

Enanta Pharmaceuticals Reports Financial Results for its Fiscal Third Quarter Ended June 30, 2016

August 8, 2016 Download this Press Release

Conference Call and Webcast Today at 4:30 p.m. ET

- Royalty revenue was \$14.0 million
- R&D expense increased to \$10.8 million in support of pipeline development
- Cash and marketable securities totaled \$244.7 million at June 30, 2016

WATERTOWN, Mass.--(BUSINESS WIRE)--Aug. 8, 2016-- Enanta Pharmaceuticals, Inc., (NASDAQ:ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today reported financial results for its fiscal third quarter ended June 30, 2016.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled \$244.7 million at June 30, 2016. This compares to a total of \$209.4 million in such accounts at September 30, 2015. Enanta expects that its current cash, cash equivalents and marketable securities will be sufficient to meet the anticipated cash requirements of its existing business for the foreseeable future.

Fiscal Third Quarter Ended June 30, 2016 Financial Results

Revenue for the three months ended June 30, 2016 was \$14.0 million, compared to \$11.6 million for the three months ended June 30, 2015. The increase in revenue in 2016 was attributable to higher royalties earned from AbbVie as a result of higher sales of its hepatitis C virus (HCV) treatment regimens outside of the U.S. For the nine months ended June 30, 2016, revenue was \$75.4 million compared to revenue of \$146.5 million for the same period in 2015. The decrease in revenue in the year-to-date 2016 period was due primarily to a reduction in milestone payments versus the comparable period in 2015. Enanta earned \$125.0 million in milestone payments from AbbVie in 2015 compared to \$30.0 million in 2016 based on timing of achievement of commercialization regulatory approvals of its HCV treatment regimens in the U.S. and Europe (2015) and Japan (2016). In 2016, the decrease in milestone payments was partially offset by higher royalties earned from AbbVie's worldwide net sales of its HCV regimens. Enanta's milestone payments, royalties and other payments received from collaborations have varied significantly from period to period, and are expected to continue to do so.

Research and development expenses totaled \$10.8 million for the three months ended June 30, 2016, compared to \$6.3 million for the three months ended June 30, 2015. For the nine months ended June 30, 2016, research and development expenses were \$29.0 million, compared to \$16.1 million for the same period in 2015. The increase in the three and nine month periods was primarily due to increased pre-clinical and clinical costs due to the progression of Enanta's wholly-owned R&D programs in HCV cyclophilin, non-alcoholic steatohepatitis (NASH), respiratory syncytial virus (RSV) and hepatitis B virus (HBV).

General and administrative expenses totaled \$4.3 million for the three months ended June 30, 2016, compared to \$3.6 million for the three months ended June 30, 2015. For the nine months ended June 30, 2016, general and administrative expenses were \$12.5 million compared to \$9.9 million for the same period in 2015. The increase in the three and nine month periods primarily reflects increases in stock-based compensation expense driven by increased headcount.

Income tax (expense) benefit for the three months ended June 30, 2016 was (\$0.4) million compared to \$0.4 million for the corresponding period in 2015. During the three months ended June 30, 2016, Enanta increased its estimate of its annual effective tax rate for fiscal 2016, which resulted in an income tax provision despite a pre-tax loss for the quarter. Income tax (expense) for the nine months ended June 30, 2016 was (\$11.7) million compared to (\$48.1) million for the corresponding period in 2015, representing annual effective tax rates of 33.3% and 39.7%, respectively, for those periods.

Net loss for the three months ended June 30, 2016 was (\$1.1) million, or (\$0.06) per diluted common share, compared to net income of \$2.4 million or \$0.13 per diluted common share, for the corresponding period in 2015. Net income for the nine months ended June 30, 2016 was \$23.5 million, or \$1.22 per diluted common share, compared to net income of \$73.2 million or \$3.80 per diluted common share, for the corresponding period in 2015.

"Enanta is fortunate to be in a position to fund substantial R&D programs to build shareholder value without dilution. Our diverse, wholly-owned pipeline is progressing well and as expected," commented Jay R. Luly, Ph.D., President and Chief Executive Officer. "EDP-305, our FXR agonist candidate for non-alcoholic steatohepatitis and primary biliary cholangitis, is on track to be in the clinic in the coming months, and we have several promising leads in RSV and HBV which we are evaluating to move forward in 2017."

Development Program and Business Review

• Enanta is planning to initiate phase 1 clinical development in the second half of calendar 2016 for EDP-305, Enanta's wholly-owned Farnesoid X Receptor (FXR) agonist candidate for non-alcoholic steatohepatitis (NASH) and Primary Biliary Cholangitis (PBC).

- Several abstracts regarding Enanta's wholly-owned pipeline programs in HCV and NASH have been accepted for presentation at The Liver Meeting[®] in November 2016.
- The U.S. Food and Drug Administration granted marketing approval for AbbVie's VIEKIRA XR [™] for the treatment of genotype 1 hepatitis C virus. VIEKIRA XR, which includes paritaprevir, is a once-daily dosing regimen of the three direct-acting antivirals (DAAs) in VIEKIRA PAK[®].
- Enanta initiated a phase 1 proof-of-concept study in HCV using EDP-494, Enanta's cyclophilin inhibitor targeted to treat resistance-associated variants, DAA failures and other hard to treat populations with HCV infection.

Upcoming Events and Presentations

- September 7-8, 2016 Baird 2016 Global Healthcare Conference, New York
- September 12-14, 2016 Morgan Stanley Global Healthcare Conference, New York
- Enanta plans to issue its fourth quarter financial results press release, and hold a conference call regarding those results, during the week of November 21, 2016.

