ENANTA PHARMACEUTICALS INC
Form 10-Q
May 12, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended March 31, 2014

OR

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

Commission File Number 001-35839

ENANTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	2834	04-3205099
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

500 Arsenal Street

Watertown, Massachusetts 02472

(617) 607-0800

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

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

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes x 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:

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	x (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 x

The number of shares of the registrant s Common Stock, $0.01 par value, outstanding as of May 9, 2014, was 18,537,844 shares.

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ENANTA PHARMACEUTICALS, INC.

FORM 10-Q Quarterly Report

For the Quarterly Period Ended March 31, 2014

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(unaudited)

(In thousands, except share and per share amounts)

	March 31, 2014	September 30, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 18,101	$ 8,859
Short-term marketable securities	76,669	92,621
Accounts receivable	998	808
Unbilled receivables	1,604	784
Prepaid expenses and other current assets	1,977	1,641
Total current assets	99,349	104,713
Property and equipment, net	1,377	1,121
Long-term marketable securities	7,184	10,703
Restricted cash	436	436
Total assets	$ 108,346	$ 116,973
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 2,041	$ 1,481
Accrued expenses	2,327	3,035
Deferred revenue	51	10
Total current liabilities	4,419	4,526
Warrant liability	1,617	1,620
Series 1 nonconvertible preferred stock	206	
Other long-term liabilities	389	359
Total liabilities	6,631	6,505
Commitments and contingencies (Note 10)		
Stockholders equity:		
Common stock; $0.01 par value; 100,000,000 shares authorized at March 31, 2014 and September 30, 2013; 18,686,449 and 18,138,597 shares issued and 18,477,633 and 17,929,781 shares outstanding at March 31, 2014 and September 30, 2013, respectively	187	181
Additional paid-in capital	219,492	217,741
Treasury stock, at par value; 208,816 shares at March 31, 2014 and September 30, 2013	(2)	(2)
Accumulated other comprehensive income (loss)	61	(2)
Accumulated deficit	(118,023)	(107,450)

Total stockholders equity	101,715	110,468
Total liabilities and stockholders equity	$ 108,346	$ 116,973

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

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ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2014	2013	2014	2013
Revenue	$ 2,160	$ 1,196	$ 3,053	$ 29,055
Operating expenses:				
Research and development	4,722	3,704	8,985	8,502
General and administrative	2,565	1,493	4,652	2,645
Total operating expenses	7,287	5,197	13,637	11,147
Income (loss) from operations	(5,127)	(4,001)	(10,584)	17,908
Other income (expense):				
Interest income	114	47	223	82
Interest expense	(4)	(9)	(9)	(16)
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	(186)	214	(203)	234
Total other income (expense), net	(76)	252	11	300
Net income (loss)	(5,203)	(3,749)	(10,573)	18,208
Accretion of redeemable convertible preferred stock to redemption value		(1,244)		(2,526)
Net income attributable to participating securities				(13,670)
Net income (loss) attributable to common stockholders	$ (5,203)	$ (4,993)	$ (10,573)	$ 2,012
Net income (loss) per share attributable to common stockholders:				
Basic	$ (0.28)	$ (2.28)	$ (0.58)	$ 1.21
Diluted	$ (0.28)	$ (2.28)	$ (0.58)	$ 1.09
Weighted average common shares outstanding:				
Basic	18,353,628	2,192,470	18,149,330	1,669,578
Diluted	18,353,628	2,192,470	18,149,330	3,084,084

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

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ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(unaudited)

(In thousands)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2014	2013	2014	2013
Net income (loss)	$ (5,203)	$ (3,749)	$ (10,573)	$ 18,208
Other comprehensive income (loss):				
Net unrealized losses on marketable securities, net of tax of $0	29	(3)	63	(17)
Total other comprehensive income (loss)	29	(3)	63	(17)
Comprehensive income (loss)	$ (5,174)	$ (3,752)	$ (10,510)	$ 18,191

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

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ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(In thousands)

