchase convertible preferred stock		622,660
Total	7,333,394	9,607,928

9. Stock Option Plans

In October 2002 the Company established its 2002 Employee, Director and Consultant Stock Plan (the 2002 Plan) which provides for the granting of stock options to employees and consultants of the Company and issuance of restricted shares of common stock. Options granted under the 2002 Plan could be either incentive stock options (ISOs) or nonqualified stock options (NSOs). ISOs could be granted only to Company employees. NSOs could be granted to Company employees and consultants.

In December 2007 the Company established its 2007 Stock Plan. No further grants will be made under the 2002 Plan. The 2007 Stock Plan provides both for the direct award or sale of shares and for the grant of options to purchase shares. Options granted under the 2007 Stock Plan could either be ISOs or NSOs. ISOs could be granted only to Company employees. NSOs could be granted to Company employees and consultants.

Options granted under the 2007 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% shareholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, respectively, as determined by the board of directors. The exercise price of a NSO shall not be less than the par value per share of common stock. The options granted generally vest over five years and vest at a rate of 20% upon the first anniversary of the issuance date and 1/60th per month thereafter.

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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 will be made under the 2007 Plan. Under the 2014 Plan 1,993,394 shares of the Company s common stock were made available for issuance, plus an additional number of shares that will be added to the 2014 Plan as of the effective time equal to the sum of (i) all shares that, as of the effective time, were reserved for issuance pursuant to the 2007 Plan, plus (ii) all shares that are 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.

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

Under the terms of the 2002 Plan and 2007 Stock Plan, all options are fully exercisable on the grant date, subject to the Company s repurchase right, which under the 2002 Plan is at the original exercise price and under the 2007 Stock Plan is at the lower of original exercise price or fair value. The repurchase rights lapse over the options vesting period of generally five years.

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. Under the ESPP, an aggregate of 262,762 shares of the Company s common stock are reserved for future grant or issuance.

Activity under the Company s stock option plans is set forth below:

		Outstanding Options		
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (thousands)
Balances, December 31, 2013	1,771,212	3,567,858	$ 1.45	$ 26,932
Additional shares reserved	2,161,944			
Options granted	(2,222,550)	2,222,550	10.77	
Options exercised		(171,424)	1.73	
Options cancelled	220,792	(224,104)	2.77	
Balances, September 30, 2014	1,931,398	5,394,880	$ 5.22	$ 72,289

The aggregate intrinsic value of options exercised was $2.2 million and $25,000 for the nine months ended September 30, 2014 and 2013, respectively.

Stock-Based Compensation

During the three and nine months ended September 30, 2014, the Company granted stock options to employees to purchase 273,000 and 2,023,000 shares of common stock, respectively, with a weighted-average grant date fair value of $13.48 and $10.60 per share, respectively. During the three and nine months ended September 30, 2013, the Company granted stock options to employees to purchase zero and 73,000 shares of common stock, respectively, with a weighted-average grant date fair value for the nine months ended September 30, 2013, of $2.72 per share. As of September 30, 2014, there was total unrecognized compensation cost of $19.5 million. This cost is expected to be recognized over a period of 4.03 years. The total fair value of employee stock options vested for the three and nine months ended September 30, 2014 was $0.2 million and $0.3 million, respectively. The total fair value of employee stock options vested for the three and nine months ended September 30, 2013 was $74,000 and $0.2 million, respectively.

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Stock-based compensation expense related to employee options for the three and nine months ended September 30, 2014 was $1.2 million and $2.8 million, respectively. Stock-based compensation expense related to employee options for the three and nine months ended September 30, 2013 was $61,000 and $0.2 million, respectively.

The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards.

The fair value of employee stock options was estimated using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Expected volatility	90% - 91%	89%	90% - 96%	89%
Risk-free interest rate	2.00% - 2.18%	1.45%	2.00% - 2.20%	1.45%
Dividend yield	0%	0%	0%	0%
Contractual life (in years)	6.75	7.25	6.75 - 7.00	7.25

Determining Fair Value of Stock Options

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Weighted-Average Expected Term: The expected term of options granted is determined using the average period the stock options are expected to remain outstanding and is based on the options vesting term, contractual terms and historical exercise and vesting information used to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

Volatility: The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers, as the Company had limited trading history for the Company s common stock due to the recent IPO. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company s common stock becomes available.

Risk-Free Interest Rate: The risk-free rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

Dividend Yield: The expected dividend assumption was based on the Company s history and expectation of dividend payouts.

Forfeitures: Forfeitures were estimated based on historical experience.

Fair Value of Common Stock: The fair value of the shares of common stock underlying the stock options has historically been the responsibility of and determined by the Company s board of directors. Subsequent to the IPO in April 2014, the fair value of common stock is determined based on the closing price of the NASDAQ Global Market exchange.

