Enanta Pharmaceuticals Reports Financial Results for Its Fiscal Third Quarter Ended June 30, 2021 with Webcast and Conference Call Today at 4:30 p.m. ET

August 5, 2021
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- *Nominates EDP-235, an Oral Protease Inhibitor Specifically Designed to Treat COVID-19, with a Phase 1 Study Planned for Early 2022*
- *On Track to Dose First Subject in a Phase 1 Study of EDP-721, an Oral, Hepatitis B Virus (HBV) RNA Destabilizer*
- *Recently Reported Positive Preliminary Data from a Phase 1b Study of EDP-514 in Viremic Chronic HBV Patients Supportive of Once Daily Dosing and Demonstrating a Mean Reduction of 3.3 Logs in HBV DNA*
- *Royalty Revenue for the Quarter was $21.6 Million*

WATERTOWN, Mass.--(BUSINESS WIRE)-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage 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, 2021.

“This was an important quarter for Enanta, and I am proud of the work we have accomplished and the significant milestones we have achieved to advance our clinical portfolio in key therapeutic areas,” stated Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “We are excited today to nominate EDP-235, our novel, potent, oral protease inhibitor specifically designed to target SARS-CoV-2. As the COVID-19 pandemic continues to have a significant impact globally, we are committed to leveraging our expertise in virology to progress this program and initiate a Phase 1 clinical study in early 2022. We are also pleased to be on track to dose our first subject this month in the Phase 1 study of EDP-721, our oral HBV RNA destabilizer, which we believe will be an important component of an all-oral, functional cure for chronic HBV. This progress follows recent positive data from two Phase 1b studies of our core inhibitor EDP-514, one in chronic HBV patients already being treated with a nucleoside reverse transcriptase inhibitor and the other in viremic patients not currently on treatment. Looking toward the second half of the year, we are excited to continue our progress and advance several clinical candidates in our pipeline.”

Fiscal Third Quarter Ended June 30, 2021 Financial Results

Total revenue of $21.6 million for the three months ended June 30, 2021 consisted of royalty revenue derived primarily from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET®. This compared to total revenue of $18.7 million for the three months ended June 30, 2020, which also consisted of royalty revenue. AbbVie has stated that net sales of MAVYRET/MAVIRET in the three months ended June 30, 2021 increased compared to 2020, although a residual impact from the pandemic continues.

Research and development expenses increased to $47.0 million for the three months ended June 30, 2021, compared to $34.7 million for the three months ended June 30, 2020. The increase was due to the timing of the company’s clinical trials year over year.

General and administrative expenses totaled $8.5 million for the three months ended June 30, 2021, compared to $6.8 million for the three months ended June 30, 2020. The increase was due to an increase in headcount and related compensation expense.

Enanta recorded an income tax benefit of $9.4 million for the three months ended June 30, 2021 compared to an income tax benefit of $7.1 million for the same period in 2020. These income tax benefits were due to the provision of the CARES Act of 2020, which enables the company through fiscal 2021 to carry back its projected current year tax loss to offset taxable income in prior years.

Net loss for the three months ended June 30, 2021 was $24.0 million, or a loss of $1.19 per diluted common share, compared to net loss of $14.3 million, or a loss of $0.71 per diluted common share, for the corresponding period in 2020.

Enanta’s cash, cash equivalents and marketable securities totaled $372.5 million at June 30, 2021. Enanta expects that its current cash, cash equivalents and short-term and long-term marketable securities, as well as its continuing royalty revenue, will continue to be sufficient to meet the anticipated cash requirements of its existing business and development programs for at least the next two years.

Pipeline Program -- Recent Events and Near-Term Milestones

Virology

- **HBV: Core Inhibitor EDP-514 and HBV RNA Destabilizer EDP-721**
  - On track to dose the first subject this month in a Phase 1 clinical study of EDP-721, an oral, potent and selective HBV RNA destabilizer being developed for use in combination with other mechanisms, with the goal of developing an all-oral regimen to achieve a functional cure. Data are expected in the first half of 2022.
  - Announced positive data from a Phase 1b study of EDP-514 in viremic chronic HBV patients, which demonstrated that the 200 mg and 400 mg doses were safe and well-tolerated through 28 days of treatment, displayed pharmacokinetics supportive of once-daily dosing, and resulted in mean HBV DNA reductions of 2.9 and 3.3 logs, respectively.

- Presented the discovery and preclinical characterization of EDP-721 in a poster at the International Liver Congress™, sponsored by the European Association for the Study of the Liver (EASL).

- **COVID-19 (SARS-CoV-2): Protease Inhibitor EDP-235**
  - Nominated EDP-235, the company's lead oral protease inhibitor specifically designed for the treatment of COVID-19 and is on track to initiate a Phase 1 study in early 2022.

- **Respiratory Syncytial Virus (RSV): N-Protein Inhibitor EDP-938**
  - While RSV, like influenza, did not emerge during the usual late-fall and winter RSV season in the Northern Hemisphere in 2020-2021, the Centers for Disease Control and Prevention recently issued a health advisory to notify clinicians and caregivers about increased interseasonal RSV activity across parts of the Southern United States. As RSV re-emerges, Enanta is continuing to establish additional trial sites in North America, Europe, the Asia-Pacific region, and the Southern Hemisphere.
  - Given the recent re-emergence of RSV is not following any normal seasonal pattern, it is very difficult to predict how significant or sustained the new incidence of RSV will be moving forward. Enanta is hopeful that enrollment in the RSVP study will be complete during the Northern Hemisphere winter season if there are no renewed social distancing interventions. Assuming this enrollment occurs, the company would expect data in first half of 2022.
  - For RSVTx and RSVPEDs, which were initiated more recently, Enanta is monitoring the trends and will update as appropriate.

