Enanta Pharmaceuticals Reports Financial Results for its Fiscal Fourth Quarter and Year Ended September 30, 2016

November 21, 2016
Download this Press Release

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

- *Royalty revenue increased $23.6 million year over year*
- *R&D expense increased $17.3 million year over year in support of pipeline development*
- *Phase 1 clinical study initiated with EDP-305, Enanta's lead Farnesoid X Receptor (FXR) agonist candidate for NASH and Primary Biliary Cholangitis (PBC), in healthy adults and in adults with presumptive non-alcoholic fatty liver disease (NAFLD)*
- *Cash and marketable securities totaled $242.2 million at September 30, 2016*

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 21, 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 fourth quarter and year ended September 30, 2016.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $242.2 million at September 30, 2016. 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 Fourth Quarter and Year Ended September 30, 2016 Financial Results
Revenue from royalties on AbbVie's hepatitis C virus (HCV) treatment regimens was $12.8 million for the three months ended September 30, 2016 compared to $14.4 million for the same period in 2015. For the twelve months ended September 30, 2016, total revenue was $88.3 million compared to total revenue of $160.9 million for the same period in 2015. The decrease in revenue in the 2016 period was due to milestone payments of $125.0 million earned in 2015, compared to milestone payments of $30.0 million earned in 2016. The decrease in milestone revenue was partially offset by an increase in royalty revenue of $23.6 million. The $125.0 million and $30.0 million milestone payments were received from AbbVie under our collaboration agreement and were based on the achievement of commercialization regulatory approvals of AbbVie's hepatitis C virus (HCV) treatment regimens in the U.S. and Europe (2015) and Japan (2016), respectively. 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 $11.5 million for the three months ended September 30, 2016, compared to $7.0 million for the same period in 2015. For the twelve months ended September 30, 2016, research and development expenses were $40.5 million, compared to $23.2 million for the same period in 2015. The increases in the three and twelve month periods were primarily due to increased pre-clinical and clinical costs associated with 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 $4.4 million for the three months ended September 30, 2016, compared to $3.7 million for the same period in 2015. For the twelve months ended September 30, 2016, general and administrative expenses were $17.0 million compared to $13.5 million for the same period in 2015. The increase in the three and twelve month periods primarily reflects increases in stock-based compensation expense driven by increased headcount.

Enanta recorded an income tax benefit for the three months ended September 30, 2016 of $0.8 million compared to $1.6 million for the same period in 2015. Income tax expense for the twelve months ended September 30, 2016 was $10.9 million compared to $46.5 million for the corresponding period in 2015, representing annual effective tax rates of 33.5% and 37.0%, respectively, for those periods. The decrease in the annual effective tax rate in 2016 was primarily driven by increases in estimated research and development tax credits year over year as we continue to expand our research and development efforts.

Net loss for the three months ended September 30, 2016 was ($1.8) million, or ($0.09) per diluted common share, compared to net income of $5.8 million or $0.29 per diluted common share, for the corresponding period in 2015. Net income for the twelve months ended September 30, 2016 was $21.7 million, or $1.13 per diluted common share, compared to net income of $79.0 million or $4.09 per diluted common share, for the corresponding period in 2015.

"Enanta made significant progress this past year and executed on its stated goals for advancing our pipeline," commented Jay R. Luly, Ph.D., President and Chief Executive Officer. "We initiated Phase 1 trials of EDP-305, our lead FXR agonist, which we are developing for the treatment of NASH, as well as EDP-494, our novel cyclophilin inhibitor. In addition, we advanced promising leads in RSV and HBV, which we are evaluating to move forward in 2017."

Development Program and Business Review for the Quarter

Hepatitis C Virus (HCV)

- AbbVie announced results from several Phase 3 studies of its investigational pan-genotypic regimen of glecaprevir (ABT-493)/pibrentasvir (ABT-530) (G/P) for the treatment of patients with HCV, in which 97.5 percent of chronic HCV infected patients without cirrhosis and new to treatment across all major genotypes (GT1-6) achieved SVR_{12} with just 8 weeks of G/P treatment. AbbVie also announced results of its EXPEDITION-4 study in chronic HCV patients with chronic kidney disease (CKD), in which 98 percent (n=102/104 of patients across all major genotypes (GT1-6) achieved SVR_{12} with 12 weeks of treatment with G/P.
- AbbVie expects to file a New Drug Application with the U.S. Food and Drug Administration by the end of 2016 and to file Marketing Authorization Applications outside the U.S. during the first quarter of 2017. AbbVie anticipates commercialization of G/P in the U.S. in 2017. Glecaprevir is Enanta's next-generation protease inhibitor, which is being developed by AbbVie in combination with pibrentasvir (ABT-530), AbbVie's next-generation NS5A Inhibitor.
- The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for the G/P combination for the treatment of genotype 1 (GT1) patients with chronic hepatitis C virus (HCV) who failed previous therapy with direct-acting antivirals (DAAs), including previous therapy with an NS5A inhibitor and/or protease inhibitor.

