Enanta Pharmaceuticals Reports Financial Results for its Fiscal Third Quarter Ended June 30, 2018

August 7, 2018
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Webcast and Conference Call today at 4:30 p.m. ET

- *Royalty revenue for the quarter increased to $57.3 million, a quarter-to-quarter increase of 30%*
- *Net income was $20.3 million, or $0.97 per diluted common share*
- *Preliminary Phase 1 results demonstrate that RSV candidate EDP-938 was generally safe and well tolerated and support its progression to Phase 2*
- *Cash and marketable securities totaled $295.5 million at June 30, 2018*

WATERTOWN, Mass.--(BUSINESS WIRE)-- 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 third quarter ended June 30, 2018.

“Enanta continues to benefit from the increasing royalty income from AbbVie’s net sales of MAVYRET, the best-selling drug for hepatitis C, which is funding development of our wholly owned programs in RSV, NASH, PBC and HBV,” commented Jay R. Luly, Ph.D., President and Chief Executive Officer, Enanta. “With net sales of MAVYRET in the first half of calendar and royalty year 2018 reaching over $1.75 billion, our royalties on 50% of those sales have moved into higher royalty rate tiers this quarter. In addition, in RSV we have completed dosing our Phase 1 trial of EDP-938, and expect to report final results later this year.”

Fiscal Third Quarter Ended June 30, 2018 Financial Results

Total revenue for the three months ended June 30, 2018 was $57.3 million, compared to $7.5 million for the three months ended June 30, 2017. The increase in revenue was due to an increase in royalties earned on AbbVie’s worldwide net sales of MAVYRET™/MAVIRET™ (glecaprevir/pibrentasvir), in major markets. For the three months ended June 30, 2017, revenue consisted exclusively of royalties earned on AbbVie’s worldwide net sales of HCV regimens containing paritaprevir.

Research and development expenses totaled $28.5 million for the three months ended June 30, 2018, compared to $15.4 million for the three months ended June 30, 2017. 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 respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH) and primary biliary cholangitis (PBC), as well as research efforts in hepatitis B virus (HBV).

General and administrative expenses totaled $6.1 million for the three months ended June 30, 2018, compared to $5.2 million for the three months ended June 30, 2017. The increase in general and administrative expenses was primarily due to an increase in headcount.

Enanta recorded income tax expense of $3.7 million for the three months ended June 30, 2018, compared to an income tax benefit of $4.1 million for the three months ended June 30, 2017. During the three months ended June 30, 2018, income tax expense reflected the significant increase in pre-tax income during the quarter, offset by the impact of excess tax benefits from employee stock award activity. Enanta’s estimated annual effective tax rate for fiscal 2018 of 22.2 percent includes the impact of a non-cash revaluation charge against deferred tax assets to reflect the reduced federal corporate income tax rate as a result of the enactment of the U.S. Tax Cuts and Jobs Act in December 2017, during the first quarter of Enanta’s current fiscal year.

Net income for the three months ended June 30, 2018 was $20.3 million, or $0.97 per diluted common share, compared to a net loss of $8.4 million, or $(0.44) per diluted common share, for the corresponding period in 2017.

Enanta’s cash, cash equivalents and short-term and long-term marketable securities totaled $295.5 million at June 30, 2018. This compares to a total of $293.7 million at September 30, 2017. 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.

Development Programs and Business Review

Respiratory Syncytial Virus

- Preliminary Phase 1 results demonstrate that EDP-938 was generally safe and well tolerated over a broad range of single and multiple doses with good pharmacokinetic (PK) data. Final results will be presented in the fourth calendar quarter of 2018.
- A Phase 2 proof-of-concept challenge study in healthy adults inoculated with RSV is expected to begin in the fourth calendar quarter of 2018.

NASH and PBC

- Enrollment continues in the ARGON-1 study for non-alcoholic steatohepatitis (NASH), and in the INTREPID study for primary biliary cholangitis (PBC) patients. We expect enrollment to continue throughout the year and into 2019.

Hepatitis B Virus

- Enanta's HBV program continues to move ahead and has generated promising inhibitors of the core protein. Enanta is targeting the selection of an HBV candidate in the fourth calendar quarter of 2018.

Upcoming Events and Presentations

- September 5-6, Baird 2018 Global Healthcare conference, New York
- September 12-14, Morgan Stanley 16th Annual Global Healthcare Conference, New York
- Enanta plans to issue its fiscal fourth quarter financial results press release, and hold a conference call regarding those results, on November 26, 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 August 7, 2018, through 11:59 p.m. ET on August 9, 2018 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 7278673. 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 is using its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery and development of small molecule drugs for the treatment of viral infections and liver diseases. Two protease inhibitors, glecaprevir and paritaprevir, discovered and developed through Enanta's collaboration with AbbVie, have now been approved around the world as part of AbbVie's regimens for the treatment of hepatitis C virus (HCV) infection, sold under the tradenames MAVYRET™ (U.S.) and MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir) and VIEKIRA PAK® (paritaprevir/ritonavir/ombitasvir/dasabuvir) (U.S.) and VIEKIRAX® (paritaprevir/ritonavir/ombitasvir) (ex-U.S.).

Royalties 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 Enanta's resulting royalty revenues, as well as the prospects and timelines for advancement of Enanta's earlier stage programs in NASH, PBC, RSV and HBV. 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 are dependent upon the success of AbbVie's continuing commercialization efforts for its HCV treatment regimens, primarily 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-Q for the quarter ended March 31, 2018 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 June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Revenue	$57,262	$ 7,511	$139,420	$ 26,887
Operating expenses				
Research and development	28,487	15,407	67,933	40,937

General and administrative	6,135	5,233	17,611	15,631
Total operating expenses	34,622	20,640	85,544	56,568
Income (loss) from operations	22,640	(13,129)	53,876	(29,681)
Other income, net	1,338	600	3,364	1,673
Income (loss) before income taxes	23,978	(12,529)	57,240	(28,008)
Income tax (expense) benefit	(3,690)	4,103	(12,704)	9,210
Net income (loss)	$20,288	$ (8,426)	$ 44,536	$(18,798)
Net income (loss) per share				
Basic	$ 1.05	$ (0.44)	$ 2.32	$ (0.99)
Diluted	$ 0.97	$ (0.44)	$ 2.17	$ (0.99)
Weighted average common shares outstanding				
Basic	19,303	19,081	19,212	19,055
Diluted	21,017	19,081	20,509	19,055

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

	June 30, 2018	September 30, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 42,477	$ 65,675
Short-term marketable securities	230,750	157,994
Accounts receivable	57,262	10,614
Prepaid expenses and other current assets	9,404	3,536
Total current assets	339,893	237,819
Long-term marketable securities	22,272	70,038
Property and equipment, net	8,383	8,049
Deferred tax assets	7,929	10,123
Restricted cash	608	608
Total assets	$379,085	$ 326,637
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,902	$ 3,714
Accrued expenses and other current liabilities	9,127	7,970
Income taxes payable	-	9,298
Total current liabilities	14,029	20,982
Warrant liability	-	807
Series 1 nonconvertible preferred stock	1,528	762
Other long-term liabilities	2,627	2,410
Total liabilities	18,184	24,961
Total stockholders' equity	360,901	301,676
Total liabilities and stockholders' equity	$379,085	$ 326,637

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