Conference Call and Webcast Information

Enanta will host a conference call and webcast today at 4:30 p.m. Eastern time. To participate in the live conference call, please dial (855) 840-0595 in the U.S. or (518) 444-4814 for international callers. A replay of the conference call will be available starting at approximately 7:30 p.m. Eastern time on August 8, 2016, through 11:59 p.m. Eastern time on August 12, 2016 by dialing (855) 859-2056 from the U.S. or (404) 537-3406 for international callers. The passcode for both the live call and the replay is 46602812. A live audio webcast of the call and replay can be accessed by visiting the "Calendar of Events" section on the "Investors" page of Enanta's website at www.enanta.com.

About Enanta

Enanta Pharmaceuticals is a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs for viral infections and liver diseases. Enanta's research and development is currently focused on four disease targets: Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Non-alcoholic Steatohepatitis (NASH) and Respiratory Syncytial Virus (RSV).

Enanta has developed direct-acting-antiviral (DAA) inhibitors designed for use against HCV. Enanta's protease inhibitors, developed through its collaboration with AbbVie, include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and ABT-493, Enanta's second protease inhibitor, which AbbVie is developing in phase 3 studies in combination with ABT-530, AbbVie's NS5A inhibitor. Enanta has also discovered a cyclophilin inhibitor, EDP-494, a novel, host-targeting mechanism for HCV, which is now in phase 1 clinical development, and EDP-305, an FXR agonist, which Enanta plans to advance into clinical development for NASH later in 2016. In addition, Enanta has early lead candidates for HBV and RSV in preclinical testing. Please visit www.enanta.com for more information on Enanta's programs and pipeline.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for further clinical development of Enanta's cyclophilin inhibitor for the treatment of HCV, the prospects for advancing EDP-305 for the treatment of NASH into clinical development, the prospects for advancement of another program in HBV or RSV, and the projected sufficiency of Enanta's cash-equivalent resources and marketable securities. Statements that are not historical facts are based on management's current expectations, estimates, forecasts and projections about Enanta's business and the industry in which it operates and management's beliefs and assumptions. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: Enanta's revenues in the short-term are dependent upon the success of AbbVie's continuing commercialization efforts for its HCV treatment regimens containing paritaprevir; Enanta's longer term revenues will be dependent upon the success of AbbVie's planned clinical development, regulatory approval and commercialization of its investigational HCV treatment regimen containing ABT-493; competitive pricing, market acceptance and reimbursement rates of AbbVie's treatment regimens containing paritaprevir or ABT-493 compared to competitive HCV products on the market and product candidates of other companies under development; the discovery and development risks of early stage discovery efforts in new disease areas such as HBV, NASH and RSV; potential competition from the development efforts of others in those new disease areas; Enanta's lack of clinical development experience; Enanta's need to attract and retain senior management and key scientific personnel; Enanta's need to obtain and maintain patent protection for its product candidates and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in "Risk Factors" in Enanta's most recent Form 10-K for the fiscal year ended September 30, 2015 and other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

ENANTA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share amounts)

Three Months Ended Nine Months Ended June 30, June 30,

	 2016		2015	_	2016		2015
Revenue	\$ 13,978	\$	11,599	\$	75,427	\$	146,464
Operating expenses							
Research and development	10,785		6,253		28,961		16,140
General and administrative	 4,282		3,643		12,526		9,850
Total operating expenses	15,067		9,896		41,487		25,990
Income (loss) from operations	 (1,089)		1,703		33,940		120,474
Other income, net	447		287		1,248		798
Income (loss) before income taxes	(642)	_	1,990		35,188		121,272
Income tax (expense) benefit	(434)		428	((11,720)	(48,092)
Net income (loss)	\$ (1,076)	\$	2,418	\$	23,468	\$	73,180
Net income (loss) per share							
Basic	\$ (0.06)	\$	0.13	\$	1.24	\$	3.92
Diluted	\$ (0.06)	\$	0.13	\$	1.22	\$	3.80
Weighted average common shares outstanding							
Basic	18,983		18,697		18,893		18,660
Diluted	18,983		19,278		19,223		19,277

ENANTA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	June 30, 2016	September 30, 2015		
Assets				
Current assets				
Cash and cash equivalents	\$ 24,789	\$ 21,726		
Short-term marketable securities	193,676	123,479		
Accounts receivable	13,978	15,289		
Unbilled receivables	-	433		
Deferred tax assets	1,147	1,447		
Prepaid expenses and other current assets	8,200	8,267		
Total current assets	241,790	170,641		
Property and equipment, net	7,499	5,886		
Long-term marketable securities	26,194	64,238		
Deferred tax assets	5,843	4,640		
Restricted cash	608	608		
Total assets	\$281,934	\$ 246,013		
Liabilities and Stockholders' Equity				
Current liabilities				
Accounts payable	\$ 2,044	\$ 1,543		
Accrued expenses and other current liabilities	4,583	3,962		
Income taxes payable	2,942	1,199		
Total current liabilities	9,569	6,704		
Warrant liability	1,237	1,276		
Series 1 nonconvertible preferred stock	158	163		
Other long-term liabilities	1,963	1,713		
Total liabilities	12,927	9,856		
Total stockholders' equity	269,007	236,157		
Total liabilities and stockholders' equity	\$281,934	\$ 246,013		

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Investor Contact Enanta Pharmaceuticals, Inc. Carol Miceli, 617-607-0710 <u>cmiceli@enanta.com</u> or

Media Contact MacDougall Biomedical Communications Kari Watson, 781-235-3060 kwatson@macbiocom.com