

Adamas Pharmaceuticals Inc  
Form 10-Q  
August 07, 2014  
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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM 10-Q**

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

**For the quarterly period ended June 30, 2014**

**or**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File No. 001-36399**

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**ADAMAS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

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

**2200 Powell Street, Suite 220**  
**Emeryville, CA**  
(Address of Principal Executive Offices)

**94608**  
(Zip Code)

**(510) 450-3500**

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of August 1, 2014 was 16,758,499

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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.

Table of Contents**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)

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 144,607	\$ 85,612
Accounts receivable	218	129
Prepaid expenses and other current assets	956	267
Total current assets	145,781	86,008
Property and equipment, net	336	199
Other assets	70	9
Total assets	\$ 146,187	\$ 86,216
<b>Liabilities, convertible preferred stock and stockholders equity</b>		
Current liabilities		
Accounts payable	\$ 3,284	\$ 2,097
Accrued liabilities	2,556	2,119
Other current liabilities	151	2
Total current liabilities	5,991	4,218
Warrant liability	-	6,232
Non-current liabilities	8	12
Total liabilities	5,999	10,462
Commitments and Contingencies (Note 6)		
Convertible preferred stock, \$0.001 par value - 5,000,000 shares and 6,700,000 authorized at June 30, 2014 and December 31, 2013, and zero and 4,719,174 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively; zero and \$77,433 liquidation preference at June 30, 2014 and December 31, 2013, respectively		
	-	19,149
Stockholders equity		
	21	14

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Common stock, \$0.001 par value - 100,000,000 shares authorized,  
16,758,499 and 9,515,528 shares issued and outstanding at  
June 30, 2014 and December 31, 2013, respectively

Additional paid-in capital	150,690	77,163
Accumulated deficit	(10,523)	(20,572)
Total stockholders' equity	140,188	56,605
<b>Total liabilities, convertible preferred stock and stockholders equity</b>	<b>\$ 146,187</b>	<b>\$ 86,216</b>

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

Table of Contents**Adamas Pharmaceuticals, Inc.****Unaudited Condensed Consolidated Statements of Operations and Comprehensive Income**

(in thousands, except per share data)

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
<b>Revenue</b>	\$ 25,154	\$ 241	\$ 25,330	\$ 30,824
<b>Operating expenses</b>				
Research and development	5,173	1,572	7,931	3,650
General and administrative	3,262	1,363	6,371	2,483
Total operating expenses	8,435	2,935	14,302	6,133
Income (loss) from operations	16,719	(2,694)	11,028	24,691
Other income (expense), net	(112)	(567)	(800)	(988)
Income (loss) before income taxes	16,607	(3,261)	10,228	23,703
Income tax expense	(178)	(92)	(179)	(287)
Net income (loss)	\$ 16,429	\$ (3,353)	\$ 10,049	\$ 23,416
Net income (loss) attributable to common stockholders				
Basic	\$ 16,429	\$ (3,353)	\$ 7,894	\$ 15,167
Diluted	\$ 16,429	\$ (3,353)	\$ 8,162	\$ 15,928
Net income (loss) per share attributable to common stockholders				
Basic	\$ 1.05	\$ (0.35)	\$ 0.63	\$ 1.60
Diluted	\$ 0.88	\$ (0.35)	\$ 0.53	\$ 1.43
Weighted average number of shares used in computing net income (loss) attributable to common stockholders				
Basic	15,604	9,506	12,581	9,504
Diluted	18,590	9,506	15,404	11,104

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)

