Enanta Pharmaceuticals Reports Financial Results for its Fourth Quarter and Year Ended September 30, 2017

November 20, 2017
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Webcast and Conference Call today at 4:30 p.m. ET

- *Cash and marketable securities totaled $293.7 million at September 30, 2017*
- *Total revenue for the quarter was $75.9 million*
- *Milestone payments totaling $65.0 million received following AbbVie's U.S. approval of MAVYRET™ (glecaprevir/pibrentasvir) and EU approval of MAVIRET™ (glecaprevir/pibrentasvir)*
- *Positive Phase 1 results for EDP-305 support further clinical evaluation in PBC and NASH patients*
- *Fast Track designation granted to EDP-305 by the U.S. FDA for the treatment of patients with primary biliary cholangitis.*

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 20, 2017-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a chemistry-driven biotechnology company dedicated to creating and developing small molecule drugs for viral infections and liver diseases, today reported financial results for its fiscal fourth quarter and year ended September 30, 2017.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $293.7 million at September 30, 2017. This compares to a total of $242.2 million in such accounts 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 and development programs for the foreseeable future.

"Enanta has made great progress this past year and has delivered on several key clinical and financial milestones," stated Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta. "Enanta is on track this quarter to earn the final regulatory milestone in our eleven year HCV collaboration with AbbVie, which would mean we would have successfully earned all clinical and regulatory milestones under the collaboration. To date, this collaboration has provided us with a total of approximately $500 million to fund and advance our internal pipeline. With these resources, we expect to initiate two clinical studies by the end of 2017: a Phase 2 study of our lead FXR agonist EDP-305 in PBC, and a Phase 1 study of our direct-acting antiviral inhibitor EDP-938 for RSV."

Fiscal Fourth Quarter and Year Ended September 30, 2017 Financial Results

Total revenue for the three months ended September 30, 2017 was $75.9 million, compared to $12.8 million for the three months ended September 30, 2016. For the twelve months ended September 30, 2017, total revenue was $102.8 million, compared to $88.3 million for the same period in 2016. The increase in revenue for the quarter was due to $65.0 million in milestone payments for the U.S. and EU approvals of AbbVie's new HCV regimen under the tradenames MAVYRET™ and MAVIRET™, respectively. For the twelve months ending September 30, 2017, revenue also included $37.8 million in royalties earned on AbbVie's worldwide net sales of HCV regimens containing paritaprevir or glecaprevir. For the 2016 twelve-month period, revenue consisted primarily of $57.7 million of royalty revenues earned on AbbVie's worldwide net sales of HCV regimens containing paritaprevir, as well as a $30.0 million milestone payment for the reimbursement approval of one of those regimens, VIEKIRAX®, in Japan in November 2015. Milestone payments and royalties have varied significantly from period to period, and we expect that variability to continue in the future.

Research and development expenses totaled $16.5 million for the three months ended September 30, 2017, compared to $11.5 million for the three months ended September 30, 2016. For the twelve months ended September 30, 2017, research and development expenses totaled $57.5 million compared to $40.5 million for the same period in 2016. The increase in research and development expenses in both periods was primarily due to increased preclinical and clinical costs associated with the progression of Enanta's wholly-owned R&D programs in non-alcoholic steatohepatitis (NASH)/primary biliary cholangitis (PBC), respiratory syncytial virus (RSV) and hepatitis B virus (HBV).

General and administrative expenses totaled $5.1 million for the three months ended September 30, 2017, compared to $4.4 million for the three months ended September 30, 2016. For the twelve months ended September 30, 2017, general and administrative expenses totaled $20.7 million, compared to $17.0 million for the same period in 2016. For the three-month period, the increase in general and administrative expenses was primarily due to increases in compensation expense driven by increased headcount. For the twelve-month period, the increase was due to increased headcount as well as achievement of milestones under existing performance-based equity awards.

Enanta recorded income tax expense of $18.4 million for the three months ended September 30, 2017 compared to an income tax benefit of $0.8 million for the same period in 2016. Enanta recorded income tax expense of $9.2 million for the year ended September 30, 2017 compared to income tax expense of $10.9 million for the same period in 2016. The Company's effective tax rate for fiscal 2017 was approximately 34%.

Net income for the three months ended September 30, 2017 was $36.5 million, or $1.86 per diluted common share, compared to a net loss of $1.8 million, or $(0.09) per diluted common share, for the corresponding period in 2016. For the twelve months ended September 30, 2017, net income was $17.7 million, or $0.91 per diluted common share, compared to net income of $21.7 million, or $1.13 per diluted common share, for the corresponding period in 2016.