Non-employee Stock-Based Compensation

During the three and nine months ended September 30, 2014, the Company granted options to purchase 29,000 and 199,550 shares of common stock to consultants, respectively. During the three and nine months ended September 30, 2013, the Company granted options to purchase zero and 15,000 shares of common stock to consultants. These options are granted in exchange for consulting services to be rendered and vest over the term of the consulting agreement.

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The Company has estimated fair value of common stock options granted to non-employees using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Expected volatility	85% - 96%	88% - 89%	72% - 98%	88%-92%
Risk-free interest rate	1.66% - 2.41%	1.70% - 2.72%	0.81% - 2.75%	1.02%-1.94%
Dividend yield	0%	0%	0%	0%
Contractual life (in years)	5.50 - 10.00	5.50 - 9.75	3.25 - 10.00	5.75- 10.00

Compensation expense related to non-employee options for the three and nine months ended September 30, 2014 was $0.8 million and $2.1 million, respectively. Compensation expense related to non-employee options for the three and nine months ended September 30, 2013 was $72,000 and $0.2 million, respectively.

Total stock-based compensation expense was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$ 642	$ 61	$ 1,737	$ 165
General and administrative	1,395	72	3,170	221
	$ 2,037	$ 133	$ 4,907	$ 386

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10. Net Income per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Historical net income (loss) per share	**2014**	**2013**	**2014**	**2013**
Numerator:				
Net income (loss)	$ (9,557)	$ (3,439)	$ 492	$ 19,977
Noncumulative dividend on preferred stock			(432)	(1,077)
Undistributed earnings allocated to preferred stock holders			(7)	(6,270)
Basic net income (loss) attributable to common stockholders	(9,557)	(3,439)	53	12,630
Adjustment to net income for dilutive securities			1	664
Diluted net income (loss) attributable to common stockholders	$ (9,557)	$ (3,439)	$ 54	$ 13,294
Denominator:				
Basic common shares outstanding:				
Basic common shares outstanding: weighted average common shares outstanding	16,801	9,514	14,009	9,510
Less: weighted average unvested common shares subject to repurchase	(14)	(4)	(11)	(4)
Weighted average number of common shares used in calculating net income (loss) per share basic	16,787	9,510	13,998	9,506
Dilutive securities:				
Common stock options			2,606	1,664
Warrants to purchase common stock			165	24
Warrants to purchase preferred stock				
Weighted average number of common shares used in calculating net income (loss) per share diluted	16,787	9,510	16,769	11,194
Net income (loss) per share to attributable to common stockholders				
Basic	$ (0.57)	$ (0.36)	$ 0.00	$ 1.33
Diluted	$ (0.57)	$ (0.36)	$ 0.00	$ 1.19

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Convertible preferred stock				4,719
Options to purchase common stock			198	
Warrants to purchase convertible preferred stock				213
Warrants to purchase common stock				623
Total			198	5,555

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with 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 risks 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 proven drugs to create novel therapeutics for use alone and in fixed-dose combination products. We are developing our lead wholly owned product candidate, ADS-5102, for a complication of Parkinson s disease known as levodopa induced dyskinesia, or LID, and are evaluating other potential CNS indications for which ADS-5102 may have applicability, including hyperkinetic and hypokinetic movement disorders. We successfully completed a Phase 2/3 clinical study in LID in 2013 and have initiated two Phase 3 registration trials and a separate open-label safety study in support of our LID indication in 2014.

The first of our two Phase 3 registration trials in support of our LID indication was initiated in June 2014. The study is planned to enroll approximately 130 subjects in a 26-week multi-center, randomized, double-blind, placebo-controlled trial and will assess the efficacy of a once daily 340 mg dose of ADS-5102 administered at bedtime for the treatment of LID in individuals with Parkinson s disease. The primary endpoint of this study is a reduction in LID as assessed by changes in the Unified Dyskinesia Rating Scale (UDysRS) along with supporting data from secondary endpoints. The second of our two Phase 3 registration trials in support of our LID indication was initiated in October 2014. The study is planned to enroll approximately 70 subjects in a 13-week multi-center, randomized, double-blind, placebo-controlled trial and will assess the efficacy of a once daily 340 mg dose of ADS-5102 administered at bedtime for the treatment of LID in individuals with Parkinson s disease. The primary endpoint of this study is a reduction in LID as assessed by changes in the Unified Dyskinesia Rating Scale (UDysRS) along with supporting data from secondary endpoints.

Our late-stage therapeutics portfolio also includes an NDA-submitted product candidate, MDX-8704, being co-developed with Forest Laboratories, Inc., a subsidiary of Actavis plc, referred to herein as Forest and Actavis, respectively, and an approved product, Namenda XR, which Forest developed and is marketing in the United States under a license from us.

Prior to November 2012, we were developing ADS-8704, a fixed-dose combination of controlled-release memantine and donepezil. Pursuant to our license agreement with Forest, we exclusively licensed to Forest certain U.S. intellectual property rights relating to controlled-release memantine and therapies including memantine. Forest has continued the ADS-8704 program under the name MDX-8704. Under our license agreement with Forest, we received a $65.0 million upfront payment in November 2012, two $20.0 million milestone payments in the fourth quarter of 2013 and a $25.0 million milestone payment in May 2014. We are eligible to receive up to an additional $30.0 million in payments based upon the first U.S. Food and Drug Administration, or FDA, approval of MDX-8704.