	Six Months Ended June 30,	
	2014	2013
<b>Cash flows from operating activities</b>		
Net income	\$ 10,049	\$ 23,416
Adjustments to reconcile net income to net cash used in operating activities		
Depreciation and amortization	57	26
Stock-based compensation	2,870	254
Change in preferred stock warrant value	983	643
Gain on fixed asset disposal	-	(32)
Changes in assets and liabilities		
Prepaid expenses and other assets	(750)	97
Accounts receivable	(89)	631
Accounts payable	611	176
Accrued liabilities and other liabilities	437	(166)
Deferred revenue	-	(29,611)
Net cash provided by (used in) operating activities	14,168	(4,566)
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(194)	(150)
Net cash used in investing activities	(194)	(150)
<b>Cash flows from financing activities</b>		
Proceeds from public offering of common stock, net of underwriters discount	45,850	-
Payment of public offering costs	(2,636)	-
Proceeds from issuance of common stock upon exercise of stock options	250	7
Proceeds from issuance of common and preferred stock upon exercise of warrants	1,557	-
Principal payments on convertible promissory notes	-	(2,280)
Net cash provided by (used in) financing activities	45,021	(2,273)
Net increase (decrease) in cash and cash equivalents	58,995	(6,989)
Cash and cash equivalents at beginning of period	85,612	62,957
Cash and cash equivalents at end of period	\$ 144,607	\$ 55,968
<b>Supplemental disclosure of noncash items</b>		
Accrued deferred offering costs	576	-



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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 indications. The Company has successfully completed a Phase 2/3 clinical study in LID, has initiated a Phase 3 registration trial in May 2014 and plans to initiate an additional Phase 3 registration trial 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., a subsidiary of Actavis plc, ( Forest ), 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**

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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 six months ended June 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.

### **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.

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**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.

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.

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**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 were converted upon close of the IPO in April 2014.

**Convertible Preferred Stock Warrants**

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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 that time, 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, which is zero as of June 30, 2014, was carried at fair value.

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**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.

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. The Company's basic net income (loss) per share attributable to common stockholders is calculated by dividing the net



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income (loss) by the weighted average number of shares of common stock outstanding for the period. The diluted net income (loss) per share attributable to common stockholders is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. For purposes of this calculation, options to purchase common stock and common stock warrants are considered common stock equivalents.

### 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.

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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 June 30, 2014			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market fund	\$ 141,695	\$ 141,695	\$ -	\$ -

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

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
<b>Balance at December 31, 2012</b>	\$ 1,706
Change in fair value recorded in Other (income)/expense, net	4,526
<b>Balance at December 31, 2013</b>	6,232
Change in fair value recorded in Other (income)/expense, net	983
Exercise of warrants	(7,215)
<b>Balance at June, 2014</b>	\$ -

#### 4. Collaboration and License Agreements

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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

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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 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 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).

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. As of June 30, 2014 and December 31, 2013, warrants to purchase 85,328 and 88,884 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 such third-party 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 June 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%, 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 June 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%, 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 June 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%, expected term of 3 years and 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, in connection with the IPO, the remaining warrants were exercised for 29,564 of Series AA preferred stock. As of June 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%, 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, in connection with our IPO, the remaining warrants were exercised for 251,750 shares of Series AA preferred stock. As of June 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 are 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.

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- 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 AA Preferred 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 AA Preferred.
- 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.

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

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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 June 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:

	<b>Number of shares outstanding</b>	
	<b>June 30, 2014</b>	<b>December 31, 2013</b>
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	178,276	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 June 30, 2014, future minimum lease payments under a non-cancelable facility operating lease were as follows (in thousands):

	<b>June 30, 2014</b>
Remainder of 2014	\$ 155
2015	\$ 551
2016	\$ 600



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2017	\$	618
2018 and thereafter		1,404
Total	\$	3,328

### Contingencies

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

### Indemnification

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

Table of Contents**Litigation**

The Company is not a party to any material litigation and does not have contingent reserves established for any litigation liabilities.

**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 June 30, 2014.

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

Series	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

**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 June 30, 2014 and December 31, 2013, 13,400 and zero shares of common stock, respectively, from early exercised options were unvested.

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*Shares reserved for Future Issuance*

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

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
Conversion of convertible preferred stock	-	3,432,908
Common stock options outstanding	5,162,378	3,567,858
Common stock options available for grant	2,205,626	1,771,212
Warrants to purchase common stock	178,276	213,290
Warrants to purchase convertible preferred stock	-	622,660
<b>Total</b>	<b>7,546,280</b>	<b>9,607,928</b>

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**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.

