Enanta Pharmaceuticals Reports Financial Results for its Fiscal Second Quarter Ended March 31, 2016

May 9, 2016
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Conference Call and Webcast Today at 4:30 p.m. ET

- *Royalty revenue from paritaprevir-containing regimens was $13.0 million*
- *Cash and marketable securities totaled $245.6 million at March 31, 2016*

WATERTOWN, Mass.--(BUSINESS WIRE)--May 9, 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 second quarter ended March 31, 2016.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $245.6 million at March 31, 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 Second Quarter Ended March 31, 2016 Financial Results

Revenue for the three months ended March 31, 2016 was $13.0 million, compared to $57.4 million for the three months ended March 31, 2015. For the six months ended March 31, 2016, revenue was $61.4 million compared to revenue of $134.9 million for the same period in 2015. The decrease in revenue in the 2016 periods was due primarily to the fact that revenue in the comparable periods in 2015 included the $50.0 million milestone payment earned in January 2015 for the European commercialization regulatory approval of VIEKIRAX™, and the six-month period in 2015 also included the $75.0 million milestone earned in December 2014 for the approval of VIEKIRA PAK® in the United States. The revenue decrease for the six month period due to the decrease in milestone payments was partially offset by higher royalties earned during the first half of fiscal 2016 from contractually specified portions of AbbVie's worldwide net sales of HCV regimens containing paritaprevir. Enanta began earning royalties from AbbVie upon its HCV product launch in Enanta's first fiscal quarter of 2015. 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 $9.1 million for the three months ended March 31, 2016, compared to $5.4 million for the three months ended March 31, 2015. For the six months ended March 31, 2016, research and development expenses were $18.2 million, compared to $9.9 million for the same period in 2015. The increase in the three and six month periods was primarily due to increased pre-clinical and clinical costs associated with Enanta's wholly-owned R&D programs in NASH, RSV, HBV and HCV cyclophilin.

General and administrative expenses totaled $4.4 million for the three months ended March 31, 2016, compared to $3.4 million for the three months ended March 31, 2015. For the six months ended March 31, 2016, general and administrative expenses were $8.2 million compared to $6.2 million for the same period in 2015. The increase in the three and six month periods primarily reflects increases in stock-based compensation expense driven by increased headcount and additional equity grants.

Income tax expense for the three months ended March 31, 2016 was $1.6 million compared to $20.0 million for the corresponding period in 2015. During the three months ended March 31, 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 six months ended March 31, 2016 was $11.3 million compared to $48.5 million for the corresponding period in 2015, representing annual effective tax rates of 31.5% and 40.7%, respectively, for those periods. For the six months ended March 31, 2016, Enanta's effective tax rate was lower than that in the comparable period of 2015 primarily due to lower state income taxes and higher federal research and development tax credits, which are factored into the annual effective tax rate.

Net loss for the three months ended March 31, 2016 was $1.6 million, or ($0.09) per diluted common share, compared to net income of $28.8 million or $1.49 per diluted common share, for the corresponding period in 2015. Net income for the six months ended March 31, 2016 was $24.5 million, or $1.28 per diluted common share, compared to net income of $70.8 million or $3.67 per diluted common share, for the corresponding period in 2015.

"Enanta remains in a strong financial position and continues to receive royalties from paritaprevir-containing regimens marketed globally," commented Jay R. Luly, Ph.D., President and Chief Executive Officer. "These ongoing royalties and our strong cash balance will continue to support our wholly-owned programs, including our cyclophilin candidate, EDP-494, currently in phase 1 development, and our NASH candidate, EDP-305, which is expected to begin phase 1 clinical development in the second half of calendar 2016."

Development Program and Business Review

- In April, new data on Enanta's second protease inhibitor, ABT-493, co-formulated in combination with AbbVie's NS5A inhibitor ABT-530, was presented at The Liver Meeting in Barcelona, Spain. Selected data from the SURVEYOR 1 and 2 studies demonstrated:
  - 97-98 percent SVR_{12} with eight weeks of treatment in genotypes 1, 2 or 3 HCV patients without cirrhosis;
  - 100 percent SVR_{12} with 12 weeks of treatment in difficult-to-treat genotype 3 patients with compensated cirrhosis

(Child-Pugh A) new to therapy; and

  - 100 percent SVR_{12} with 12 weeks of treatment in genotypes 4, 5 or 6 patients without cirrhosis; eight-week treatment duration is also being investigated in these genotypes in this ongoing study.

