

Enanta Pharmaceuticals Reports Financial Results for its Fiscal Second Quarter Ended March 31, 2019

5/7/2019

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

- Data from Phase 2a RSV program anticipated mid-2019 and Phase 2a NASH program by the end of third quarter of calendar 2019
- Royalty revenue for the quarter was \$39.6 million
- Cash and marketable securities totaled \$386.7 million at March 31, 2019

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 second quarter ended March 31, 2019.

"Enanta remains in a strong financial position that allows us to continue to execute and advance our planned clinical objectives, with important data readouts by the end of next quarter," said Jay R. Luly, Ph.D. President and CEO, Enanta Pharmaceuticals. "We expect to announce three clinical milestones in the coming months – topline data from our Phase 2a human challenge study of EDP-938 for RSV by mid-year, followed by initiation of a Phase 1 study of EDP-514, our first HBV molecule, in the third quarter, and then Phase 2a data from our study of EDP-305 in NASH by the end of the third quarter."

Fiscal Second Quarter Ended March 31, 2019 Financial Results

Total revenue for the three months ended March 31, 2019 was \$39.6 million and consisted of royalty revenue derived primarily from worldwide net sales of AbbVie's hepatitis C virus (HCV) regimen MAVYRET™/MAVIRET™. For

the three months ended March 31, 2018, total revenue was \$44.0 million, which consisted of royalty revenue earned on AbbVie's global net sales of its HCV regimens. The decrease in royalty revenue in 2019 was due to a decrease in AbbVie's international HCV sales quarter over quarter.

Research and development expenses totaled \$34.2 million for the three months ended March 31, 2019, compared to \$21.5 million for the three months ended March 31, 2018. 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 preclinical efforts in hepatitis B virus (HBV) preparing EDP-514 for an initial clinical trial.

General and administrative expenses totaled \$6.8 million for the three months ended March 31, 2019, compared to \$5.7 million for the three months ended March 31, 2018. The increase in general and administrative expenses was primarily due to increases in compensation expense driven by increased headcount.

Enanta recorded an income tax benefit of \$3.2 million for the three months ended March 31, 2019 compared to income tax expense of \$5.4 million for the same period in 2018. Despite reporting pre-tax income, Enanta recorded an income tax benefit during the quarter due to tax deductions from employee stock award-related activity during the quarter. Enanta's effective tax rate for the six months ended March 31, 2019 was approximately 2% and differs from the federal statutory rate of 21% due to federal research and development tax credits and tax deductions from employee stock award-related activity.

Net income for the three months ended March 31, 2019 was \$4.1 million, or \$0.20 per diluted common share, compared to net income of \$12.6 million, or \$0.61 per diluted common share, for the corresponding period in 2018.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled \$386.7 million at March 31, 2019. This compares to a total of \$325.1 million at September 30, 2018. Enanta expects that its current cash, cash equivalents and marketable securities, as well as its continuing royalty revenue, 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

EDP-938, N-Protein Inhibitor for Respiratory Syncytial Virus (RSV):

- As announced in March, enrollment is complete in the Phase 2a human challenge study of EDP-938 in RSV. This study is a randomized, double-blind, placebo-controlled study in healthy adult subjects randomized into 1 of 2 dosing arms or a placebo arm. Topline data is expected mid-calendar 2019.
- Assuming the Phase 2a challenge study data are positive, our goal is to initiate a Phase 2b study by the end of

calendar 2019 in adult outpatients with RSV infections.

EDP-305, FXR Agonist for Non-Alcoholic Steatohepatitis (NASH):

- As announced in March, enrollment is complete in the ARGON-1 study in NASH. ARGON-1 is a 12-week, randomized, double-blind, placebo-controlled Phase 2a study evaluating the safety, tolerability, pharmacokinetics and efficacy of EDP-305 in subjects with NASH. Topline data is expected by the end of the third quarter of calendar 2019.
- Enanta also expects to identify a follow-on FXR clinical candidate in calendar 2019.