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.

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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 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.

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

	<b>Outstanding Options</b>			
	<b>Shares Available for Grant</b>	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Aggregate Intrinsic Value (thousands)</b>
<b>Balances, December 31, 2013</b>	1,771,212	3,567,858	\$ 1.45	\$ 26,932
Additional shares reserved	2,161,944	-		
Options granted	(1,920,550)	1,920,550	9.71	
Options exercised	-	(129,698)	1.92	
Options cancelled	193,020	(196,332)	2.88	
<b>Balances, June 30, 2014</b>	2,205,626	5,162,378	\$ 4.46	\$ 71,369

The aggregate intrinsic value of options exercised was \$1.6 million and \$25,000 for the six months ended June 30, 2014 and 2013, respectively.

**Stock-Based Compensation**

During the three and six months ended June 30, 2014, the Company granted stock options to employees to purchase 43,000 and 1,750,000 shares of common stock, respectively, with a weighted-average grant date fair value of \$14.18 and \$10.15 per share, respectively. During the three and six months ended June 30, 2013, the Company granted stock options to employees to purchase 73,000 shares of common stock, respectively, with a weighted-average grant date fair value of \$2.72 per share. As of June 30, 2014, there was total unrecognized compensation cost of \$17.1 million. This cost is expected to be recognized over a period of 4.34 years. The total fair value of employee stock options vested for the three and six months ended June 30, 2014 was \$186,000 and \$247,000, respectively. The total fair value of employee stock options vested for the three and six months ended June 30, 2013 was \$68,000 and \$178,000, respectively.

Stock-based compensation expense related to employee options for the three and six months ended June 30, 2014 was \$1.0 million and \$1.6 million, respectively. Stock-based compensation expense related to employee options for the three and six months ended June 30, 2013 was \$59,000 and \$116,000, 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:

	<b>Three Months Ended June 30, 2014</b>	<b>Six Months Ended June 30, 2014</b>
Expected volatility	90% - 92%	90% - 96%
Risk-free interest rate	2.06% - 2.13%	2.06% - 2.20%
Dividend yield	-	-
Expected term (in years)	7.00	7.00

*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.

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*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 six months ended June 30, 2014, the Company granted options to purchase 12,550 and 170,550 shares of common stock to consultants, respectively. During the three and six months ended June 30, 2013, the Company granted options to purchase 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.

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:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Expected volatility	94% - 96%	89% - 92%	72% - 98%	88% - 92%
	1.74% -	1.02% -	0.81% -	1.02% -
Risk-free interest rate	2.50%	1.94%	2.75%	1.94%
Dividend yield	-	-	-	-
Expected term (in years)	5.75 - 10.00	5.75 - 10.00	3.25 - 10.00	5.75 - 10.00



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Compensation expense related to non-employee options for the three and six months ended June 30, 2014 was \$801,000 and \$1.3 million, respectively. Compensation expense related to non-employee options for the three and six months ended June 30, 2013 was \$75,000 and \$138,000, respectively.

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Research and development	\$ 670	\$ 55	\$ 1,095	\$ 104
General and administrative	1,153	79	1,775	150
	\$ 1,823	\$ 134	\$ 2,870	\$ 254

Table of Contents**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):