Financial operations overview

Summary

Our revenue to date has been generated primarily from license, milestone and development revenue pursuant to our license agreement with Forest. We have not generated any commercial product revenue. As of September 30, 2014, we had an accumulated deficit of $20.1 million. Although we reported net income for the nine months ended September 30, 2014 and in each of the years ending December 31, 2013 and 2012, this was primarily due to the recognition of revenue pursuant to our license agreement with Forest. 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. We cannot assure you that we will receive additional collaboration revenue in the future.

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In 2010, we suspended further activities on our influenza product candidate, ADS-8902, due to the expected length of the clinical trial and a change in our strategic focus. At the same time, we entered into an agreement with the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, or NIH, and its subcontractor under which we provided clinical trials supply, protocols, and operational support for further clinical development. We retained the rights to any clinical study data generated by the NIH with respect to clinical studies conducted by the NIH. We had supplied clinical operations support through a subcontract with the independent third-party subcontractor that was cancelled as of March 31, 2014.

We were 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, which has not yet commenced, is in non-core areas to the Company.

We expect our research and development expenses to increase as we continue to advance our product candidates through clinical development. In addition, if any of our product candidates receive regulatory approval for commercial sale in the United States, we expect to incur significant expenses associated with the establishment of a specialty sales force. 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 approximately $87.2 million through the sale of convertible preferred stock and $1.0 million through the exercise of preferred stock warrants. On April 15, 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. On May 6, 2014, we issued and sold 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 of approximately $91,000. In connection with the completion of our IPO, all convertible preferred stock converted into common stock.

Under our agreement with Forest we received a non-refundable upfront license fee of $65.0 million in 2012, $40.0 million in development milestone fees in 2013, and $25.0 million in milestone fees related to acceptance of Forest s New Drug Application, or NDA, submission by the FDA in May 2014, and we may receive up to an additional $30.0 million in future milestone fees upon FDA approval. Forest has stated that it projects FDA approval and commercial launch of MDX-8704 in the first half of 2015. Beginning in 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, five years after commercial launch, in the low double digits to the mid-teens for sales of MDX-8704 in the United States, if approved.

As of September 30, 2014, we had cash and cash equivalents of $137.5 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.

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The following table summarizes the sources of our revenue for the three and nine months ended September 30, 2014 and 2013 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Forest:				
Recognition of upfront license fee and milestones	$	$	$ 25,000	$ 29,611
Reimbursement of development expenses	215	74	390	1,055
Forest total	215	74	25,390	30,666
NIH grants		46	109	159
Government contracts		41	46	160
Total revenue	$ 215	$ 161	$ 25,545	$ 30,985

We recognized collaboration revenue of zero and $25.0 million for the three and nine months ended September 30, 2014, respectively, and zero and $29.6 million for the three and nine months ended September 30, 2013, respectively, pursuant to our license agreement with Forest. We also recognized revenue from Forest of approximately $0.2 million and $0.4 million in development funding for the three and nine months ended September 30, 2014, respectively, as well as $74,000 and $1.1 million for the three and nine months ended September 30, 2013, respectively. We expect that our revenue will continue to fluctuate in future periods.

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;

- other consulting fees paid to third parties; and

- employee-related expenses, which include salaries, benefits and stock-based compensation.

We anticipate our research and development expenses will increase as we continue our Phase 3 registration trials for ADS-5102, during 2014 and 2015.

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The following table summarizes our research and development expenses incurred during the three and nine months ended September 30, 2014 and 2013 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Product candidate				
ADS-5102	$ 4,695	$ 393	$ 9,529	$ 1,726
ADS-8704(1)	181	115	325	995
Unallocated research and development expenses(2)	536	879	3,489	2,316
Total research and development expenses	$ 5,412	$ 1,387	$ 13,343	$ 5,037

(1) ADS-8704 includes program costs that we incurred related to the fixed-dose combination drug that was licensed to Forest. Subsequent to the execution of the license agreement Forest assigned the name MDX-8704 to the program in the United States.

(2) Unallocated costs include research and development not allocated to a specific program. No employee-related expenses were allocated to ADS-5102 in 2013.

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. 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 expect our research and development expenses to increase in the future. 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, we have entered into collaborations with 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 costs, facilities costs, and other expenses for outside professional services, including legal, intellectual property, human resources, board of directors, audit, and accounting services. Personnel costs consist of salaries, benefits, and stock-based compensation. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of the NASDAQ Global Market on which our securities are traded, additional insurance expenses, investor relations activities, and other administration and professional services.

Interest and other income, net

Interest and other income, net consists primarily of interest received on our cash and cash equivalents and 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.

