Enanta Pharmaceuticals Reports Financial Results for its Fiscal First Quarter Ended December 31, 2016

February 8, 2017
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WATERTOWN, Mass.--(BUSINESS WIRE)--

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, 2016.' Enanta Pharmaceuticals, Inc. (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, 2016.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $244.4 million at December 31, 2016. This compares to a total of $242.4 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 for the foreseeable future.

Fiscal First Quarter Ended December 31, 2016 Financial Results

Total revenue for the three months ended December 31, 2016 was $10.4 million, compared to $48.4 million for the three months ended December 31, 2015. For the current quarter, revenue consisted exclusively of royalties earned on AbbVie's worldwide net sales of HCV regimens containing paritaprevir. For the 2015 period, revenue primarily consisted of royalty revenue of $17.9 million and a $30.0 million milestone payment for the reimbursement approval of VIEKIRAX® in Japan. 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 $12.5 million for the three months ended December 31, 2016, compared to $9.0 million for the three months ended December 31, 2015. The increase in research and development expenses 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 $4.9 million for the three months ended December 31, 2016, compared to $3.8 million for the three months ended December 31, 2015. The increase in general and administrative expenses was primarily due to increases in stock-based compensation expense driven by increased headcount and achievement of milestones under existing performance-based restricted stock unit awards.

Enanta recorded an income tax benefit for the three months ended December 31, 2016 of $1.5 million compared to income tax expense of $9.7 million for the same period in 2015. The Company's estimated annual effective tax rate for fiscal 2017 of 23.6% was driven by federal research and development tax credits which reduced the Company's annual effective tax rate below the statutory rate of 35.0%. For the three months ended December 31, 2015, the Company's effective tax rate of 27.1% was also driven by federal research and development tax credits.

Net loss for the three months ended December 31, 2016 was $5.0 million, or $(0.26) per diluted common share, compared to net income of $26.2 million, or $1.36 per diluted common share, for the corresponding period in 2015.

"With the NDA for glecaprevir/pibrentasvir, or G/P, now having been granted priority review in the U.S. and the MAA for G/P validated with accelerated assessment in the EU, we expect to earn a substantial portion of the $80 million in commercialization regulatory approval milestone payments for G/P in calendar 2017," commented Jay R. Luly, Ph.D., President and Chief Executive Officer. "This collaboration, along with our existing financial resources, is providing funding for our advancing pipeline. We expect to complete our Phase 1 study of EDP-305 mid-year and later this year plan to initiate a Phase 2 study of EDP-305 in PBC. We also plan the initiation of clinical development of our lead RSV compound, EDP-938 in calendar 2017."

Development Program and Business Review

- In December, AbbVie submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for AbbVie's investigational HCV regimen of glecaprevir/pibrentasvir (G/P) for the treatment of patients infected with any of the major genotypes (GT1-6) of chronic hepatitis C virus. The FDA granted G/P Breakthrough Therapy Designation, and the NDA received priority review status. In the EU, the Marketing Authorization Application (MAA) for G/P was validated by the European Medicines Agency and was granted accelerated assessment in January 2017. Glecaprevir is Enanta's second protease inhibitor under development with AbbVie.
- In January, EDP-305, Enanta's lead FXR agonist, was granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of NASH patients with liver fibrosis.
- New data on EDP-305 was presented in a poster presentation at the NASH-TAG conference in Park City, Utah in early 2017. Data presented by Dr. Yury V. Popov demonstrated that treatment with EDP-305 improved pre-established liver injury and hepatic fibrosis in an MCD-induced model of steatohepatitis in mice. EDP-305 had a strong inhibitory effect on liver fibrosis progression.
- Enanta selected EDP-938, a non-fusion inhibitor, as its first development candidate for RSV, and is planning to initiate a

Phase 1 clinical study in the fourth quarter of calendar 2017. Pre-clinical data presented at the 35th Annual J.P. Morgan Healthcare Conference demonstrated a rapid reduction in viral load, below the limits of detection (LOD) in animals treated with EDP-938.

Upcoming Events and Presentations

- February 15, 2017 – Leerink Partners 6th Annual Global Healthcare Conference, New York
- February 16, 2017 – Enanta Annual Meeting of Stockholders, 4:00 p.m. ET, Boston
- February 22, 2017 – 2017 RBC Capital Markets Global Healthcare Conference, New York
- Enanta plans to issue its fiscal second quarter financial results press release, and hold a conference call regarding those results, in the week of May 8, 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 February 8, 2017, through 11:59 p.m. Eastern time on February 13, 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 57578644. 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 the following disease targets: non-alcoholic steatohepatitis (NASH)/ primary biliary cholangitis (PBC), respiratory syncytial virus (RSV) and hepatitis B virus (HBV).

Enanta has discovered novel protease inhibitors for use against the hepatitis C virus (HCV). These protease inhibitors, developed through Enanta's collaboration with AbbVie, include paritaprevir, currently marketed in AbbVie's HCV regimens, and glecaprevir (ABT-493), Enanta's second protease inhibitor product, which AbbVie is developing as part of its investigational HCV regimen of glecaprevir/pibrentasvir (G/P) now in registration in the U.S. and the E.U. Royalties and any further milestone payments from this collaboration will provide funding for Enanta's earlier development programs, including its Phase 1 FXR agonist program for NASH/PBC, and its preclinical programs for HBV and RSV. Please visit www.enanta.com for more information on Enanta's programs and pipeline.

Forward Looking Statements
This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's investigational G/P regimen in HCV and the prospects for advancement of Enanta's earlier stage programs in NASH/PBC and RSV. 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 efforts to obtain regulatory approvals for G/P and commercialize that regimen; 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, 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 BALANCE SHEETS

UNAUDITED

(in thousands)

	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
Total stockholders' equity	268,168	269,936
Total liabilities and stockholders' equity	$ 278,379	$ 281,277

ENANTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share amounts)

	Three Months Ended December 31,	
	2016	**2015**
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, 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 common shares outstanding		
Basic	19,038	18,776
Diluted	19,038	19,269

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