Historical net income (loss) per share	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
<b>Numerator:</b>				
Net income (loss)	\$ 16,429	\$ (3,353)	\$ 10,049	\$ 23,416
Noncumulative dividend on preferred stock	-	-	(432)	(718)
Undistributed earnings allocated to preferred stock holders	-	-	(1,723)	(7,531)
Basic net income (loss) attributable to common stockholders	16,429	(3,353)	7,894	15,167
Adjustment to net income for dilutive securities	-	-	268	761
Diluted net income (loss) attributable to common stockholders	\$ 16,429	\$ (3,353)	\$ 8,162	\$ 15,928
<b>Denominator:</b>				
<b>Basic common shares outstanding:</b>				
Basic common shares outstanding: weighted average common shares outstanding	15,619	9,506	12,590	9,506
Less: weighted average unvested common shares subject to repurchase	(15)	-	(9)	(2)
Weighted average number of common shares used in calculating net income (loss) per share basic	15,604	9,506	12,581	9,504
<b>Dilutive securities:</b>				
Common stock options	2,772	-	2,644	1,600
Warrants to purchase common stock	214	-	179	-
Warrants to purchase preferred stock	-	-	-	-
Weighted average number of common shares used in calculating net income (loss) per share diluted	18,590	9,506	15,404	11,104
<b>Net income (loss) per share to attributable to common stockholders</b>				
Basic	\$ 1.05	\$ (0.35)	\$ 0.63	\$ 1.60
Diluted	\$ 0.88	\$ (0.35)	\$ 0.53	\$ 1.43

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  
June 30,

Six Months Ended  
June 30,

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	2014	2013	2014	2013
Convertible preferred stock	-	-	-	4,719
Options to purchase common stock	55	-	55	-
Warrants to purchase convertible preferred stock	-	-	-	213
Warrants to purchase common stock	-	-	-	623
Total	55	-	55	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 is evaluating other potential indications. We have successfully completed a Phase 2/3 clinical study in LID, have initiated a Phase 3 registration trial in LID in May 2014 and plan to initiate an additional Phase 3 registration trial in support of our LID indication. 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 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 June 30, 2014, we had an accumulated deficit of \$10.5 million. Although we reported net income for the three and six months ended June 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 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, we expect to incur significant expenses associated with the establishment of a specialty sales force in the United

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States. Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of expenses incurred or when, or if, we will be able to achieve sustained profitability.

Prior to our initial public offering of our common stock, or IPO in April 2014, we had raised an aggregate of 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, the Company 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 June 30, 2014, we had cash and cash equivalents of \$144.6 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Forest:				
Recognition of upfront license fee and milestones	\$ 25,000	\$ -	\$ 25,000	\$ 29,611
Reimbursement of development expenses	73	153	175	981
Forest total	25,073	153	25,175	30,592

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NIH grants	81	36	109	113
Government contracts	-	52	46	119
<b>Total revenue</b>	\$ 25,154	\$ 241	\$ 25,330	\$ 30,824

We recognized collaboration revenue of \$25.0 million for both of the three and six months ended June 30, 2014 and zero and \$29.6 million for the three and six months ended June 30, 2013, respectively, pursuant to our license agreement with Forest. We also recognized revenue from Forest of approximately \$73,000 and \$0.2 million in development funding for the three and six months ended June 30, 2014, respectively, as well as \$0.2 million and \$1.0 million for the three and six months ended June 30, 2013, respectively. We expect that our revenue will continue to fluctuate in future periods.

Table of Contents**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.

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

	Three Months Ended		Six Months Ended	
	2014	June 30, 2013	2014	June 30, 2013
<b>Product candidate</b>				
ADS-5102	\$ 3,715	\$ 669	\$ 5,444	\$ 1,334
ADS-8704(1)	61	123	148	918
Unallocated research and development expenses(2)	1,397	780	2,339	1,398



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<b>Total research and development expenses</b>	\$	5,173	\$	1,572	\$	7,931	\$	3,650
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(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

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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.

**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 six months ended June 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.



Table of Contents**Results of operations***Comparison of the three and six months ended June 30, 2014 and 2013*

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

	Three Months Ended				Six Months Ended			
	June 30,		Increase/	Increase/	June 30,		Increase/	Increase/
	2014	2013	(Decrease)	(Decrease)	2014	2013	(Decrease)	(Decrease)
Revenue	\$ 25,154	\$ 241	\$ 24,913	10337%	\$ 25,330	\$ 30,824	\$ (5,494)	(18)%
Research and development	5,173	1,572	3,601	229%	7,931	3,650	4,281	117%
General and administrative	3,262	1,363	1,899	139%	6,371	2,483	3,888	157%
Other income (expense), net	(112)	(567)	(455)	(80)%	(800)	(988)	(188)	(19)%