- A phase 1 clinical trial of EDP-494, Enanta's cyclophilin inhibitor targeted to treat RAVs, DAA failures and other hard to treat populations, is ongoing and Enanta plans to initiate a proof-of-concept study next quarter.
- In April, Enanta Pharmaceuticals announced that the U.S. FDA had approved AbbVie's supplemental New Drug Application for use of VIEKIRA PAK® without ribavirin in genotype 1b chronic hepatitis C patients with compensated cirrhosis (Child Pugh-A), which followed earlier approval in the European Union of AbbVie's VIEKIRAX® + EXVIERA® for similar genotype 1b patients.
- Enanta is on track to initiate a phase 1 clinical trial in the second half of calendar 2016 with EDP-305, Enanta's wholly-owned Farnesoid X Receptor (FXR) agonist candidate for non-alcoholic steatohepatitis (NASH) and Primary Biliary Cholangitis (PBC).

Upcoming Events and Presentations

- June 7-10, 2016 - Jefferies 2016 Healthcare Conference, New York
- June 21-22, 2016 - JMP Securities Life Sciences Conference, New York
- Enanta plans to issue its fiscal third quarter financial results press release, and hold a conference call regarding those results, during the week of August 8, 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 May 9, 2016, through 11:59 p.m. Eastern time on May 13, 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 99296308. 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 novel protease inhibitors and NS5A inhibitors that are members of the direct-acting-antiviral (DAA) inhibitor classes designed for use against the hepatitis C virus (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. 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 future royalties on sales of AbbVie's HCV treatment regimens containing paritaprevir, the prospects for AbbVie's development and regulatory approval of a new regimen containing ABT-493, 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 trials, 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 and commercialization of its investigational regimen containing ABT-493; regulatory actions affecting any approval of an 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, as well as HCV; 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 March 31,		Six Months Ended March 31,	
	2016	2015	2016	2015
Revenue	$ 13,004	$ 57,367	$ 61,449	$134,865
Operating expenses				
Research and development	9,143	5,368	18,176	9,887
General and administrative	4,426	3,438	8,244	6,207
Total operating expenses	13,569	8,806	26,420	16,094
Income (loss) from operations	(565)	48,561	35,029	118,771
Other income, net	472	210	801	511
Income (loss) before income taxes	(93)	48,771	35,830	119,282
Income tax expense	(1,552)	(20,018)	(11,286)	(48,520)
Net income (loss)	$ (1,645)	$ 28,753	$ 24,544	$ 70,762
Net income (loss) per share				
Basic	$ (0.09)	$ 1.54	$ 1.30	$ 3.80
Diluted	$ (0.09)	$ 1.49	$ 1.28	$ 3.67
Weighted average common shares outstanding				
Basic	18,921	18,680	18,848	18,641
Diluted	18,921	19,269	19,225	19,276

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

	March 31, 2016	September 30, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 56,360	$ 21,726
Short-term marketable securities	164,062	123,479
Accounts receivable	13,004	15,289
Unbilled receivables	-	433
Deferred tax assets	1,581	1,447
Prepaid expenses and other current assets	7,658	8,267
Total current assets	242,665	170,641
Property and equipment, net	7,691	5,886
Long-term marketable securities	25,224	64,238
Deferred tax assets	5,407	4,640
Restricted cash	608	608
Total assets	$ 281,595	$ 246,013
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,572	$ 1,543
Accrued expenses and other current liabilities	2,632	3,962
Income taxes payable	6,784	1,199
Total current liabilities	11,988	6,704
Warrant liability	1,223	1,276
Series 1 nonconvertible preferred stock	156	163
Other long-term liabilities	1,813	1,713
Total liabilities	15,180	9,856
Total stockholders' equity	266,415	236,157
Total liabilities and stockholders' equity	$ 281,595	$ 246,013

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