EDP-514, Core Inhibitor for Hepatitis B Virus (HBV):

- New preclinical data was presented in a poster at the International Liver Congress™ 2019, (ILC) in Vienna, Austria in April. Data in this poster demonstrate that EDP-514, a novel class II HBV core inhibitor, is a potent inhibitor of HBV replication, and prevents the de novo formation of new cccDNA in primary human hepatocytes when given early during infection. Data also show that EDP-514 is pan-genotypic, and that combinations of EDP-514 with nucleoside reverse-transcriptase inhibitors (NRTIs – the current anti-viral therapies for HBV) or a class I core inhibitor, result in additive to synergistic antiviral effects in vitro. In vivo, EDP-514 demonstrates excellent efficacy with >4-log viral load reduction in HBV-infected PXB mice.
- A Phase 1 study of EDP-514 is expected to begin in the third calendar quarter of 2019. The study will evaluate single and multiple doses of EDP-514 in healthy volunteers and will incorporate a Phase 1b arm in patients with chronic HBV infection.

Upcoming Events and Presentations

- May 22, 2019 - RBC Capital Markets Healthcare Conference, New York
- June 18-19, 2019 - Raymond James Life Science and MedTech Conference, New York
- June 19-20, 2019 - 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, on August 6, 2019.

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 May 7, 2019, through 11:59 p.m. ET on May 8, 2019 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 1191209. 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 Pharmaceuticals, Inc.

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. Enanta’s research and development efforts are currently focused on the following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH)/ primary biliary cholangitis (PBC), and hepatitis B virus (HBV).

Enanta’s research and development activities are funded by royalties from HCV products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is now sold by AbbVie in numerous countries as part of its newest treatment for chronic hepatitis C virus (HCV) infection. This leading HCV regimen is sold under the tradenames MAVYRET™ (U.S.) and MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir). 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 advancement of Enanta’s clinical programs in RSV and NASH/PBC and its preclinical program in HBV, as well as the prospects for future royalty revenue to Enanta from sales of AbbVie’s MAVYRET™/MAVIRET™ regimen for HCV. 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 continued success of AbbVie’s commercialization of its MAVYRET™/MAVIRET™ HCV regimen; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for RSV, NASH, PBC and HBV; competitive pricing, market acceptance and reimbursement rate actions affecting MAVYRET™/MAVIRET™ compared to competitive HCV products on the market; the discovery and development risks of Enanta’s programs in RSV, NASH, PBC, and HBV; the competitive impact of development, regulatory and marketing efforts of others in those disease areas; Enanta’s lack of clinical development experience; Enanta’s need to attract and retain senior management and key research and development 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 December 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 March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Revenue	\$ 39,631	\$ 44,049	\$ 109,517	\$ 82,158
Operating expenses				
Research and development	34,155	21,484	69,033	39,446
General and administrative	6,780	5,706	13,932	11,476
Total operating expenses	40,935	27,190	82,965	50,922
Income (loss) from operations	(1,304)	16,859	26,552	31,236
Other income, net	2,245	1,066	4,130	2,026
Income before income taxes	941	17,925	30,682	33,262
Income tax (expense) benefit	3,204	(5,370)	(526)	(9,014)
Net income	\$ 4,145	\$ 12,555	\$ 30,156	\$ 24,248
Net income per share				
Basic	\$ 0.21	\$ 0.65	\$ 1.55	\$ 1.27
Diluted	\$ 0.20	\$ 0.61	\$ 1.44	\$ 1.20
Weighted average common shares outstanding				
Basic	19,549	19,206	19,487	19,167
Diluted	21,084	20,601	20,946	20,256

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

	March 31, 2019	September 30, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 106,030	\$ 63,902
Short-term marketable securities	264,127	244,828
Accounts receivable	39,631	67,205
Prepaid expenses and other current assets	14,052	4,454
Total current assets	423,840	380,389
Long-term marketable securities	16,510	16,389
Property and equipment, net	11,476	8,374
Deferred tax assets	9,052	8,375
Restricted cash	608	608
Other long-term assets	92	92
Total assets	<u>\$ 461,578</u>	<u>\$ 414,227</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 8,884	\$ 4,745
Accrued expenses and other current liabilities	11,607	9,892
Income taxes payable	-	1,388
Total current liabilities	20,491	16,025
Series 1 nonconvertible preferred stock	1,628	1,628
Other long-term liabilities	3,249	2,895
Total liabilities	25,368	20,548
Total stockholders' equity	436,210	393,679
Total liabilities and stockholders' equity	<u>\$ 461,578</u>	<u>\$ 414,227</u>

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