ENANTA PHARMACEUTICALS INC
Form 10-Q
February 09, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended December 31, 2016

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 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 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 (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

The number of shares of the registrant's Common Stock, $0.01 par value, outstanding as of February 1, 2017, was 19,041,267 shares.

ENANTA PHARMACEUTICALS, INC.

FORM 10-Q — Quarterly Report

For the Quarterly Period Ended December 31, 2016

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PART I—FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS
ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands, except per share amounts)

	December 31, 2016	September 30, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 20,618	$ 16,577
Short-term marketable securities	188,740	193,507
Accounts receivable	10,417	12,841
Prepaid expenses and other current assets	4,290	9,231
Total current assets	224,065	232,156
Property and equipment, net	8,306	8,004
Long-term marketable securities	35,037	32,119
Deferred tax assets	10,363	8,390
Restricted cash	608	608
Total assets	$ 278,379	$ 281,277
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,952	$ 3,377
Accrued expenses and other current liabilities	4,479	4,512
Total current liabilities	6,431	7,889
Warrant liability	1,262	1,251
Series 1 nonconvertible preferred stock	161	159
Other long-term liabilities	2,357	2,042
Total liabilities	10,211	11,341
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock; $0.01 par value, 100,000 shares authorized; 19,040 and 19,036 shares issued and outstanding at December 31, 2016 and September 30, 2016, respectively	190	190
Additional paid-in capital	245,397	242,081
Accumulated other comprehensive income (loss)	(85)	19
Retained earnings	22,666	27,646
Total stockholders' equity	268,168	269,936
Total liabilities and stockholders' equity	$ 278,379	$ 281,277

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended December 31, 2016	2015
Revenue		
Royalties	$10,417	$17,869
Milestones	—	30,000
Other	—	576
Total revenue	$10,417	$48,445
Operating expenses:		
Research and development	12,526	9,033
General and administrative	4,937	3,818
Total operating expenses	17,463	12,851
Income (loss) from operations	(7,046)	35,594
Other income (expense):		
Interest income	549	356
Interest expense	(12)	(12)
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	(13)	(15)
Total other income (expense), net	524	329
Income (loss) before income taxes	(6,522)	35,923
Income tax (expense) benefit	1,542	(9,734)
Net income (loss)	$(4,980)	$26,189
Net income (loss) per share:		
Basic	$(0.26)	$1.39
Diluted	$(0.26)	$1.36
Weighted average shares outstanding:		
Basic	19,038	18,776
Diluted	19,038	19,269

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(unaudited)

(in thousands)

	Three Months Ended December 31,	
	2016	2015
Net income (loss)	$(4,980)	$26,189
Other comprehensive income (loss):		
Net unrealized gains (losses) on marketable securities, net of tax of ($63) and ($135)	(104)	(222)
Total other comprehensive income (loss)	(104)	(222)
Comprehensive income (loss)	$(5,084)	$25,967

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three Months Ended December 31,	
	2016	2015
Cash flows from operating activities		
Net income (loss)	$(4,980)	$26,189
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation expense	3,267	1,992
Depreciation and amortization expense	493	339
Deferred income taxes	(1,910)	382
Premium on marketable securities	(324)	(171)
Amortization of premium on marketable securities	188	562
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	13	15
Change in operating assets and liabilities:		
Accounts receivable	2,424	(2,580)
Unbilled receivables	—	(576)
Prepaid expenses and other current assets	4,941	(276)
Accounts payable	(1,290)	149
Accrued expenses	(10)	150
Income taxes payable	—	3,741
Other long-term liabilities	333	77
Net cash provided by operating activities	3,145	29,993
Cash flows from investing activities		
Purchase of property and equipment	(953)	(2,197)
Purchase of marketable securities	(73,671)	(34,622)
Maturities of marketable securities	75,489	31,187
Net cash provided by (used in) investing activities	865	(5,632)
Cash flows from financing activities		
Proceeds from exercise of stock options	49	162
Payments of capital lease obligations	(18)	(16)
Net cash provided by financing activities	31	146
Net increase in cash and cash equivalents	4,041	24,507
Cash and cash equivalents at beginning of period	16,577	21,726
Cash and cash equivalents at end of period	$20,618	$46,233
Supplemental disclosure of cash flow information:		

Cash paid for income taxes	$1,018	$5,707

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

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 robust, chemistry-driven approach and drug discovery capabilities to create small molecule drugs primarily for the treatment of viral infections and liver diseases. The Company’s success to date has been built on protease inhibitors discovered for the treatment of hepatitis C virus, or (“HCV”), which are licensed to AbbVie Inc. (“AbbVie”) and included in its HCV treatment regimens. The Company’s new research and development programs are currently focused primarily on the following disease areas: hepatitis B virus (“HBV”); non-alcoholic steatohepatitis (“NASH”); primary biliary cholangitis (“PBC”); and respiratory syncytial virus (“RSV”).

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

Unaudited Interim Financial Information

The consolidated balance sheet at September 30, 2016 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 December 31, 2016 and for the three months ended December 31, 2016 and 2015 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 included in the Company’s Annual Report on Form 10-K for the year ended September 30, 2016.

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 December 31, 2016 and results of operations for the three months ended December 31, 2016 and 2015 and cash flows for the three months ended December 31, 2016 and 2015, have been made. The results of operations for the three months ended December 31, 2016 are not necessarily indicative of the results of operations that may be expected for subsequent quarters or the year ending September 30, 2017.

