



## Enanta Pharmaceuticals Reports Financial Results for its Fiscal Second Quarter Ended March 31, 2017

May 8, 2017

[Download this Press Release](#)

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

- **Royalty revenue was \$9.0 million**
- **R&D expense increased to \$13.0 million in support of pipeline development**
- **Cash and marketable securities totaled \$240.9 million at March 31, 2017**

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

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled \$240.9 million at March 31, 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.

### Fiscal Second Quarter Ended March 31, 2017 Financial Results

Total revenue for the three months ended March 31, 2017 was \$9.0 million, compared to \$13.0 million for the three months ended March 31, 2016. For the six months ended March 31, 2017, total revenue was \$19.4 million, compared to \$61.4 million for the same period in 2016. For the three and six month periods ended March 31 2017, revenue consisted exclusively of royalties earned on AbbVie's worldwide net sales of HCV regimens containing paritaprevir. For the 2016 six month period, revenue consisted primarily of royalty revenues as well as 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 \$13.0 million for the three months ended March 31, 2017, compared to \$9.1 million for the three months ended March 31, 2016. For the six months ended March 31, 2017, research and development expenses totaled \$25.5 million compared to \$18.2 million for the same period in 2016. 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 \$5.5 million for the three months ended March 31, 2017, compared to \$4.4 million for the three months ended March 31, 2016. For the six months ended March 31, 2017, general and administrative expenses was \$10.4 million, compared to \$8.2 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 stock-based compensation expense driven by increased headcount. For the six month period, the increase was due to increased headcount as well as achievement of milestones under existing performance-based stock awards.

Enanta recorded an income tax benefit for the three months ended March 31, 2017 of \$3.6 million compared to an income tax expense of \$1.6 million for the same period in 2016. The Company's estimated annual effective tax rate for fiscal 2017 of 33.0 percent was slightly below the statutory rate of 35.0 percent due to the availability of federal research and development tax credits.

Net loss for the three months ended March 31, 2017 was \$5.4 million, or \$(0.28) per diluted common share, compared to net loss of \$1.6 million, or \$(0.09) per diluted common share, for the corresponding period in 2016. For the six months ended March 31, 2017, net loss was \$10.4 million, or \$(0.54) per diluted common share, compared to net income of \$24.5 million, or \$1.28 million per diluted common share, for the corresponding period in 2016.

"With our second partnered protease inhibitor product, glecaprevir, expected to launch starting in August as part of AbbVie's new, investigational G/P treatment for HCV, the prospects for additional milestone and royalty payments to us for G/P are significant," stated Jay R. Luly, Ph.D., President and Chief Executive Officer, Enanta. "Any such payments, coupled with our existing financial resources, will allow us to advance our clinical program in NASH/PBC and also fund our additional R&D programs, including our lead compound EDP-938 for RSV, scheduled to begin clinical development later this year."

### Development Program and Business Review

- Enanta presented new preclinical data on EDP-305, its wholly-owned FXR agonist for non-alcoholic steatohepatitis, at the International Liver Congress™ (ILC) 2017 in Amsterdam. Data from three poster presentations presented at the Congress demonstrated that EDP-305 is a potent Farnesoid X receptor (FXR) agonist that has been shown to reduce expression of fibrogenic genes, reduce fibrosis progression and improve non-alcoholic fatty liver disease (NAFLD) activity scores (NAS) in a variety of preclinical models.

- Enanta expects to present clinical data from our ongoing Phase 1 clinical study of EDP-305 in healthy volunteers and presumed NAFLD subjects<sup>1</sup> and to initiate NASH-enabling studies in the second half of this year. A Phase 2 study in PBC is expected to begin in the fourth quarter of calendar 2017 and Phase 2 studies in NASH are expected to begin in early 2018.
- Also at the ILC, AbbVie presented new data from its investigational, pan-genotypic, ribavirin-free regimen for hepatitis C virus (HCV) consisting of a combination of glecaprevir/pibrentasvir (G/P). Data from the EXPEDITION-1 study demonstrated that 99 percent (n=145/146) of chronic HCV infected patients with genotype 1, 2, 4, 5 or 6 and compensated cirrhosis (Child-Pugh A) achieved sustained virologic response at 12 weeks post-treatment (SVR<sub>12</sub>) with G/P. This high SVR<sub>12</sub> rate was seen following 12 weeks of G/P treatment without ribavirin. Data were also presented at the ILC from the ENDURANCE-3 study. In this study, 95 percent (n=149/157) of genotype 3 (GT3) chronic HCV-infected patients without cirrhosis and who were new to treatment, achieved sustained virologic response at 12 weeks post-treatment (SVR<sub>12</sub>) following 8 weeks of treatment with G/P.
- In March, Enanta announced the Japanese Ministry of Health, Labour and Welfare (MHLW) granted priority review designation to AbbVie's G/P combination for the treatment of all major genotypes (GT1-6) of chronic hepatitis C virus (HCV) infection. AbbVie had submitted the NDA for the G/P regimen in Japan in February 2017. The NDAs for G/P in the U.S and Japan have been granted priority review designation, and the MAA for G/P has been granted accelerated assessment in the E.U.