	Six Months Ended March 31,	
	2014	**2013**
Cash flows from operating activities		
Net income (loss)	$ (10,573)	$ 18,208
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	154	87
Non-cash interest expense	9	16
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	203	(234)
Stock-based compensation expense	1,111	538
Premium on marketable securities	(473)	
Amortization of premium on marketable securities	1,202	401
Change in operating assets and liabilities:		
Accounts receivable	(190)	380
Unbilled receivables	(820)	1,125
Prepaid expenses and other current assets	(293)	271
Accounts payable	316	(469)
Accrued expenses	(718)	(1,369)
Deferred revenue	41	98
Other long-term liabilities	30	26
Net cash provided by (used in) operating activities	(10,001)	19,078
Cash flows from investing activities		
Purchases of property and equipment	(165)	(352)
Purchases of marketable securities	(24,572)	(45,706)
Sales of marketable securities	7,413	2,454
Maturities of marketable securities	35,921	30,245
Net cash provided by (used in) investing activities	18,597	(13,359)
Cash flows from financing activities		
Proceeds from exercise of stock options	646	415
Proceeds from initial public offering, net of commissions		59,892
Payments of initial public offering costs		(2,073)
Net cash provided by financing activities	646	58,234
Net increase in cash and cash equivalents	9,242	63,953
Cash and cash equivalents at beginning of period	8,859	10,511
Cash and cash equivalents at end of period	$ 18,101	$ 74,464
Supplemental disclosure of noncash financing activities:		
Accretion of redeemable convertible preferred stock to redemption value	$	$ 2,526

Initial public offering costs included in accounts payable or accrued expenses	$	$ 1,466
Conversion of preferred stock into common stock	$	$ 161,808
Exercise of Series 1 warrant into Series 1 nonconvertible preferred stock	$ 206	$

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

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ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except share and per share data)

1. Nature of the Business and Basis of Presentation

Enanta Pharmaceuticals, Inc. (the Company), incorporated in Delaware in 1995, is a research and development-focused biotechnology company that uses its chemistry-driven approach and drug discovery capabilities to create small molecule drugs in the infectious disease field. The Company is developing novel protease, NS5A, cyclophilin and nucleotide polymerase inhibitors targeted against the hepatitis C virus (HCV). Additionally, the Company has created a new class of bridged bicyclic antibiotics known as Bicyclolides to overcome bacterial resistance. Antibacterial focus areas include superbugs, respiratory tract infections, and intravenous and oral treatments for hospital and community methicillin-resistant *Staphylococcus aureus* (MRSA).

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, difficulties in developing new therapies, competition from innovations of others, dependence on collaborative arrangements, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need for financial resources to fund research and development activities. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance reporting capabilities.

Unaudited Interim Financial Information

The consolidated balance sheet at September 30, 2013 was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America (GAAP). The accompanying unaudited consolidated financial statements as of March 31, 2014 and for the three and six months ended March 31, 2014 and 2013 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These financial statements should be read in conjunction with the Company s audited financial statements and the notes thereto for the year ended September 30, 2013 included in the Company s 2013 Annual Report on Form 10-K.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company s financial position as of March 31, 2014 and results of operations for the three and six months ended March 31, 2014 and 2013 and cash flows for the six months ended March 31, 2014 and 2013 have been made. The results of operations for the six months ended March 31, 2014 are not necessarily indicative of the results of operations that may be expected for the year ending September 30, 2014.

The accompanying consolidated financial statements have been prepared in conformity with GAAP. All dollar amounts in the consolidated financial statements and in the notes to the consolidated financial statements, except share and per share amounts, are in thousands unless otherwise indicated.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, management s judgments of separate units of accounting and

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ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

(Amounts in thousands, except share and per share data)

best estimate of selling price of those units of accounting within its revenue arrangements; the valuation of common stock for the periods prior to the completion of the Company s initial public offering (IPO), valuation of warrants, Series 1 nonconvertible preferred stock and stock-based awards; the useful lives of property and equipment; and the accounting for income taxes, including uncertain tax positions and the valuation of net deferred tax assets. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company s estimates.

Revenue Recognition

The Company s revenue is generated primarily through collaborative research and license agreements. The terms of these agreements contain multiple deliverables, which may include (i) licenses, (ii) research and development activities, and (iii) participation in joint research and development steering committees. The terms of these agreements may include nonrefundable upfront license fees, payments for research and development activities, payments based upon the achievement of certain milestones, and royalty payments based on product sales derived from the collaboration. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered, collectibility of the resulting receivable is reasonably assured, and the Company has fulfilled its performance obligations under the contract.

