

Enanta Pharmaceuticals Reports Financial Results for its Fiscal Third Quarter Ended June 30, 2019

8/6/2019

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

- Royalty revenue for the quarter was \$44.4 million
- Phase 2a NASH data expected by the end of the third calendar quarter
- Cash and marketable securities totaled \$389.2 million at June 30, 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 third quarter ended June 30, 2019.

"Enanta executed on key clinical milestones during the past few months, the most significant being the completion of a successful Phase 2a challenge study of EDP-938 for RSV. In addition, we recently initiated a Phase 1 study of EDP-514, our lead candidate for the treatment of HBV," commented Jay R. Luly, Ph.D., Enanta President and CEO. "Our pipeline is maturing, and we now have clinical studies ongoing with three compounds, all of which have been granted Fast Track designation."

Fiscal Third Quarter Ended June 30, 2019 Financial Results

Total revenue of \$44.4 million for the three months ended June 30, 2019 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 June 30, 2018, total revenue was \$57.3 million, which consisted of royalty revenue earned on

AbbVie's global net sales of its HCV regimens. AbbVie has stated that the decrease in royalty revenue in 2019 was mainly driven by lower treated patient volumes in select international markets.

Research and development expenses increased to \$34.5 million for the three months ended June 30, 2019, compared to \$28.5 million for the three months ended June 30, 2018, primarily due to increased clinical costs associated with the progression of Enanta's wholly-owned clinical programs in respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), and hepatitis B virus (HBV).

General and administrative expenses totaled \$6.2 million for the three months ended June 30, 2019, compared to \$6.1 million for the three months ended June 30, 2018.

Enanta recorded an income tax benefit of \$0.9 million for the three months ended June 30, 2019 compared to income tax expense of \$3.7 million for the same period in 2018. The income tax benefit was driven by a federal tax benefit associated with foreign derived royalty income from our AbbVie collaboration agreement.

Net income for the three months ended June 30, 2019 was \$7.0 million, or \$0.33 per diluted common share, compared to net income of \$20.3 million, or \$0.97 per diluted common share, for the corresponding period in 2018.

Enanta's cash, cash equivalents and marketable securities totaled \$389.2 million at June 30, 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):

- In June, Enanta announced topline results from its Phase 2a human challenge study of EDP-938 in healthy adults infected with respiratory syncytial virus (RSV). Data demonstrated EDP-938 achieved highly statistically significant ($p < 0.001$) reductions in viral load and in resolution of clinical symptoms compared to placebo.
- Enanta's first Phase 2b study in adult outpatients with RSV infection is planned to begin by the end of calendar 2019.

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

- Topline data from the Phase 2a ARGON-1 study in NASH are 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):

- In July, Enanta announced that it had initiated part 1 of a Phase 1a/1b clinical study of EDP-514. Part 1 of the randomized, double-blind, placebo-controlled study is designed to evaluate the safety, tolerability and pharmacokinetics (PK) of single ascending doses (SAD) and multiple ascending doses (MAD) of EDP-514 in healthy subjects. Part 2 will then evaluate the antiviral activity of EDP-514 in nucleos(t)ide-reverse-transcriptase (NUC)-suppressed patients with chronic HBV infection.

Hepatitis C Virus (HCV) collaboration with AbbVie:

- AbbVie announced that the European Commission has granted marketing authorization to AbbVie for MAVIRET™ (glecaprevir/pibrentasvir) to shorten once-daily treatment duration from 12 to 8 weeks in treatment-naïve, chronic hepatitis C (HCV) patients with compensated cirrhosis and genotype (GT)1, 2, 4, 5, or 6 infection.
- Glecaprevir, is one of the two direct-acting antivirals (DAAs) in MAVIRET and is Enanta's second protease inhibitor developed and commercialized by AbbVie.

Upcoming Events and Presentations

- September 4, 2019 – Baird 2019 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 21, 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 August 6, 2019, through 11:59 p.m. ET on August 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 6794018. 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 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, NASH/PBC and 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: the dependence of Enanta's revenues in the short-term upon the continued success of AbbVie's sales 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; treatment rates, competitive pricing, 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 March 31, 2019, 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,

| | 2019 | 2018 | 2019 | 2018 |
|--|-----------|-----------|------------|------------|
| Revenue | \$ 44,367 | \$ 57,262 | \$ 153,884 | \$ 139,420 |
| Operating expenses | | | | |
| Research and development | 34,461 | 28,487 | 103,494 | 67,933 |
| General and administrative | 6,151 | 6,135 | 20,083 | 17,611 |
| Total operating expenses | 40,612 | 34,622 | 123,577 | 85,544 |
| Income from operations | 3,755 | 22,640 | 30,307 | 53,876 |
| Other income, net | 2,415 | 1,338 | 6,545 | 3,364 |
| Income before income taxes | 6,170 | 23,978 | 36,852 | 57,240 |
| Income tax (expense) benefit | 866 | (3,690) | 340 | (12,704) |
| Net income | \$ 7,036 | \$ 20,288 | \$ 37,192 | \$ 44,536 |
| Net income per share | | | | |
| Basic | \$ 0.36 | \$ 1.05 | \$ 1.90 | \$ 2.32 |
| Diluted | \$ 0.33 | \$ 0.97 | \$ 1.77 | \$ 2.17 |
| Weighted average common shares outstanding | | | | |
| Basic | 19,673 | 19,303 | 19,549 | 19,212 |
| Diluted | 21,105 | 21,017 | 20,999 | 20,509 |

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

| | June 30, 2019 | September 30, 2018 |
|--|------------------|-----------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 94,206 | \$ 63,902 |
| Short-term marketable securities | 295,042 | 244,828 |
| Accounts receivable | 44,367 | 67,205 |
| Prepaid expenses and other current assets | 17,647 | 4,454 |
| Total current assets | 451,262 | 380,389 |
| Long-term marketable securities | - | 16,389 |
| Property and equipment, net | 11,373 | 8,374 |
| Deferred tax assets | 10,149 | 8,375 |
| Restricted cash | 608 | 608 |
| Other long-term assets | 92 | 92 |
| Total assets | \$ 473,484 | \$ 414,227 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | | |
| Accounts payable | \$ 6,504 | \$ 4,745 |
| Accrued expenses and other current liabilities | 13,997 | 9,892 |
| Income taxes payable | - | 1,388 |
| Total current liabilities | 20,501 | 16,025 |
| Series 1 nonconvertible preferred stock | 1,628 | 1,628 |
| Other long-term liabilities | 3,258 | 2,895 |
| Total liabilities | 25,387 | 20,548 |
| Total stockholders' equity | 448,097 | 393,679 |
| Total liabilities and stockholders' equity | \$ 473,484 | \$ 414,227 |

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