**Revenue**

Revenue increased by \$24.9 million, or 10,337%, to \$25.2 million from \$0.3 million for the three months ended June 30, 2014 and 2013, respectively. Revenue decreased by \$5.5 million, or 18%, to \$25.3 million from \$30.8 million for the six months ended June 30, 2014 and 2013, respectively. Both the increase in revenue for the three months ended June 30, 2014 and the decrease in revenue for the six months ended June 30, 2014 were due to the upfront license payment, milestone payments and development funding recognized with respect to our license agreement with Forest, NIH grants and government contracts. We recognized upfront license and development milestone revenue of \$25.0 million in the three and six months ended June 30, 2014, respectively; whereas, we recognized upfront license and development milestone revenue of zero and \$29.6 million in the three and six months ended June 30, 2013, respectively. Reimbursement of development expenses decreased by \$80,000, or 52%, to \$73,000 from \$0.2 million for the three months ended June 30, 2014 and 2013, respectively. Reimbursement of development expenses decreased by \$0.8 million, or 82%, to \$0.2 million from \$1.0 million for the six months ended June 30, 2014 and 2013, respectively. NIH grant and government contract revenues decreased by \$7,000, or 8%, to \$81,000 from \$88,000 for the three months ended June 30, 2014 and 2013, respectively. NIH grant and government contract revenues decreased by \$77,000, or 33%, to \$0.2 million from \$0.2 million for the six months ended June 30, 2014 and 2013, respectively.

**Research and development expenses**

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Research and development expenses increased by \$3.6 million, or 229%, to \$5.2 million from \$1.6 million for the three months ended June 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 \$3.0 million, or 455%, to \$3.7 million from \$0.7 million for the three months ended June 30, 2014 and 2013, respectively. Increased expenses related to the commencement of our Phase 3 efficacy and safety studies and additional Phase 1 studies. There were also increased expenses of \$0.6 million that were not allocated to a specific program. In addition there was a decrease of \$62,000, or 50%, to \$61,000 from \$0.1 million for the three months ended June 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 increased by \$4.3 million, or 117%, to \$7.9 million from \$3.7 million for the six months ended June 30, 2014 and 2013, respectively. The increase in research and development expenses was due to a \$4.1 million, or 308% increase in program costs related to ADS-5102, to \$5.4 million from \$1.3 million for the six months ended June 30, 2014 and 2013, respectively. Increased expenses related to manufacturing, commencement of our Phase 3 efficacy and safety studies and additional Phase 1 studies. There were also increased expenses that were not allocated to a specific program of \$1.0 million. In addition there was a decrease of \$0.8 million, or 84%, to \$1.0 million from \$0.9 million for the three months ended June 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.

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***General and administrative expenses***

General and administrative expenses increased \$1.9 million, or 139%, to \$3.3 million for the three months ended June 30, 2014 from \$1.4 million for the three months ended June 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 \$1.0 million and \$1.0 million, respectively. Included in the headcount and professional services related costs during the three months ended June 30, 2014 was an increase in stock-based compensation expenses of approximately \$1.1 million resulting from the increased fair value of new stock options leading up to and after going public during the three months ended June 30, 2014. These increases were partially offset by decreases in other general expenses of \$88,000.

General and administrative expenses increased \$3.9 million, or 157%, to \$6.4 million for the six months ended June 30, 2014 from \$2.5 million for the six months ended June 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 \$1.8 million and \$1.9 million, respectively. Included in the headcount and professional services related costs during the six months ended June 30, 2014 was an increase in stock-based compensation expenses of approximately \$1.6 million resulting from the increased fair value of new stock options leading up to and after going public during the six months ended June 30, 2014. There were also increases in other general expenses of \$0.2 million.