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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 nine months ended September 30, 2014, as compared to those disclosed in MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS - Critical accounting policies and significant judgments and estimates in our prospectus dated April 9, 2014, filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, or Securities Act.

Results of operations

Comparison of the three and nine months ended September 30, 2014 and 2013

The following table summarizes our results of operations for the three and nine months ended September 30, 2014 and 2013 (in thousands, except percentages):

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2014	2013			2014	2013		
Revenue	$ 215	$ 161	$ 54	34%	$ 25,545	$ 30,985	$ (5,440)	(18)%
Research and development	5,412	1,387	4,025	290%	13,343	5,037	8,306	165%
General and administrative	4,353	1,571	2,782	177%	10,724	4,054	6,670	165%
Other income (expense), net	(1)	(426)	(425)	(100)%	(801)	(1,414)	(613)	(43)%

Revenue

Revenue increased by $54,000, or 34%, to $0.2 million from $0.2 million for the three months ended September 30, 2014 and 2013, respectively. The slight increase in revenue for the three months ended September 30, 2014 was due to increased reimbursement of development expenses from Forest of $0.1 million, or 191%, to $0.2 million from $74,000 for the three months ended September 30, 2014 and 2013, respectively. This was partially offset by decreased revenue from NIH grants and government contracts of $87,000, or 100%, to zero from $87,000 for the three months ended September 30, 2014 and 2013, respectively.

Revenue decreased by $5.5 million, or 18%, to $25.5 million from $31.0 million for the nine months ended September 30, 2014 and 2013, respectively. The decrease in revenue for the nine months ended September 30, 2014 was primarily due to the timing of milestones being achieved under the license agreement with Forest. We recognized license and development milestone revenue of $25.0 million in the nine months ended September 30, 2014; whereas, we recognized license and development milestone revenue of $29.6 million in the nine months ended September 30, 2013. Reimbursement of development expenses decreased by $0.7 million, or 63%, to $0.4 million from $1.1 million for the nine months ended September 30, 2014 and 2013, respectively. NIH grant and government contract revenues decreased by $0.2 million, or 51%, to $0.1 million from $0.3 million for the nine months ended September 30, 2014 and 2013, respectively.

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Research and development expenses

Research and development expenses increased by $4.0 million, or 290%, to $5.4 million from $1.4 million for the three months ended September 30, 2014 and 2013, respectively. The increase in research and development expenses was due to a significant increase in program costs related to ADS-5102 of $4.3 million, or 1,095%, to $4.7 million from $0.4 million. Increased expenses related primarily to the continuation of our Phase 3 efficacy and safety studies. In addition, there was an increase in spending for ADS-8704 of $66,000, or 57%, to $0.2 million from $0.1 million for the three months ended September 30, 2014 and 2013, respectively, which we incurred as part of our licensing the U.S. rights to the program to Forest. These increases were partially offset by decreased expenses of $0.3 million that were not allocated to a specific program. Research and development expenses also included stock-based compensation expense of $0.6 million compared to $61,000 for the three months ended September 30, 2014 and 2013, respectively.

Research and development expenses increased by $8.3 million, or 165%, to $13.3 million from $5.0 million for the nine months ended September 30, 2014 and 2013, respectively. Increased research and development expenses related primarily to manufacturing, commencement, and continued enrollment of our Phase 3 efficacy and safety studies in support of ADS-5102, which increased $7.8 million, or 452%, to $9.5 million from $1.7 million for the nine months ended September 30, 2014 and 2013, respectively. There were also increased expenses that were not allocated to a specific program of $3.5 million in the current period. In addition there was a decrease of $0.7 million, or 67%, to $0.3 million from $1.0 million for the three months ended September 30, 2014 and 2013, respectively, for ADS-8704, which we incurred as part of our licensing the U.S. rights to the program to Forest. Research and development expenses also included stock-based compensation expense of $1.7 million compared to $0.2 million for the nine months ended September 30, 2014 and 2013, respectively.

General and administrative expenses

General and administrative expenses increased $2.8 million, or 177%, to $4.4 million from $1.6 million for the three months ended September 30, 2014 and 2013, respectively. The increase in general and administrative expenses was primarily due to the increase in headcount-related expenses, as well as professional services related to our IPO and being a public company totaling $1.3 million and $1.2 million, respectively. General and administrative expenses also included stock-based compensation expense of $1.4 million compared to $72,000 for the three months ended September 30, 2014 and 2013, respectively.

General and administrative expenses increased $6.7 million, or 165%, to $10.7 million for the nine months ended September 30, 2014 from $4.0 million for the nine months ended September 30, 2013. The increase in general and administrative expenses was primarily due to the increase in headcount related expenses and professional services relating to our IPO and being a public company totaling $3.2 million and $2.7 million, respectively. General and administrative expenses also included stock-based compensation expense of $3.2 million compared to $0.2 million for the nine months ended September 30, 2014 and 2013, respectively.