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

For the Company’s Significant Accounting Policies, please refer to its Annual Report on Form 10-K for the fiscal year ended September 30, 2016. There were no significant changes to the Company’s Significant Accounting Policies during the quarter.

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 best estimate of selling price of those units of accounting within its revenue arrangements; valuation of warrants, Series 1 nonconvertible preferred stock and stock-based awards; 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.

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (the "FASB") issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) ("ASU 2014-15"), which requires management to assess a company's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. This amendment will be effective for the Company for fiscal year ended September 30, 2016. The Company does not expect the adoption of ASU 2014-15 to have an impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"), which intends to simplify several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, a choice to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This amendment will be effective for the Company in the fiscal year beginning October 1, 2017. The Company is currently evaluating the potential impact that ASU 2016-09 may have on its financial position and results of operations.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09") which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The FASB has continued to issue accounting standards updates to clarify and provide implementation guidance related to Revenue from Contracts with Customers, including ASU 2016-08, Revenue from Contract with Customers: Principal versus Agent Considerations, ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing, and ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients. These amendments address a number of areas, including an entity's identification of its performance obligations in a contract, collectibility, non-cash consideration, presentation of sales tax and an entity's evaluation of the nature of its promise to grant a license of intellectual property and whether or not that revenue is recognized over time or at a point in time. These new standards will be effective for the Company beginning October 1, 2018. The Company is currently evaluating the potential impact that Topic 606 may have on its financial position and results of operations.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash ("ASU 2016-18") that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This amendment is effective for the Company in the fiscal year beginning October 1, 2018, but early adoption is permissible. The Company is currently evaluating the potential impact that ASU 2016-18 may have on its financial position and statement of cash flows.

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"), which will replace the existing guidance in ASC 840, "Leases." The updated standard aims to increase transparency and comparability among organizations by requiring lessees to recognize leased assets and leased liabilities on the consolidated balance sheets and requiring disclosure of key information about leasing arrangements. This amendment is effective for the Company in the fiscal year beginning October 1, 2019, but early adoption is permissible. The Company is currently evaluating the potential impact that ASU 2016-02 may have on its financial position and results of operations.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses ("ASU 2016-13"), which introduces a new methodology for accounting for credit losses on financial instruments, including available-for-sale debt securities. The guidance establishes a new "expected loss model" that requires entities to estimate current expected credit losses on financial instruments by using all practical and relevant information. Any expected credit losses are to be reflected as allowances rather than reductions in the amortized cost of available-for-sale debt securities. This amendment is effective for the Company in the fiscal year beginning October 1, 2019. The Company is currently evaluating the potential impact that ASU 2016-13 may have on its financial position and results of operations.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company’s financial statements upon adoption.

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 December 31, 2016 and September 30, 2016 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements at December 31, 2016 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
U.S. Treasury notes	$83,011	$—	$—	$83,011
Cash equivalents	17,263	—	—	17,263
Corporate bonds	—	91,199	—	91,199
Commercial paper	—	29,550	—	29,550
U.S. Agency bonds	—	20,017	—	20,017
	$100,274	$140,766	$—	$241,040
Liabilities:				
Warrant liability	$—	$—	$1,262	$1,262
Series 1 nonconvertible preferred stock	—	—	161	161
	$—	$—	$1,423	$1,423

	Fair Value Measurements at September 30, 2016 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
U.S. Treasury notes	$69,608	$—	$—	$69,608
Cash equivalents	15,295	—	—	15,295
Corporate bonds	—	76,073	—	76,073
Commercial paper	—	49,900	—	49,900
U.S. Agency bonds	—	30,045	—	30,045
	$84,903	$156,018	$—	$240,921
Liabilities:				
Warrant liability	$—	$—	$1,251	$1,251
Series 1 nonconvertible preferred stock	—	—	159	159
	$—	$—	$1,410	$1,410

Cash equivalents at December 31, 2016 and September 30, 2016 consist primarily of money market funds.

During the three months ended December 31, 2016 and 2015, there were no transfers between Level 1, Level 2 and Level 3.

As of December 31, 2016 and September 30, 2016, the Company's warrant liability was comprised of the value of warrants for the purchase of its Series 1 nonconvertible preferred stock. These warrants are financial instruments that may require a transfer of assets because of the liquidation features and are therefore recorded as liabilities and measured at fair value. The outstanding Series 1 nonconvertible preferred stock was also measured at fair value. The fair value of these instruments was based on significant inputs not observable in the market, which represented 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 upon exercise. Changes in the fair value of the warrant liability and Series 1 nonconvertible preferred stock are recognized in other income (expense), net 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) December 31, 2016	September 30, 2016
Warrant liability and Series 1 nonconvertible preferred stock	Probabilities of payout	0%-60%	0%-60%
	Periods in which payout is expected to occur	2017-2018	2017-2018
	Discount rate	4.75%	4.50%

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:

	Warrant Liability	Series 1 Nonconvertible Preferred Stock
Balance, September 30, 2016	$ 1,251	$ 159
Increase in fair value	11	2
Balance, December 31, 2016	$ 1,262	$ 161

4. Marketable Securities

As of December 31, 2016 and September 30, 2016, the fair value of available-for-sale marketable securities, by type of security, was as follows:

December 31, 2016			
Amortized Cost	Gross Unrealized	Gross Unrealized	Fair Value

		Gains	Losses	
Corporate bonds	$91,259	$ 21	$ (81)	$91,199
U.S. Treasury notes	83,080	7	(76)	83,011
Commercial paper	29,550	—	—	29,550
U.S. Agency bonds	20,025	3		