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

Other income (expense), net decreased by \$0.5 million, or 80%, to \$0.1 million from \$0.6 million for the three months ended June 30, 2014 and 2013, respectively. Other income (expense), net decreased by \$0.2 million, or 19%, to \$0.8 million from \$1.0 million for the six months ended June 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 dissolution related expenses related to 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 sales of our common stock in our IPO, sales of convertible preferred stock and warrants, bank debt, the issuance of convertible debt and payments received pursuant to our license agreement with Forest. 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 months ended March 31, 2014. In 2012, 2013 and for the six months ended June 30, 2014, we recognized a profit and positive cash flow as a result of our license agreement with Forest. As of June 30, 2014 and December 31, 2013, our principal sources of liquidity were our cash and cash equivalents, which totaled \$144.6 million and \$85.6 million, respectively.

As of June 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, for net proceeds of approximately \$1.2 million, after deducting underwriting discounts and

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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 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,

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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):

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2014</b>	<b>2013</b>
Net cash (used in) provided by:		
Operating activities	\$ 14,168	\$ (4,566)
Investing activities	(194)	(150)
Financing activities	45,021	(2,273)
Net increase (decrease) in cash and cash equivalents	\$ 58,995	\$ (6,989)

Net cash provided by operating activities was \$14.2 million for the six months ended June 30, 2014. This significant increase in cash and cash equivalents was the result of receiving a \$25.0 million milestone payment from Forest in May 2014. The primary use of cash was to fund the Phase 3 clinical studies activities related to ADS-5102. Net cash used in operating activities was \$4.6 million for the six months ended June 30, 2013 and was primarily attributable to the Phase 2/3 EASED clinical study activities related to ADS-5102.

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

Net cash provided by financing activities amounted to \$45.0 million for the six months ended June 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 six months ended June 30, 2013 was \$2.3 million, which was all related to the payment 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.

**Contractual obligations**



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

	Payments due by period				Total
	Less than 1	1 to 3	3 to 5	More than 5	
	year	years	years	years	
<b>Contractual obligations:</b>					
Operating lease obligations	\$ 412	\$ 1,828	\$ 1,088	\$ -	\$ 3,328
Total contractual obligations	\$ 412	\$ 1,828	\$ 1,088	\$ -	\$ 3,328

#### 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 and cash equivalents in a variety of securities of high credit quality. As of June 30, 2014, we had cash

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and cash equivalents of \$144.6 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, 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 June 30, 2014. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2014, our disclosure controls and procedures were effective at the reasonable assurance level.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

As of August 6, 2014, we had received notice that thirteen companies had 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 or will not be infringed by the companies' manufacture, use or sale of generic versions of

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Namenda XR. In January, February and April 2014, we, Forest, Forest Laboratories Holdings Ltd., Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH filed lawsuits in the U.S. District Court for the District of Delaware for infringement of the relevant patents against twelve of these companies that had then submitted ANDAs. We are seeking judgment that (i) the defendants have infringed the patents at issue, (ii) that 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) that 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) that we, Forest, Forest Laboratories Holdings Ltd., Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH be awarded monetary relief, in addition to any attorney's fees, costs and expenses relating to the actions. 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 begin to expire in June 2016.

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**Item 1A. Risk Factors**

*We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes. The risks relating to our business set forth in Item 1A of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, filed with the Securities and Exchange Commission on May 13, 2014 are set forth below and are unchanged substantively as of June 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 and six months ended June 30, 2014, we incurred significant losses in prior years and expect to incur substantial losses in the future.\**

We are a clinical-stage specialty pharmaceutical company and do not currently directly market any products. We currently exclusively license U.S. patent rights for one approved product, Namenda XR, to a wholly owned subsidiary of Forest Laboratories, Inc., or 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 and six months ended June 30, 2014, this was almost entirely due to milestone payments we received pursuant to our license agreement with Forest. We incurred significant operating losses in 2011 and prior years and expect to incur substantial and increasing losses for the foreseeable future. As of June 30, 2014, we had an accumulated deficit of \$10.5 million.