#### Upcoming Events and Presentations

- On June 25 at the XIX International Symposium on Respiratory Viral Infections in Berlin, Germany, Enanta will present data on EDP-938, its respiratory syncytial virus inhibitor candidate in an oral presentation titled: "*EDP-938, a Novel Non-Fusion Replication Inhibitor of Respiratory Syncytial Virus, Demonstrates Potent Antiviral Activities both In Vitro and In Vivo*".
- Enanta plans to issue its fiscal third quarter financial results press release, and hold a conference call regarding those results, on August 7, 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 May 8, 2017, through 11:59 p.m. Eastern time on May 12, 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 6851190. 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](http://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, pan-genotypic HCV regimen of glecaprevir/pibrentasvir (G/P) now in registration in the U.S., the E.U. and Japan and other jurisdictions. Royalties and any further milestone payments from this collaboration will provide additional 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](http://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 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.

<sup>1</sup> Presumed NAFLD subjects in this study are obese subjects, with or without pre-diabetes or type-2 diabetes.

**ENANTA PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**UNAUDITED**  
(in thousands, except per share amounts)

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>March 31,</b>		<b>March 31,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Revenue	\$ 8,959	\$ 13,004	\$ 19,376	\$ 61,449
Operating expenses				
Research and Development	13,004	9,143	25,530	18,176
General and administrative	5,461	4,426	10,398	8,244
Total operating expenses	<u>18,465</u>	<u>13,569</u>	<u>35,928</u>	<u>26,420</u>
Income (loss) from operations	(9,506)	(565)	(16,552)	35,029
Other income, net	549	472	1,073	801
Income (loss) before income taxes	(8,957)	(93)	(15,479)	35,830
Income tax (expense) benefit	3,565	(1,552)	5,107	(11,286)
Net income (loss)	<u>\$ (5,392)</u>	<u>\$ (1,645)</u>	<u>\$ (10,372)</u>	<u>\$ 24,544</u>
Net income (loss) per share				
Basic	\$ (0.28)	\$ (0.09)	\$ (0.54)	\$ 1.30
Diluted	\$ (0.28)	\$ (0.09)	\$ (0.54)	\$ 1.28
Weighted average common shares outstanding				
Basic	19,047	18,921	19,042	18,848
Diluted	19,047	18,921	19,042	19,225

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

	<b>March 31,</b>	<b>September 30,</b>
	<b>2017</b>	<b>2016</b>
Assets		
Current assets		
Cash and cash equivalents	\$ 19,211	\$ 16,577
Short-term marketable securities	156,362	193,507
Accounts receivable	8,959	12,841
Prepaid expenses and other current assets	<u>6,059</u>	<u>9,231</u>
Total current assets	190,591	232,156
Property and equipment, net	8,526	8,004
Long-term marketable securities	65,330	32,119
Deferred tax assets	13,903	8,390
Restricted cash	<u>608</u>	<u>608</u>
Total assets	<u>\$ 278,958</u>	<u>\$ 281,277</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 4,056	\$ 3,377
Accrued expenses and other current liabilities	<u>5,098</u>	<u>4,512</u>
Total current liabilities	9,154	7,889
Warrant liability	1,276	1,251
Series 1 nonconvertible preferred stock	162	159
Other long-term liabilities	<u>2,355</u>	<u>2,042</u>

	Total liabilities	<u>12,947</u>	<u>11,341</u>
Total stockholders' equity		<u>266,011</u>	<u>269,936</u>
	Total liabilities and stockholders' equity	<u>\$ 278,958</u>	<u>\$ 281,277</u>



View source version on businesswire.com: <http://www.businesswire.com/news/home/20170508006042/en/>

Source: Enanta Pharmaceuticals, Inc.

**Investor Contact**

Enanta Pharmaceuticals, Inc.

Carol Miceli, 617-607-0710

[cmiceli@enanta.com](mailto:cmiceli@enanta.com)

or

**Media Contact**

MacDougall Biomedical Communications

Kari Watson, 781-235-3060

[kwatson@macbiocom.com](mailto:kwatson@macbiocom.com)