Development Program and Business Review

- On October 23, Enanta announced positive results from its Phase 1 clinical study of EDP-305, Enanta's lead FXR agonist for non-alcoholic steatohepatitis (NASH) and primary biliary cholangitis (PBC). In this study of single ascending doses (SAD) and multiple doses at ascending dose levels per subject cohort (MAD), EDP-305 was generally safe and well tolerated over a broad range of single and multiple doses with pharmacokinetic (PK) data supporting once daily oral dosing. EDP-305 also exhibited strong engagement of the FXR receptor as evidenced by increased FGF19 levels and reduced C4 levels. These results support the ability to administer EDP-305 in future trials at doses that neither elicited clinically significant changes in lipids nor resulted in pruritus (itching).
- Enanta expects to initiate two clinical studies by the end of 2017: a Phase 2 clinical study of EDP-305 in patients with primary biliary cholangitis (PBC) and a Phase 1 study of respiratory syncytial virus (RSV) development candidate EDP-938 in healthy volunteers. A Phase 2 clinical study of EDP-305 in patients with NASH is expected to begin in early 2018.
- The U.S. Food and Drug Administration (FDA) has granted Enanta's drug candidate EDP-305, an FXR agonist, Fast Track designation for the treatment of patients with primary biliary cholangitis.
- Bryan Goodwin, Ph.D., has recently joined Enanta as Vice President of Biology. Dr. Goodwin will provide senior leadership to the virology and NASH biology groups.
- During the quarter, Enanta received milestone payments of $65.0 million for the U.S. and European approvals of AbbVie's new MAVYRET™/MAVIRET™ (glecaprevir/pibrentasvir) regimen. Glecaprevir, Enanta's second protease inhibitor product, is part of this new HCV treatment regimen that will earn royalties for Enanta.
- On September 27, Enanta announced that AbbVie also received approval in Japan for MAVIRET™ (glecaprevir/pibrentasvir). Enanta will earn a $15.0 million milestone payment from AbbVie upon price reimbursement approval of MAVIRET™ in Japan, which is expected in the quarter ending December 31, 2017.

Financial Guidance for Fiscal Year Ending September 30, 2018

- Research and development expense between $90 million and $110 million
- General and administration expense between $22 million and $28 million

Upcoming Events and Presentations

- 36th Annual J.P. Morgan Healthcare Conference, January 7-11, 2018
- Enanta plans to issue its fiscal first quarter financial results press release, and hold a conference call regarding those results, on February 7, 2018.

Conference Call and Webcast Information

Enanta will host a conference call and webcast today at 4:30 p.m. ET. 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. ET on November 20, 2017, through 11:59 p.m. ET on November 23, 2017 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 6197609. A live audio webcast of the call and replay can be accessed by visiting the "Events and Presentation" section on the "Investors" page of Enanta's website at www.enanta.com.

About Enanta

Enanta Pharmaceuticals has used its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery of small molecule drugs for the treatment of viral infections and liver diseases. Two protease inhibitors, paritaprevir and glecaprevir, discovered and developed through Enanta's collaboration with AbbVie, have now been approved in jurisdictions around the world as part of AbbVie's direct-acting antiviral (DAA) regimens for the treatment of hepatitis C virus (HCV) infection, including the U.S.-marketed regimens MAVYRET™ (glecaprevir/pibrentasvir) and VIEKIRA PAK® (paritaprevir/ritonavir/ombitasvir/dasabuvir).

Royalties and milestone payments from the AbbVie collaboration are helping to fund Enanta's research and development efforts, which are currently focused on the following disease targets: non-alcoholic steatohepatitis (NASH)/ primary biliary cholangitis (PBC), respiratory syncytial virus (RSV) and hepatitis B virus (HBV). Please visit www.enanta.com for more information.

Forward Looking Statements

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's MAVYRET/MAVIRET regimen in HCV and the prospects for advancement of Enanta's earlier stage programs in NASH/PBC and RSV, as well as Enanta's projections of its expenses in 2018. 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 and its new MAVYRET/MAVIRET regimen; competitive pricing, market acceptance and reimbursement rates for AbbVie's HCV treatment regimens compared to competitive HCV products on the market; the discovery and development risks of early stage

discovery efforts in other disease areas such as NASH, PBC, RSV and HBV; potential competition from the development efforts of others in those other 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, 2016 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
UNAUDITED
(in thousands, except per share amounts)

	Three Months Ended September 30,		Year Ended September 30,	
	2017	2016	2017	2016
Revenue	$ 75,927	$ 12,841	$102,814	$ 88,268
Operating expenses				
Research and development	16,514	11,500	57,451	40,461
General and administrative	5,118	4,440	20,749	16,966
Total operating expenses	21,632	15,940	78,200	57,427
Income (loss) from operations	54,295	(3,099)	24,614	30,841
Other income, net	660	471	2,333	1,719
Income (loss) before income taxes	54,955	(2,628)	26,947	32,560
Income tax (expense) benefit	(18,447)	826	(9,237)	(10,894)
Net income (loss)	$ 36,508	$ (1,802)	$ 17,710	$ 21,666
Net income (loss) per share				
Basic	$ 1.91	$ (0.09)	$ 0.93	$ 1.14
Diluted	$ 1.86	$ (0.09)	$ 0.91	$ 1.13
Weighted average common shares outstanding				
Basic	19,097	19,036	19,066	18,929
Diluted	19,611	19,036	19,407	19,224

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

	September 30, 2017	September 30, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 65,675	$ 16,577
Short-term marketable securities	157,994	193,507
Accounts receivable	10,614	12,841
Prepaid expenses and other current assets	3,536	9,231
Total current assets	237,819	232,156
Property and equipment, net	8,049	8,004
Long-term marketable securities	70,038	32,119
Deferred tax assets	10,123	8,390
Restricted cash	608	608
Total assets	$ 326,637	$ 281,277
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,714	$ 3,377
Accrued expenses and other current liabilities	7,970	4,512
Income taxes payable	9,298	-

Total current liabilities	20,982	7,889
Warrant liability	807	1,251
Series 1 nonconvertible preferred stock	762	159
Other long-term liabilities	2,410	2,042
Total liabilities	24,961	11,341
Total stockholders' equity	301,676	269,936
Total liabilities and stockholders' equity	$ 326,637	$ 281,277

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