Prior to our IPO, we had financed our operations primarily through private placements of our convertible preferred stock, our collaboration with Forest and, to a lesser extent, government grants, venture debt and with the benefit of 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 Phase 3 registration trials of our lead wholly owned product candidate, ADS-5102 in levodopa induced dyskinesia, or LID;
- develop 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;

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- 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 commercialization efforts;
- 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, completing clinical studies of product candidates, obtaining regulatory approval for those product candidates and manufacturing, marketing and selling those products for which regulatory approval is 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 certain milestone payments under our license agreement with Forest, which will only be received if and when the FDA approves MDX-8704. We

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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 partnered product candidate, MDX-8704, until five years after its commercial launch in the United States, assuming it is approved and launched.

Although we reported net income for 2012, 2013 and the three and six months ended June 30, 2014, this was primarily due to the recognition of revenue pursuant to our license agreement with Forest. 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 depress the value of our stock and could 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 certain milestone payments under our license agreement with Forest. Accordingly, our revenue will depend on the achievement of these milestones 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 timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our products, should any of our product candidates receive approval, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies;

- the timing and success or failure of clinical studies for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; and
- the changing and 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 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

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approval, will require substantial funds. As of June 30, 2014, we had approximately \$144.6 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 if any of our product candidates is approved, including expanding our sales, marketing and distribution activities;
  
- the degree and rate of market acceptance of any products launched by us, Forest or any future partners;
  
- the coverage of our products by third-party payors and the formulary tier in which health plans and other payors place our products, if approved, 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 technologies 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 product and royalty revenue to finance our cash requirements, 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 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.

**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 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,

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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 or 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 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.

*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 anticipated 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;

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- 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;

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- 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 or used.

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

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***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 a Phase 3 registration trial of ADS-5102 for LID and a separate open-label safety study, and we plan to initiate an additional Phase 3 registration trial in support of our LID indication. 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 obtain 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 our manufacturer will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturer is 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 version of a drug 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.

***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.

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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 thirteen companies had submitted ANDAs to the FDA requesting permission to manufacture and market generic versions of Namenda XR, on which we are entitled to receive royalties from Forest beginning in June 2018. In the notices, these companies allege that the patents associated with Namenda XR, one of which is owned by Forest, one of which is exclusively licensed to Forest by Merz Pharma GmbH & Co. KGaA and others of which are owned by us and licensed by us exclusively to Forest in the United States, are invalid, unenforceable or will not be infringed by the companies' manufacture, use or sale of generic versions of Namenda XR. In January, February, April and May 2014, we, Forest, Forest Laboratories Holdings Ltd., Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH filed lawsuits for infringement of the relevant patents against the twelve 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.

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.

***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 success in the U.S. market.





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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 and establish 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.

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, sale and distribution. 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 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 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.***

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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, and side effects have been observed in

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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;
  
- 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.

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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 and then release the active drug and other breakdown substances. 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

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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 for 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.

***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

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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 a third party.

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 underestimate the size of sales force required to market our products, our commercialization efforts will be adversely affected. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our future approved products.

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

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

- the prevalence and severity of any side effects;
  
- 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.

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***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. Location and enrollment of eligible patients may be adversely affected by, for example, 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 and 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 Pharmaceuticals, 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 AG), PRX002 (Prothena Biosciences), BIA 9 1067 (Bial Portela), SYN115 (Biotie Therapies Corp.), 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 of the planned initiation of two Phase 3 clinical trials of extended release amantadine for LID. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications. In addition, many of our competitors are large pharmaceutical companies that will have a greater ability to reduce prices for their competing drugs in an effort to gain market share and undermine the value proposition that we might otherwise be able to offer to payors.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing 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.



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***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. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability or associated costs that may arise.

***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.***

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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.

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

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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.

On July 1, 2014, Actavis plc 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. We rely on third parties, such as contract research organizations, or 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 practices, 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

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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.

We currently rely on single source suppliers for each of our product candidates under a development agreement. We do not have a long-term supply agreement 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.

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**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 strategy. 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 June 30, 2014, we had 29 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 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

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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.

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***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 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.

*Our internal computer systems, or those of our CROs 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 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. 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. 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.

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**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.

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.

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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.

***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 twelve 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

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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.

***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.

***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



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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 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;

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- 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 saf