



Enanta Pharmaceuticals Reports Financial Results for its Fiscal First Quarter Ended December 31, 2014

February 5, 2015

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- Reports total revenues for the quarter of \$77.5 million
- GAAP earnings of \$2.18 per diluted common share

WATERTOWN, Mass.--(BUSINESS WIRE)--Feb. 5, 2015-- 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 first quarter ended December 31, 2014.

Fiscal First Quarter Ended December 31, 2014 Financial Results

Revenue for the three months ended December 31, 2014 was \$77.5 million, compared to \$0.9 million for the three months ended December 31, 2013. The increase in revenue for the most recent quarter was primarily due to the achievement of a \$75 million milestone payable from AbbVie for the U.S. regulatory approval of VIEKIRA PAK™, as well as \$1.4 million in royalty revenue, which was earned from a portion of AbbVie's net sales of VIEKIRA PAK in the U.S. from the December 19, 2014 approval date through December 31, 2014. VIEKIRA PAK contains paritaprevir, Enanta's lead hepatitis C virus (HCV) protease inhibitor identified within the ongoing AbbVie-Enanta collaboration, and is one of the direct-acting antivirals in the regimen. Milestone payments, royalties and other payments from collaborations have varied significantly from period to period, and are expected to continue to do so.

Research and development expenses totaled \$4.5 million for the three months ended December 31, 2014, compared to \$4.3 million for the three months ended December 31, 2013. The increase in the three month period is primarily due to increased spending on Enanta's proprietary research programs.

General and administrative expenses totaled \$2.8 million for the three months ended December 31, 2014, compared to \$2.1 million for the three months ended December 31, 2013. The increase in the three month period primarily reflects increases in stock-based compensation expense, due principally to increases in Enanta's stock price, as well as additional expenses incurred as Enanta expands its operations.

Net income for the three months ended December 31, 2014 was \$42.0 million, or \$2.18 per diluted common share, compared to a net loss of \$5.4 million, or \$(0.30) per diluted common share, for the corresponding period in 2013. The increase in net income during the three-month period ended December 31, 2014 was primarily due to the milestone amount of \$75 million payable from AbbVie.

Cash, cash equivalents and short-term and long-term marketable securities totaled \$127.6 million at December 31, 2014, excluding the \$75 million milestone earned but not received during the quarter. This compares to a total of \$131.8 million in such accounts at September 30, 2014. Enanta expects that its current cash, cash equivalents and marketable securities will be sufficient to meet its anticipated cash requirements for at least the next 24 months.

"Our first wave of HCV market opportunity has begun with our HCV partner AbbVie's recent U.S. and European marketing approvals for VIEKIRA PAK™ and VIEKIRAX®, respectively," commented Jay R. Luly, Ph.D., President and Chief Executive Officer. "With a third potential HCV regimen approval anticipated in Japan later this year, and our next generation protease inhibitor candidate expected to advance into phase 3 studies this year as well, Enanta expects to have a portfolio of revenue-producing assets to support our research and development in new therapeutic areas of growth, beginning with our new NASH program targeting candidate selection for later this year."

Program and Business Review of the Quarter

- Enanta earned a \$75 million milestone payment from AbbVie for the U.S. Food and Drug Administration (FDA) approval of AbbVie's VIEKIRA PAK, an HCV treatment regimen for genotype 1 HCV patients. Paritaprevir, Enanta's lead protease inhibitor identified within the ongoing AbbVie-Enanta collaboration, is one of the direct-acting antivirals in the regimen.
- AbbVie announced that Enanta's next-generation protease inhibitor, ABT-493, is expected to advance into phase 3 clinical studies later this year. ABT-493 is being developed in combination with ABT-530, AbbVie's next generation NS5A inhibitor, and this regimen is designed to provide an all-oral, interferon-free, once-daily, pan-genotypic treatment option for HCV patients.
- Enanta regained all rights to EDP-239, an NS5A inhibitor for HCV which was discovered by Enanta and was being developed by Novartis. Enanta expects to complete a proof-of-concept study of EDP-239 initiated by Novartis and is evaluating the development path forward for this asset.

Recent Developments since January 1, 2015

- Topline phase 3 results from AbbVie's GIFT-1 study of its 2-DAA combination in Japan (paritaprevir/ombitasvir/ritonavir,

once daily) demonstrated a 95 percent (n=106/112) sustained virologic response rate at 12 weeks post-treatment (SVR₁₂) in the sub-group of previously untreated non-cirrhotic adult GT1b Japanese patients who were eligible for therapy with interferon (IFN) and had a high viral load. AbbVie has stated it expects to submit an application for regulatory approval of this regimen in Japan during the first calendar quarter of 2015.