Other income (expense), net

Other income (expense), net decreased by $0.4 million, or 100%, to $1,000 from $0.4 million for the three months ended September 30, 2014 and 2013, respectively. Other income (expense), net decreased by $0.6 million, or 43%, to $0.8 million from $1.4 million for the nine months ended September 30, 2014 and 2013, respectively. These decreases were related to other income recorded as a result of the repayment of a note

receivable of $0.2 million in June 2014 that had been fully reserved and a decrease of $0.1 million in other general expenses. In addition, there were expenses related to the dissolution of our India subsidiary of $0.2 million in 2013 and an insignificant amount in 2014.

Liquidity, capital resources and plan of operation

We have funded our operations primarily through payments received pursuant to our license agreement with Forest, sales of convertible preferred stock and warrants, sales of our common stock in our IPO, bank debt, and the issuance of convertible debt. We have not generated any revenue from the sale of any products. We have incurred losses and generated negative cash flows from operations since inception through 2011 and for the three month periods ended March 31 and September 30, 2014. In 2012, 2013, and for the nine months ended September 30, 2014, we recognized a profit and positive cash flow as a result of payments received pursuant to our license agreement with Forest. Our principal sources of liquidity were our cash and cash equivalents, which totaled $137.5 million and $85.6 million at September 30, 2014 and December 31, 2013, respectively.

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As of September 30, 2014, we had raised an aggregate of approximately $87.2 million through the sale of convertible preferred stock and $1.0 million through the exercise of preferred stock warrants. On April 15, 2014, we completed our IPO of shares of our common stock pursuant to which we issued 3,000,000 shares of common stock and received net proceeds of approximately $41.5 million, after underwriting discounts, commissions, and offering expenses. On May 6, 2014, the Company issued and sold 81,371 shares of common stock pursuant to the underwriters partial exercise of their option to purchase additional shares, and received net proceeds of approximately $1.2 million, after deducting underwriting discounts and commissions of approximately $91,000. In connection with the completion of our IPO, all convertible preferred stock converted into common stock.

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

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

	Nine Months Ended September 30,	
	2014	**2013**
Net cash (used in) provided by:		
Operating activities	$ 7,240	$ (9,772)
Investing activities	(194)	(162)
Financing activities	44,868	(3,975)
Net increase (decrease) in cash and cash equivalents	$ 51,914	$ (13,909)

Net cash provided by operating activities was $7.2 million for the nine months ended September 30, 2014. This increase in cash and cash equivalents was the result of receiving a $25.0 million milestone payment from Forest in May 2014. Net cash used in operating activities was $9.8 million for the nine months ended September 30, 2013 and was primarily attributable to the development of ADS-8704 and ADS-5102.

Net cash used in investing activities amounted to $0.2 million and $0.2 million for the nine months ended September 30, 2014 and 2013, respectively, which consisted mainly of property and equipment purchases.

Net cash provided by financing activities amounted to $44.9 million for the nine months ended September 30, 2014, which consisted primarily of $43.2 million of net proceeds from the IPO after payment of offering costs. Net cash used in financing activities for the nine months ended September 30, 2013 was $4.0 million, all of which related to the repayment of convertible notes.

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.

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Contractual obligations

Our future contractual obligations at September 30, 2014 were as follows (in thousands):

	Payments due by period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Contractual obligations:					
Operating lease obligations	$ 486	$ 1,837	$ 983	$	$ 3,306
Total contractual obligations	$ 486	$ 1,837	$ 983	$	$ 3,306

Recent Accounting Pronouncements

See Note 2 of our Notes to Condensed Consolidated Financial Statements included in this report for recent accounting pronouncements, including the expected dates of adoption and estimated effects on our financial statements.

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, cash equivalents, and marketable securities in a variety of securities of high credit quality. As of September 30, 2014, we had cash and cash equivalents of $137.5 million consisting of cash and liquid investments deposited in highly rated financial institutions in the United States. 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 mature prior to our need for operating cash, we believe that our exposure to interest rate risk is not significant and 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 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 September 30, 2014. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2014, our disclosure controls and procedures were effective at the reasonable assurance level.

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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. 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.

In early November 2014, we, Forest, and Merz entered into a Settlement Agreement with Wockhardt Limited, one of the parties sued by us and Forest for infringement of our patents. Pursuant to this agreement, Worckhardt received a non-exclusive license to make and sell its generic versions of Namenda XR starting March 23, 2026, which is two months prior to the expiration of the last to expire of our relevant patents.

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 condensed consolidated financial statements and related notes. The risks relating to our business set forth in Item 1A of our Quarterly Reports on Form 10-Q for the quarter ended June 30, 2014, filed with the Securities and Exchange Commission on August 7, 2014 are set forth below and are unchanged substantively as of September 30, 2014, except for those risks designated by an asterisk (*).

