

Adamas Pharmaceuticals Inc  
Form 10-Q  
May 10, 2016  
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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 March 31, 2016

or

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

For the transition period from                      to

Commission File No. 001-36399

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ADAMAS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

(510) 450-3500

(Registrant's Telephone Number, Including Area Code)

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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 Smaller reporting company  
(Do not check if a  
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 May 5, 2016 was 21,627,631.

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## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## ADAMAS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands, except share and per share data)

	March 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	\$ 98,406	\$ 33,104
Available-for-sale securities	64,876	73,691
Accounts receivable	461	1,284
Prepaid expenses and other current assets	5,837	5,108
Total current assets	169,580	113,187
Property and equipment, net	2,916	2,353
Available-for-sale securities, non-current	5,924	13,165
Other assets	38	38
Total assets	\$ 178,458	\$ 128,743
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 3,509	\$ 3,052
Accrued liabilities	6,884	8,457
Other current liabilities	266	298
Total current liabilities	10,659	11,807
Non-current liabilities	699	749
Total liabilities	11,358	12,556
Commitments and Contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.001 par value — 5,000,000 shares authorized, and zero shares issued and outstanding at March 31, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value — 100,000,000 shares authorized, 21,473,236 and 18,505,462 shares issued and outstanding at March 31, 2016 and December 31, 2015,	26	23

respectively

Additional paid-in capital	243,042	178,473
Accumulated other comprehensive income (loss)	11	(158)
Accumulated deficit	(75,979)	(62,151)
Total stockholders' equity	167,100	116,187
Total liabilities and stockholders' equity	\$ 178,458	\$ 128,743

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

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ADAMAS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three Months Ended March 31,	
	2016	2015
Revenue	\$ 175	\$ 226
Operating expenses		
Research and development	7,522	7,533
General and administrative, net	6,641	4,919
Total operating expenses	14,163	12,452
Loss from operations	(13,988)	(12,226)
Interest and other income, net	160	78
Loss before income taxes	(13,828)	(12,148)
Provision for income taxes	—	54
Net loss	\$ (13,828)	\$ (12,202)
Net loss per share attributable to common stockholders:		
Basic	\$ (0.65)	\$ (0.69)
Diluted	\$ (0.65)	\$ (0.69)
Weighted average number of shares used in computing net loss attributable to common stockholders:		
Basic	21,253	17,643
Diluted	21,253	17,643

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

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ADAMAS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(unaudited)

(in thousands)

	Three Months Ended	
	March 31,	
	2016	2015
Net loss	\$ (13,828)	\$ (12,202)
Unrealized gain on available-for-sale securities	169	127
Comprehensive loss	\$ (13,659)	\$ (12,075)

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



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## ADAMAS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities		
Net loss	\$ (13,828)	\$ (12,202)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	137	70
Stock-based compensation	2,553	2,142
Net accretion of discounts and amortization of premiums of available-for-sale securities	258	194
Changes in assets and liabilities		
Accrued interest of available-for-sale securities	(105)	(114)
Prepaid expenses and other assets	(729)	138
Accounts receivable	823	39
Accounts payable	57	2
Accrued liabilities and other liabilities	(1,668)	(4,334)
Net cash used in operating activities	(12,502)	(14,065)
Cash flows from investing activities		
Purchases of property and equipment	(461)	(18)
Purchases of available-for-sale securities	—	(18,435)
Maturities of available-for-sale securities	16,072	—
Net cash provided by (used in) investing activities	15,611	(18,453)
Cash flows from financing activities		
Proceeds from public offerings, net of offering costs	62,030	—
Proceeds from issuance of common stock upon exercise of stock options	163	300
Net cash provided by financing activities	62,193	300
Net increase (decrease) in cash and cash equivalents	65,302	(32,218)
Cash and cash equivalents at beginning of period	33,104	61,446
Cash and cash equivalents at end of period	\$ 98,406	\$ 29,228
Supplemental disclosure of noncash investing and financing activities		
Public offering costs in accounts payable	\$ 208	\$ —
Purchase of property and equipment in accounts payable and accrued expenses	\$ 400	\$ —

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



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ADAMAS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. DESCRIPTION OF BUSINESS

Adamas Pharmaceuticals, Inc. (the “Company”) is a pharmaceutical company focused on the development and commercialization of therapeutics targeting chronic disorders of the central nervous systems (“CNS”). The Company seeks to achieve this by enhancing the pharmacokinetic profiles of approved 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 (amantadine hydrochloride) for a complication associated with the treatment of Parkinson’s disease known as levodopa-induced dyskinesia (“LID”). ADS-5102 is an extended-release version of amantadine that is intended for once daily administration at bedtime. The Company completed a Phase 2/3 clinical study in LID in 2013, and initiated two confirmatory Phase 3 trials and a separate open-label safety study in 2014. The Company completed enrollment in the larger of these trials, EASE LID, in July 2015, and the smaller, EASE LID 3, in December 2015. The Company announced top-line results of EASE LID in December 2015 and EASE LID 3 in April 2016. The Company is also exploring the utility of ADS-5102 for the treatment of major symptoms associated with multiple sclerosis in patients with walking impairment with the initiation of a Phase 2 clinical study in June 2015.