- Building on its expertise in liver and viral diseases, Enanta announced that preclinical candidate identification is ongoing for its Farnesoid X Receptor (FXR) agonist program for treatment of non-alcoholic steatohepatitis (NASH). Enanta expects to select a candidate during 2015.
- On January 16, 2015, Enanta announced that the European Commission granted marketing authorizations for AbbVie's two paritaprevir-containing regimens, one for genotype 1 HCV infection and one for genotype 4. Enanta is entitled to a \$50 million milestone payment from AbbVie upon commercialization regulatory approval in Europe for a regimen containing paritaprevir. Enanta expects to receive this payment during its fiscal second quarter ending March 31, 2015.

Upcoming Events and Presentations

Enanta management will participate in the following upcoming investor conferences and events:

- February 12, Leerink Global Healthcare Conference, New York
- February 19, Annual Meeting of Stockholders, Boston, MA
- March 10, Barclay's Global Healthcare Conference, Miami
- Week of May 4-8, fiscal second quarter financial results press release and conference call

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 is discovering, and in some cases developing, novel inhibitors designed for use against the hepatitis C virus (HCV). These inhibitors include members of the direct-acting-antiviral (DAA) inhibitor classes – protease (partnered with AbbVie), NS5A, and nucleotide polymerase – as well as a host-targeted antiviral (HTA) inhibitor class targeted against cyclophilin. In addition, Enanta has a preclinical program in non-alcoholic steatohepatitis, or NASH, which is a condition that results in liver inflammation and liver damage caused by a buildup of fat in the liver.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for regulatory filing and approval in Japan for AbbVie's HCV treatment regimen containing paritaprevir, the prospects for AbbVie's development of a regimen containing ABT-493, the prospects for completion of a proof-of-concept study of EDP-239, the prospects for selection of a NASH development candidate, the prospects for future revenues generated from products sales and development 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 reliance on AbbVie's planned regulatory approval and commercialization efforts for its treatment regimens containing paritaprevir; Enanta's reliance on AbbVie's planned clinical development of ABT-493; regulatory actions affecting further approvals of treatment regimens containing paritaprevir or any approval of a treatment regimen containing ABT-493; the pricing, market acceptance and reimbursement rates of such treatment regimens compared to competitive HCV product candidates of other companies; the risk of early stage discovery efforts in 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, 2014 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	
	December 31,	
	2014	2013
Revenue	\$ 77,498	\$ 893
Operating expenses		
Research and development	4,519	4,263

General and administrative	2,769	2,087
Total operating expenses	<u>7,288</u>	<u>6,350</u>
Income (loss) from operations	70,210	(5,457)
Other income, net	<u>301</u>	<u>87</u>
Income (loss) before income taxes	70,511	(5,370)
Income tax expense	<u>(28,502)</u>	<u>-</u>
Net income (loss)	<u>\$ 42,009</u>	<u>\$(5,370)</u>

Net income (loss) per share		
Basic	\$ 2.26	\$ (0.30)
Diluted	\$ 2.18	\$ (0.30)
Weighted average common shares outstanding		
Basic	18,603	17,949
Diluted	19,283	17,949

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

	<u>December 31,</u> <u>2014</u>	<u>September 30,</u> <u>2014</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 34,130	\$ 30,699
Short-term marketable securities	69,892	60,065
Accounts receivable	76,626	1,724
Unbilled receivables	1,882	2,770
Deferred tax assets	1,348	11,123
Prepaid expenses and other current assets	<u>1,218</u>	<u>1,594</u>
Total current assets	185,096	107,975
Property and equipment, net	1,922	1,803
Long-term marketable securities	23,568	41,003
Deferred tax assets	4,405	4,198
Restricted cash	<u>436</u>	<u>436</u>
Total assets	<u>\$ 215,427</u>	<u>\$ 155,415</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 567	\$ 1,874
Accrued expenses	2,403	2,872
Income taxes payable	<u>16,896</u>	<u>-</u>
Total current liabilities	19,866	4,746
Warrant liability	1,427	1,584
Series 1 nonconvertible preferred stock	183	202
Other long-term liabilities	<u>238</u>	<u>229</u>
Total liabilities	21,714	6,761
Total stockholders' equity	<u>193,713</u>	<u>148,654</u>
Total liabilities and stockholders' equity	<u>\$ 215,427</u>	<u>\$ 155,415</u>



Source: Enanta Pharmaceuticals, Inc.

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