Risks related to our financial condition and need for additional capital

Although we reported net income for 2012, 2013, and the three months ended March 31, 2014, we incurred significant losses in prior years and in two of the three most recent fiscal quarters ended September 30, 2014, 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 one approved product, Namenda XR, to a wholly owned subsidiary of Forest, and Forest markets Namenda XR in the United States, but we do not currently receive royalties on the sales of that product. 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 2012 2013, and the three months ended March 31, 2014, this was almost entirely due to the timing of milestone payments we received pursuant to our license agreement with Forest. We incurred significant operating losses in 2011 and prior years and in the two of the three most recent fiscal quarters ended September 30, 2014. We expect to incur substantial and increasing losses for the foreseeable future. As of September 30, 2014, we had an accumulated deficit of $20.1 million.

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Prior to our IPO, we had financed our operations primarily through our collaboration with Forest, private placements of our convertible preferred stock, 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:

- initiate and 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 and develop additional product candidates;

- seek regulatory approvals for our product candidates that successfully complete clinical studies;

- establish a specialty CNS sales force and improve our 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 and development 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. In the near term, our only anticipated source of significant revenue is from a final milestone payment under our license agreement with Forest, which will only be received if and when the FDA approves MDX-8704. 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 candidate, MDX-8704, until five years after its commercial launch in the United States, assuming it is approved and launched.

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 sustained 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. Our sole anticipated source of significant revenue in the near term is from a final milestone payment under our license agreement with Forest. Accordingly, our revenue will depend on the achievement of that milestone as well as any potential future collaboration and license agreements and sales of our product candidates, if approved. 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;

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- 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 revenue or 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 revenue 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 September 30, 2014, we had approximately $137.5 million in cash and cash equivalents. We believe that our available cash and cash equivalents 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 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;

- 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 marketing and distribution arrangements or other 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 public or private 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.

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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 U.S. approval and successful U.S. commercialization by Forest of MDX-8704, 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 MDX-8704 or 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-nightly controlled-release version of the FDA-approved drug amantadine, and MDX-8704, a fixed-dose combination of the FDA-approved drugs memantine and donepezil. MDX-8704 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 milestone, product and royalty revenue will depend heavily on the successful development, regulatory approval and eventual commercialization of ADS-5102 and MDX-8704 and successful commercialization of 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 MDX-8704 until five years after it is launched, assuming it is approved and launched. The success of these drugs will depend on numerous factors, including:

- successfully completing clinical studies for ADS-5102;
- receiving marketing approvals 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;
- 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 Namenda XR and, if approved, MDX 8704 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 to MDX-8704, if approved. 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 or, if approved, MDX-8704, our future royalty income could be materially adversely affected.

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If clinical studies of our 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.

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 result 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, may not be repeated in our Phase 3 registration trials.

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;

- 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;

- 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

- 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.

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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.

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.*

Forest has completed the clinical trials that it and we believe are necessary to support the submission to the FDA of a New Drug Application, or NDA, for MDX-8704 for the treatment of moderate to severe dementia in Alzheimer s disease patients. Forest submitted an NDA to the FDA for MDX-8704 in February 2014. We believe those trials indicated that a single dose of MDX-8704 is bioequivalent to separate doses of Namenda XR and donepezil and that MDX-8704 exhibits the same bioavailability whether administered after fasting, after a meal or when sprinkled on apple sauce. We initiated two Phase 3 registration trials and 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 Forest or us to conduct additional studies of MDX-8704 or ADS-5102 to support NDAs for approval for the product candidates in their currently contemplated indications, 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. These risks can 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 impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our product candidates and Namenda XR are complex to manufacture, and manufacturing disruptions may occur.

Our product candidates 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 Forest s fixed-dose combination product candidate MDX-8704. If any such issues were to arise with respect to our product candidates or future products, if any, or if Forest s sales of Namenda XR or the regulatory approval or Forest s sales of MDX-8704 were to be negatively impacted by such issues, our business, financial results or stock price could be adversely affected.

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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.

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 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 severalcompanies 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. 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. In early November 2014, we, Forest, and Merz entered into a Settlement Agreement with Wockhardt Limited, one of the parties sued by us and Forest for infringement of our patents. Pursuant to this agreement, Worckhardt received a non-exclusive license to make and sell its generic versions of Namenda XR starting March 23, 2026, which is two months prior to the expiration of the last to expire of our relevant patents.

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 MDX-8704 and ADS-5102, if they are 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.

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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 MDX-8704, generally are not well-reimbursed. As a result, we anticipate that the commercial success of Namenda XR, ADS-5102, and MDX-8704 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 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 successfully commercialize any product candidate that we successfully develop and Forest may be unable to successfully market Namenda XR or MDX-8704.

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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.

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 proposed 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 harmed.

Safety issues with Namenda XR, MDX-8704, or ADS-5102, or the parent drugs or other components of Namenda XR, MDX-8704, or ADS-5102, or with approved products of third parties that are similar to Namenda XR, MDX-8704, or ADS-5102, could decrease the potential sales of Namenda XR, MDX-8704 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 label for Namenda XR lists potential side effects, such as headache, diarrhea, and dizziness. Side effects have been observed in clinical trial subjects taking MDX-8704 and ADS-5102, such as constipation, dizziness, hallucination, dry mouth, fall, confusion, headache, nausea, and weakness in the case of ADS-5102 and dizziness, headache, and diarrhea in the case of MDX-8704.