For multiple element agreements entered into or materially modified after October 1, 2011, the Company applies the principles included in Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13) to account for revenue. Under this guidance the selling prices of deliverables under the arrangement may be derived using third-party evidence (TPE) or a best estimate of selling price (BESP), if vendor specific objective evidence (VSOE) is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the license agreement was sold on a standalone basis. Establishing BESP involves management s judgment and considers multiple factors, including market conditions and company-specific factors including those factors contemplated in negotiating the agreements as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success, and the time needed to commercialize a product candidate pursuant to the license. In validating the Company s BESP, the Company considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within the control of the Company. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element, and revenue is accordingly recognized as each element is delivered. The Company may exercise significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting, the Company evaluates whether the license has standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the collaborator and the availability of relevant research expertise in the marketplace. In addition, the Company considers whether or not

(i) the collaborator can use the license for its intended purpose without the receipt of the remaining deliverables, (ii) the value of the license is dependent on the undelivered items, and (iii) the collaborator or other vendors can provide the undelivered items.

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ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

(Amounts in thousands, except share and per share data)

Under a collaborative research and license agreement, a steering committee is typically responsible for overseeing the general working relationships, determining the protocols to be followed in the research and development performed, and evaluating the results from the continued development of the product in order to determine the clinical studies to be performed. The Company evaluates whether its participation in joint research and development steering committees is a substantive obligation or whether the services are considered inconsequential or perfunctory. The Company s participation on a steering committee is considered participatory and therefore accounted for as a separate element when the collaborator requires the participation of the Company to ensure all elements of an arrangement are maximized. Steering committee services that are considered participatory are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations. Alternatively, the Company s participation on a steering committee is considered protective and therefore not accounted for as a separate element in a case where the Company can exercise or control when to be involved at its own discretion. Factors the Company considers in determining if its participation in a joint steering committee is participating or protective include: (i) which party negotiated or requested the steering committee, (ii) how frequently the steering committee meets, (iii) whether or not there are any penalties or other recourse if the Company does not attend the steering committee meetings, (iv) which party has decision making authority on the steering committee, and (v) whether or not the collaborator has the requisite experience and expertise associated with the research and development of the licensed intellectual property.

For agreements entered into prior to October 1, 2011, the Company accounted for the multiple elements within the agreements as a single unit of accounting and all payments received were recognized as revenue over the estimated period of performance of the entire arrangement as the Company was not able to separately recognize revenue for the elements under the provisions of previously applicable revenue recognition guidance.

For all periods presented, whenever the Company determines that an element is delivered over a period of time, revenue is recognized using either a proportional performance model or a straight-line model over the period of performance, which is typically the research and development term. Full-time equivalents (FTEs) are typically used as the measure of performance. At each reporting period, the Company reassesses its cumulative measure of performance and makes appropriate adjustments, if necessary. The Company recognizes revenue using the proportional performance model whenever the Company can make reasonably reliable estimates of the level of effort required to complete its performance obligations under an arrangement. Revenue recognized under the proportional performance model at each reporting period is determined by multiplying the total expected payments under the contract (excluding royalties and payments contingent upon achievement of milestones) by the ratio of the level of effort incurred to date to the estimated total level of effort required to complete the performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance model as of each reporting period. Alternatively, if the Company cannot make reasonably reliable estimates the level of effort required to complete its performance obligations under an arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period expected to complete the Company s performance obligations. If and when a contingent milestone payment is earned, the additional consideration to be received is allocated to the separate units of accounting in the arrangement based on their relative selling prices at the inception of the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined on a straight-line basis as of the period end date. If the Company cannot reasonably estimate when its performance obligation period ends, then revenue is deferred until the Company can reasonably estimate when the performance obligation period ends.

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ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

(Amounts in thousands, except share and per share data)

Royalty revenue, if any, is recognized based on contractual terms when reported sales are reliably measurable and collectibility is reasonably assured, provided that there are no performance obligations then remaining. To date, none of the Company s products have been approved, and therefore the Company has not earned any royalty revenue from product sales.

During the three and six months ended March 31, 2014 and 2013 the Company also generated revenue from a government contract, under which the Company is reimbursed for certain allowable costs for the funded project. Revenue from the government contract is recognized when the related service is performed. The related costs incurred by the Company under the government contract are included in research and development expenses in the statements of operations.

Amounts received prior to satisfying all revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the next twelve months of the consolidated balance sheet date are classified as long-term deferred revenue.