Through a license agreement with Forest Laboratories Holdings Limited (“Forest Laboratories” or “Forest”), an indirect wholly-owned subsidiary of Allergan plc, the Company’s portfolio also includes two drugs exclusively licensed to Forest and commercially available in the United States for indications relating to Alzheimer’s disease: Namzaric™ (memantine hydrochloride extended-release and donepezil hydrochloride) capsules (formerly MDX-8704) and Namenda XR® (memantine hydrochloride) extended-release capsules, launched in May 2015 and June 2013, respectively.

In April 2014, the Company issued and sold 3,081,371 shares of its common stock in its initial public offering (“IPO”), which includes the partial exercise by the underwriters of their option to purchase additional shares, at a public offering price of \$16.00 per share. Proceeds from the IPO were \$42.6 million, net of underwriting discounts and offering-related transaction costs.

In June 2015, the Company entered into a Controlled Equity Offering Sales Agreement, pursuant to which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to \$25.0 million. As of March 31, 2016, the Company had issued 509,741 shares of common stock at an average price of \$20.04 and raised net proceeds of \$9.7 million under the Sales Agreement.

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

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

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the Company believes are necessary for a fair

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presentation of the periods presented. The condensed consolidated balance sheet at December 31, 2015 was derived from the audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP. These interim financial results are not necessarily indicative of results to be expected for the full fiscal year or any other future period and should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2015, included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC.

## Liquidity and Financial Condition

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

Based upon the current status of, and plans for, its product development, the Company believes that the existing cash, cash equivalents, and investments of \$169.2 million as of March 31, 2016 will be adequate to satisfy the Company's capital needs through at least the next twelve months. However, the process of developing and commercializing products requires significant research and development, preclinical testing and clinical trials, manufacturing arrangements, as well as regulatory approvals. These activities, together with the Company's general and administrative expenses, are expected to result in significant operating losses until the commercialization of the Company's products or license agreements generate sufficient revenue to cover expenses. While the Company had net income during 2014 and 2013, it has not generated any commercial revenue from sales of its products. Under its license agreement with Forest, the Company received the final milestone payment in 2014, and is not entitled to receive any royalties for sales of Namzaric until mid-2020 and Namenda XR until mid-2018. To achieve sustained profitability, the Company, alone or with others, must successfully develop its product candidates, obtain required regulatory approvals, and successfully manufacture and market its products.

## Use of Estimates

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

## Forward Stock Split

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

## Revenue Recognition

The Company recognizes revenue when all four of the following criteria have been met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable and (iv) collectability is reasonably assured. Revenue under license arrangements is recognized based on the

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performance requirements of the contract. Determinations of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments regarding the fixed nature of the fees charged for deliverables and the collectability of those fees. Should changes in conditions cause management to determine that these criteria are not met for any new or modified transactions, revenue recognized could be adversely affected.

The Company generates revenue from collaboration and license agreements for the development and commercialization of products. Collaboration and license agreements may include non-refundable upfront license fees, partial or complete reimbursement of research and development costs, contingent consideration payments based on the achievement of defined objectives and royalties on sales of commercialized products. The Company's performance obligations under the collaboration and license agreements may include the license or transfer of intellectual property rights, obligations to provide research and development services and related materials and obligations to participate on certain development and/or commercialization committees with the partners.

For revenue agreements with multiple-element arrangements, the Company allocates revenue to each non-contingent element based on the relative-selling-price of each element in an arrangement. When applying the relative-selling-price method, the Company determines the selling price for each deliverable using the following estimation hierarchy: (i) vendor-specific objective evidence of fair value of the deliverable, if it exists, (ii) third-party evidence of selling price, if vendor-specific objective evidence is not available or (iii) vendor's best estimate of selling price, if neither vendor-specific nor third-party evidence is available. Revenue allocated is then recognized when the four basic revenue recognition criteria, mentioned above, are met for each element.

The Company recognizes payments that are contingent upon achievement of a substantive milestone in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can only be achieved based on the Company's performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones subject to this guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms within the agreement and commensurate with the Company's performance to achieve the milestone after commencement of the agreement.

Amounts related to research and development funding and full-time equivalents assigned to the license agreement are recognized as the related services or activities are performed, in accordance with the contract terms.