If we or others identify additional undesirable side effects caused by Namenda XR, or by MDX-8704 and ADS-5102 after approval:

- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications, or field alerts to physicians and pharmacies;

- regulatory authorities may withdraw their approval of the product and require us to take our approved drug off the market;

- we may be required to change the way the product is administered, conduct additional clinical trials, change the labeling of the product, or implement a Risk Evaluation and Mitigation Strategy;

- we may have limitations on how we promote our drugs;

- third-party payors may limit coverage or reimbursement for our drugs;

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- sales of products may decrease significantly;

- we may be subject to litigation or product liability claims; and

- our reputation may suffer.

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

Namenda XR, MDX-8704 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 MDX-8704, donepezil, which is a component MDX-8704, 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 of, or in patients 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, MDX-8704 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, MDX-8704, 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, MDX-8704, 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 and MDX-8704, if approved, will be limited to use in the treatment of specific indications, and if we or Forest want to expand the indications for which these product candidates may be marketed, additional regulatory approvals will need to be obtained, which may not be granted.

We are currently seeking regulatory approval of ADS-5102 for the treatment of LID, and Forest is seeking regulatory approval of MDX-8704 for the treatment of moderate to severe dementia related to Alzheimer s disease. If these product candidates are approved, the FDA will restrict our and Forest s ability to market or advertise the products for other indications, which could limit physician and patient adoption. We or Forest may attempt to develop, promote and commercialize new treatment indications and protocols for the products 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.

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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 and MDX-8704, if approved. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product s approved labeling. For example, if we receive marketing approval for ADS-5102 for the treatment of LID, the first indication we are pursuing, we cannot prevent physicians from using our ADS-5102 products on their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses prior to FDA approval for an additional indication, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management s attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

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

We 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 MDX-8704 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.

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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;
- 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 enrollment of patients in any of our clinical trials could increase our development costs and delay completion of the study.

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. 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, 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. 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.

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 MDX-8704 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 Pharmaceutcials, Inc.), Apokyn (Mylan Laboratories, Inc.), Bromocriptine (Mylan Laboratories, Inc.), Zelapar (Valeant Pharmaceuticals International), Eldepryl (Somerset Pharmaceuticals Inc.), Tasmar (Valeant Pharmaceuticals International), Cogentin (Oaks Pharma Akorn), Exelon (Novartis Pharmaceuticals Corp.), and Stalevo (Novartis Pharmaceuticals Corp.). ADS-5102 may also face competition from drugs currently in development for Parkinson s or LID, such as safinamide (Newron Pharmaceuticals S.p.A.), AVP-923 (Avanir Pharmaceuticals, Inc.), eltoprazine (Amarantus BioScience Holdings, Inc.), DM-1992 (Depomed Inc.), IPX-066 (Impax Laboratories, Inc.), ABT-SLV187 (AbbVie Inc.), AVE8112 (Sanofi), MK0657 (Cerecor, Inc.), AAV-hAADC-2 (Sanofi), OS-320 (Osmotica Pharmaceuticals, Corp), AFFITOPE PD01A (Affiris

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AG), PRX002 (Prothena Biosciences), BIA 9 1067 (Bial Portela), SYN115 (Biotie Therapies Corp.), and PF-06669571 (Pfizer Inc.). 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 of these companies has posted a notice on clinicaltrials.gov regarding plans to conduct 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 an amount 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.

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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 MDX-8704 and Namenda XR, and may enter into additional license or collaboration agreements. These arrangements may place the development of these product candidates 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 may not reach their full market potential.

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 MDX-8704, 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. 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;

- 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;

- collaborators may not aggressively or adequately pursue litigation against ANDA filers or may settle such litigation on unfavorable terms;

- 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;

- 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.

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On July 1, 2014, Actavis and Forest announced the completion of the previously announced acquisition of Forest by Actavis. We cannot predict whether this acquisition will have an impact on our business or on the license agreement with Forest.

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.

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 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.

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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. 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 for alternative suppliers, 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.

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 September 30, 2014, we had 34 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 companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the

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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.

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

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- difficulties in assuring compliance with foreign corrupt practices laws;

- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

- workforce uncertainty in countries where labor unrest is more common than in the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods, and fires.

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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

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.

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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 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.

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

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.

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

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

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

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we or our licensees may be required to file infringement claims, which can be expensive and time-consuming. For example, 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.

In early November 2014, we, Forest, and Merz entered into a Settlement Agreement with Wockhardt Limited, one of the parties sued by us and Forest for infringement of our patents. Pursuant to this agreement, Worckhardt received a non-exclusive license to make and sell its generic versions of Namenda XR starting March 23, 2026, which is two months prior to the expiration of the last to expire of our relevant patents.