In the event that a collaborative research and license agreement is terminated and the Company then has no further performance obligations, the Company recognizes as revenue any amounts that had not previously been recorded as revenue but were classified as deferred revenue at the date of such termination.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company s financial assets and liabilities that were subject to fair value measurement on a recurring basis as of March 31, 2014 and September 30, 2013 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 15,282	$	$	$ 15,282
Commercial paper		9,335		9,335
Corporate bonds		74,518		74,518
	$ 15,282	$ 83,853	$	$ 99,135
Liabilities:				
Warrant liability	$	$	$ 1,617	$ 1,617
Series 1 nonconvertible preferred stock			206	206
	$	$	$ 1,823	$ 1,823

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ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

(Amounts in thousands, except share and per share data)

	Fair Value Measurements as of September 30, 2013 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 7,517	$	$	$ 7,517
U.S. Treasury notes	1,005			1,005
Commercial paper		10,596		10,596
Corporate bonds		84,755		84,755
U.S. Agency bonds		3,518		3,518
Certificate of deposit		3,450		3,450
	$ 8,522	$ 102,319	$	$ 110,841
Liabilities:				
Warrant liability	$	$	$ 1,620	$ 1,620
	$	$	$ 1,620	$ 1,620

Cash equivalents at March 31, 2014 and September 30, 2013 consist of money market funds.

During the three and six months ended March 31, 2014 and 2013, there were no transfers between Level 1, Level 2 and Level 3.

As of March 31, 2014 and September 30, 2013, respectively, the warrant liability, comprised of the values of warrants for the purchase of Series 1 nonconvertible preferred stock measured at fair value. At March 31, 2014 the outstanding Series 1 nonconvertible preferred stock is also measured at fair value based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company utilized a probability-weighted valuation model which takes into consideration various outcomes that may require the Company to transfer assets and determined that the fair value of the Series 1 warrants was $1,617 and $1,620, at March 31, 2014 and September 30, 2013, respectively. The fair value of Series 1 nonconvertible preferred stock was $206 as of March 31, 2014. Changes in the fair value of the warrant liability and Series 1 nonconvertible preferred stock are recognized in the consolidated statements of operations.

The recurring Level 3 fair value measurements of the Company s warrant liability and Series 1 nonconvertible preferred stock using probability-weighted discounted cash flow include the following significant unobservable inputs:

	Unobservable Input	Range (Weighted Average)
Warrant liability and Series 1 nonconvertible preferred stock	Probabilities of payout	25% 90%
	Periods in which payout is expected to occur	2014 2018
	Discount rate	4.25%

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ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

(Amounts in thousands, except share and per share data)

The following table provides a rollforward of the aggregate fair values of the Company s warrants for the purchase of Series 1 nonconvertible preferred stock and the outstanding Series 1 nonconvertible preferred stock for which fair value is determined by Level 3 inputs:

	Warrants	Series 1 nonconvertible preferred stock
Balance, September 30, 2013	$ 1,620	$
Warrants exercised	(206)	206
Increase in fair value	203	
Balance, March 31, 2014	$ 1,617	$ 206

4. Marketable Securities

As of March 31, 2014 and September 30, 2013, the fair value of available-for-sale marketable securities by type of security was as follows:

	March 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 9,335	$	$	$ 9,335
Corporate bonds	74,457	62	(1)	74,518
	$ 83,792	$ 62	$ (1)	$ 83,853

	September 30, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 10,596	$	$	$ 10,596
Corporate bonds	84,757	23	(25)	84,755
U.S. Agency bonds	3,519		(1)	3,518
Certificate of deposit	3,450			3,450
U.S. Treasury notes	1,004	1		1,005
	$ 103,326	$ 24	$ (26)	$ 103,324

As of March 31, 2014, marketable securities consisted of investments that mature within one year, with the exception of certain corporate bonds, which have maturities within two years and an aggregate fair value of $7,184.

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ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

(Amounts in thousands, except share and per share data)

5. Accrued Expenses and Other Long-Term Liabilities

Accrued expenses (current) and other long-term liabilities consisted of the following as of March 31, 2014 and September 30, 2013:

	March 31, 2014	September 30, 2013
Accrued expenses:		
Accrued professional fees	$ 249	$ 378
Accrued payroll and related expenses	562	1,041
Accrued preclinical and clinical expenses	590	127
Accrued third-party license fees	245	240
Accrued vendor manufacturing	456	989
Accrued other	225	260
	$ 2,327	$ 3,035
Other long-term liabilities:		
Present value of accrued third-party license fees	$ 188	$ 184
Accrued rent expense	140	127
Asset retirement obligation	61	48