## Clinical Trial Accruals

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with

multiple research institutions and clinical research organizations (“CROs”) that conduct and manage clinical trials on the Company’s behalf.

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



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### Research and Development

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

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

### Basic and Diluted Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is based upon the weighted average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders is based upon the weighted average number of common shares outstanding and dilutive common stock equivalents outstanding during the period. Common stock equivalents are options granted under the Company’s stock awards plans and are calculated under the treasury stock method. Common equivalent shares from unexercised stock options and unvested restricted stock units are excluded from the computation when there is a loss as their effect is anti-dilutive, or if the exercise price of such options is greater than the average market price of the stock for the period. The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. At March 31, 2016 and 2015, approximately 5,370,000 and 456,000, respectively, shares of potentially dilutive securities were excluded from the computation of diluted net income per share of common stock as their effect would have been anti-dilutive.

### Stock-Based Compensation

The Company accounts for stock-based compensation of stock options granted to employees and directors and for employee stock purchase plan shares by estimating the fair value of stock-based awards using the Black-Scholes option-pricing model. The Company accounts for stock-based compensation of restricted stock units granted to employees based on the closing price of the Company's common stock on the date of grant. The fair value of stock-based awards are recognized and amortized over the applicable vesting period. All stock options awarded to non-employees are accounted for at the fair value of the consideration received or the fair value of the equity instrument issued, as calculated using the Black-Scholes model. Stock options granted to non-employees are subject to periodic revaluation at each reporting date as the underlying equity instruments vest.

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

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any of these estimates, stock-based compensation expense and the Company's results of operations could be materially impacted.

### Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers. The amendment in this ASU provides guidance on the revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The core principle of this update provides guidance to identify the performance obligations under the contract(s) with a customer and how to allocate the transaction price to the performance obligations in the contract. It further provides guidance to recognize revenue when (or as) the entity satisfies a performance obligation. This standard will replace most existing revenue recognition guidance. On July 9, 2015, the FASB approved a one-year deferral of the effective date of this standard to 2018 for public companies, with an option that would permit companies to adopt the standard as early as the original effective date of 2017. Early adoption prior to the original effective date is not permitted. The Company has not yet selected a transition method nor has it determined the effect of the standard on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This ASU provides guidance on management's responsibility in evaluating whether there is substantial doubt about a Company's ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about the company's ability to continue as a going concern within one year from the date the financial statements are issued. The amendments in this update are effective for annual periods ending after December 15, 2016, and for interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company is evaluating the impact the revised guidance will have on its consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. Under ASU 2015-17, a reporting entity is required to classify deferred tax assets and liabilities as noncurrent in a classified statement of financial position. Current guidance requiring the offsetting of deferred tax assets and liabilities of a tax-paying component of an entity and presentation as a single noncurrent amount is not affected. This ASU is effective for public business entities issuing financial statements for the annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for financial statements as of the beginning of an interim or annual reporting period. Entities may apply the update prospectively to all deferred tax assets and liabilities and taxes, or retrospectively for all periods presented. The effects of this update on the Company's consolidated financial statements are not expected to be material.

In February 2016, the FASB issued ASU No. 2016-02, Leases. The authoritative guidance significantly amends the current accounting for leases. Under the new provisions, all lessees will report a right-of-use asset and a liability for the obligation to make payments for all leases with the exception of those leases with a term of 12 months or less. All

other leases will fall into one of two categories: (i) a financing lease or (ii) an operating lease. Lessor accounting remains substantially unchanged with the exception that no leases entered into after the effective date will be classified as leveraged leases. For sale leaseback transactions, a sale will only be recognized if the criteria in the new revenue recognition standard are met. For public business entities, this guidance is effective for fiscal periods beginning after December 15, 2018 and interim periods thereafter. Early adoption is permitted. The Company is currently evaluating the effect the new guidance will have on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation. The new guidance simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows.

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This guidance is effective for fiscal years beginning after December 15, 2016. The Company is currently evaluating the effect the new guidance will have on its consolidated financial statements.

### 3. FAIR VALUE MEASUREMENTS

In accordance with ASC 820-10, Fair Value Measurements and Disclosures, the Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1 inputs which include quoted prices in active markets for identical assets or liabilities;
- Level 2 inputs which include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability. For available-for-sale securities, the Company reviews trading activity and pricing as of the measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data; and
- Level 3 inputs which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

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

	Fair Value Measurements at			
	March 31, 2016			
	Total	Level 1	Level 2	Level 3
Assets				
Money market	\$ 87,998	\$ 87,998	\$ —	\$ —
Corporate debt	40,633	—	40,633	—
U.S. Treasury notes	30,167	—	30,167	—
Total assets measured at fair value	\$ 158,798	\$ 87,998	\$ 70,800	\$ —