- **Respiratory Virology Discovery Initiatives** – Having recently nominated EDP-235 as a clinical development candidate, Enanta's goal in the second half of 2021is to identify one more clinical development candidate among the two discovery initiatives below:
  - **RSV L-Protein Inhibitor**
    - Continuing to optimize leads with potent nanomolar activity against both RSV-A and RSV-B.
  - **Human Metapneumovirus (hMPV)**
    - Continuing lead optimization on potent nanomolar hMPV inhibitors.

Non-Alcoholic Steatohepatitis

- **Farnesoid X Receptor (FXR) Agonist EDP-305**
  - ARGON-2, a Phase 2b study of EDP-305, is on track for a planned 12-week internal interim analysis on a subset of patients in the third quarter of 2021 to inform next steps.
- **EDP-297, a Highly Potent and Targeted FXR Agonist**
  - Data are expected from the Phase 1 study of EDP-297 in the third quarter of 2021.

Corporate

- Announced the planned retirement of Nathalie Adda, M.D., Senior Vice President and Chief Medical Officer, in February 2022, with a period of consulting thereafter.

Upcoming Events and Presentations

- H.C. Wainwright 23rd Annual Global Investment Conference (September 13-14, 2021)
- Baird 2021 Global Healthcare Conference (September 14-15, 2021)
- Enanta plans to issue its fiscal fourth quarter and year-end financial results press release, and hold a conference call regarding those results, on November 22, 2021.

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 5, 2021, through 11:59 p.m. ET on August 9, 2021 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 **5637368**. A live audio webcast of the call and replay can be accessed by visiting the "Events and Presentations" section on the "Investors" page of Enanta's website at www.enanta.com.

About Enanta

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 have produced clinical candidates for the following disease targets: respiratory syncytial virus (RSV), hepatitis B virus (HBV), non-alcoholic steatohepatitis (NASH) and SARS-CoV-2 (COVID-19). Enanta is also conducting research in human metapneumovirus (hMPV).

Enanta's research and development activities are funded by royalties from hepatitis C virus (HCV) products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is sold by AbbVie in numerous countries as part of its leading treatment for chronic HCV infection 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 research and development programs in RSV, HBV, NASH, SARS-CoV-2 and hMPV, as well as future royalty revenue 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, HBV, hMPV and SARS-CoV-2; treatment rates, competitive pricing, and reimbursement rate actions affecting MAVYRET/MAVIRET compared to competitive HCV products on the market; any continuing impact of COVID-19 on AbbVie's MAVYRET/MAVIRET sales; the discovery and development risks of Enanta's research and development programs in RSV, NASH, HBV, hMPV and SARS-CoV-2; 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; the realizability of our deferred tax assets; 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, 2021, 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,	
	2021	2020	2021	2020
Revenue	$ 21,624	$ 18,653	$ 73,499	$ 98,842
Operating expenses				
Research and development	46,994	34,682	125,165	100,070
General and administrative	8,477	6,823	24,180	20,628
Total operating expenses	55,471	41,505	149,345	120,698
Loss from operations	(33,847)	(22,852)	(75,846)	(21,856)
Other income, net	439	1,445	1,661	5,471
Loss before income taxes	(33,408)	(21,407)	(74,185)	(16,385)
Income tax benefit	9,384	7,142	19,788	9,558
Net loss	$ (24,024)	$ (14,265)	$ (54,397)	$ (6,827)
Net loss per share				
Basic	$ (1.19)	$ (0.71)	$ (2.70)	$ (0.34)
Diluted	$ (1.19)	$ (0.71)	$ (2.70)	$ (0.34)
Weighted average common shares outstanding				
Basic	20,201	20,020	20,155	19,897
Diluted	20,201	20,020	20,155	19,897

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

	June 30, 2021	September 30, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 4,601	$ 87,131
Short-term marketable securities	252,223	299,518
Accounts receivable	21,624	23,492
Prepaid expenses and other current assets	12,137	13,655
Income tax receivable	30,570	13,041
Total current assets	321,155	436,837
Long-term marketable securities	115,706	32,634

Property and equipment, net	6,613	8,596
Deferred tax assets	345	345
Operating lease, right-of-use assets	5,917	7,020
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 450,436	$ 486,132
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 5,895	$ 5,737
Accrued expenses and other current liabilities	17,695	14,159
Operating lease liabilities	5,034	4,261
Total current liabilities	28,624	24,157
Operating lease liabilities, net of current portion	1,637	3,838
Series 1 nonconvertible preferred stock	1,479	1,479
Other long-term liabilities	846	1,078
Total liabilities	32,586	30,552
Total stockholders' equity	417,850	455,580
Total liabilities and stockholders' equity	$ 450,436	$ 486,132

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Media and Investor Contact:
Jennifer Viera
Tel: 617-744-3848
jviera@enanta.com

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