NASH (non-alcoholic steatohepatitis)

- Several poster presentations regarding Enanta's wholly-owned pipeline program in NASH were presented at The Liver Meeting® in November. Preclinical data presented demonstrated that EDP-305 is a potent and selective FXR agonist that reduces fibrosis progression and shows favorable lipid metabolism in pre-clinical models.
- In September Enanta initiated a phase 1 clinical study of EDP-305, its lead Farnesoid X Receptor (FXR) agonist candidate for NASH and Primary Biliary Cholangitis (PBC), in healthy adults and in adults with presumptive non-alcoholic fatty liver disease (NAFLD).

Respiratory Syncytial Virus (RSV)

- Enanta presented promising data on EP-023938, a lead compound for the treatment of Respiratory Syncytial Virus (RSV) based on promising preclinical data presented at the 10th Annual Respiratory Syncytial Virus Conference in September 2016. Data demonstrated that EP-023938 is a potent inhibitor of both RSV-A and RSV-B with a high barrier to resistance post-infection, and maintains antiviral potency across all clinical isolates tested, as well as virus that was resistant to fusion inhibitors.

Financial Guidance

- For the full fiscal year ending September 30, 2017, Enanta expects to incur between $50.0 and $60.0 million of research and development expense.

Upcoming Events and Presentations

- J.P. Morgan Healthcare conference January 9-12, 2017, San Francisco, CA
- Enanta plans to issue its fiscal first quarter 2017 financial results press release, and hold a conference call regarding those results, during the week of February 6, 2017.

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 November 21, 2016, through 11:59 p.m. Eastern time on November 25, 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 9163079. 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 efforts are 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 discovered novel protease inhibitors that are members of the direct-acting-antiviral (DAA) inhibitor classes designed for use against the hepatitis C virus (HCV). These protease inhibitors, developed through Enanta's collaboration with AbbVie, include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and glecaprevir (ABT-493), Enanta's second protease inhibitor product, which AbbVie has developed in Phase 3 studies in a fixed-dose combination (G/P) with AbbVie's second NS5A inhibitor, pibrentasvir (ABT-530), and is preparing for regulatory approval filings in the U.S., Europe and Japan.

Enanta has also discovered EDP-305, an FXR agonist product candidate for NASH, currently in Phase 1 clinical development, as well as a cyclophilin

inhibitor, EDP-494, a novel host-targeting mechanism for HCV, which is also in Phase 1 clinical development. In addition, Enanta has early lead candidates for HBV and RSV in preclinical development. Please visit www.enanta.com for more information on our 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 EDP-305 for the treatment of NASH and EDP-494 for the treatment of HCV, the prospects for advancement of Enanta's other programs in HBV and 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 regulatory approval and commercialization of G/P, its investigational HCV treatment combination containing glecaprevir (ABT-493); competitive pricing, market acceptance and reimbursement rates of AbbVie's treatment regimens containing paritaprevir or its G/P combination 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 September 30,		Year Ended September 30,	
	2016	2015	2016	2015
Revenue	$ 12,841	$ 14,416	$ 88,268	$160,880
Operating expenses				
Research and development	11,500	7,049	40,461	23,189
General and administrative	4,440	3,693	16,966	13,543
Total operating expenses	15,940	10,742	57,427	36,732
Income (loss) from operations	(3,099)	3,674	30,841	124,148
Other income, net	471	509	1,719	1,307
Income (loss) before income taxes	(2,628)	4,183	32,560	125,455
Income tax (expense) benefit	826	1,629	(10,894)	(46,463)
Net income (loss)	$ (1,802)	$ 5,812	$ 21,666	$ 78,992
Net income (loss) per share				
Basic	$ (0.09)	$ 0.30	$ 1.14	$ 4.23
Diluted	$ (0.09)	$ 0.29	$ 1.13	$ 4.09
Weighted average common shares outstanding				
Basic	19,036	18,714	18,929	18,673
Diluted	19,036	19,337	19,224	19,295

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

	September 30, 2016	September 30, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 16,577	$ 21,726
Short-term marketable securities	193,507	123,479
Accounts receivable	12,841	15,289
Unbilled receivables	-	433
Deferred tax assets	-	1,447
Prepaid expenses and other current assets	9,231	8,267

Total current assets	232,156	170,641
Property and equipment, net	8,004	5,886
Long-term marketable securities	32,119	64,238
Deferred tax assets	8,390	4,640
Restricted cash	608	608
Total assets	$ 281,277	$ 246,013
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,377	$ 1,543
Accrued expenses and other current liabilities	4,512	3,962
Income taxes payable	-	1,199
Total current liabilities	7,889	6,704
Warrant liability	1,251	1,276
Series 1 nonconvertible preferred stock	159	163
Other long-term liabilities	2,042	1,713
Total liabilities	11,341	9,856
Total stockholders' equity	269,936	236,157
Total liabilities and stockholders' equity	$ 281,277	$ 246,013

View source version on businesswire.com: http://www.businesswire.com/news/home/20161121005884/en/

Source: Enanta Pharmaceuticals, Inc.

Investor Contact
Enanta Pharmaceuticals, Inc.
Carol Miceli, 617-607-0710
cmiceli@enanta.com
or
Media Contact
MacDougall Biomedical Communications
Kari Watson, 781-235-3060
kwatson@macbiocom.com