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.

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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

approval of an NDA. We have not submitted an application or received marketing approval

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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;
- 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. 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.

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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, and Forest is developing MDX-8704, 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 or Forest 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 MDX-8704, 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

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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;
- 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.

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.

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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;

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- 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 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.

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;

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- introductions and announcements of new products and product candidates by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;

- actions taken by regulatory agencies with respect to our or our competitors products, product candidates, clinical studies, manufacturing process, or sales and marketing terms;

- variations in our financial results or those of companies that are perceived to be comparable to us;

- the success of our efforts to acquire or in-license additional products or product candidates;

- developments concerning our collaborations, including but not limited to those with our sources of manufacturing and our commercialization partners;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;

- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our current or future products;

- our ability or inability to raise additional capital and the terms on which we raise it;

- the recruitment or departure of key personnel;

- changes in the structure of healthcare reimbursement systems;

- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our current or future products;

- market conditions in the pharmaceutical and biotechnology sectors;

- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

- trading volume of our common stock;

- sales of our common stock by us or our stockholders;

- general economic, industry, and market conditions; and

- the other risks described in this Risk Factors section.

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

A significant portion of our total outstanding shares currently are restricted from resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.*

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could result in a decrease in the market price of our common stock. As of October 30, 2014, we had outstanding 17,125,780 shares of common stock. 7,509,812 of these shares are currently restricted securities as such term is defined in Rule 144 under the Securities Act. Moreover, certain holders of an aggregate of 9,936,991 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also have registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock up agreements described above.

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Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to stockholders for approval.

As of October 30, 2014, our executive officers, directors and stockholders who own more than 5% of our outstanding common stock beneficially owned approximately 65.6% of our common stock. These stockholders, acting together, are 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. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, will control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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 will 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 our 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.

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

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

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

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

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

- our board of directors has the right to 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.

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

Recent Sales of Unregistered Equity Securities

From January 1, 2014 through April 9, 2014, we granted to employees options to purchase an aggregate of 1,865,000 shares of common stock under our 2007 Stock Plan, as amended (the 2007 Plan), at an exercise price ranging from $9.00 to $11.23 per share for an aggregate exercise price of approximately $17.7 million.

From January 1, 2014 through April 9, 2014, we issued and sold to employees, consultants and other service providers an aggregate of 71,366 shares of common stock upon the exercise of options under the 2002 and 2007 Plan at exercise prices ranging from $0.53 to $11.23 per share, for an aggregate exercise price of approximately $0.2 million.

From January 1, 2014 through September 30, 2014, we issued 587,148 shares of our common stock upon the cash exercise of warrants to purchase our common stock. We received proceeds of $2.0 million representing the aggregate exercise price of such warrants.

From January 1, 2014 through September 30, 2014, we issued 183,023 shares of our common stock upon the net exercise of warrants to purchase our common stock. We did not receive proceeds from the exercises of these warrants.

The issuance of such common stock underlying the warrants was exempt from the registration requirements of the Securities Act pursuant to Section 4(a)(2) of the Securities Act.

The offers, sales and issuances of the securities described in this Item 2 were deemed to be exempt from registration under the Securities Act under Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

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. Credit Suisse and Piper Jaffray acted as joint book-running managers for the IPO. William Blair and Needham & Company acted as co-managers. The offering

commenced on April 9, 2014 and did not terminate until the sale of all of the shares offered.

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.

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.

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SIGNATURES

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

	Adamas Pharmaceuticals, Inc. (Registrant)
Date: November 4, 2014	/s/ Gregory Went, Ph.D. Gregory Went, Ph.D. Chief Executive Officer (Principal Executive Officer)
Date: November 4, 2014	/s/ William J. Dawson William J. Dawson Chief Financial Officer (Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Adamas Pharmaceuticals, Inc.	8-K	001-36399	3.1	4/15/2014
3.2	Amended and Restated Bylaws of Adamas Pharmaceuticals, Inc.	8-K	001-36399	3.2	4/15/2014
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate of Adamas Pharmaceuticals, Inc.	S-1	333-194342	4.1	3/26/2014
4.3	Fourth Amended and Restated Investor Rights Agreement, dated as of September 30, 2011, by and among the registrant and certain of its stockholders.	S-1	333-194342	10.5	3/5/2014
10.8	Offer Letter by and between Adamas Pharmaceuticals, Inc. and William J. Dawson, dated as of August 12, 2014.	8-K	001-36399	10.8	8/13/2014
10.9	Separation Agreement by and between Adamas Pharmaceuticals, Inc. and Anthony Rimac, dated as of August 12, 2014.	8-K	001-36399	10.9	8/13/2014
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(2)				
101.SCH	XBRL Taxonomy Extension Schema Document(2)				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document(2)				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document(2)				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document(2)				
101.PRE					

XBRL Taxonomy Extension Presentation Linkbase
Document (2)

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(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.

(2) Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements.