Enanta Pharmaceuticals Reports Financial Results for its Fiscal Third Quarter Ended June 30, 2022 With Webcast and Conference Call Today at 4:30 p.m. ET

August 8, 2022

- *Presented Positive Phase 1 Study Data for EDP-235, a Coronavirus 3CL Protease Inhibitor in Development as an Oral, Once-Daily Treatment for COVID-19; Phase 2 Study Planned to Start in 4Q 2022*
- *Progressing Respiratory Syncytial Virus (RSV) Portfolio with a Phase 2 Study of EDP-938 in High-Risk Adults and a Phase 1 Study of EDP-323, an RSV L-Protein Inhibitor, Planned to Start in 4Q 2022*
- *Royalty Revenue for the Quarter was $19.5 Million*

WATERTOWN, Mass.--(BUSINESS WIRE)--Aug. 8, 2022-- 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, 2022.

“Currently approved COVID-19 vaccines offer less protection against infection from new SARS-CoV-2 variants, especially BA.5, and we continue to see the need for an easily accessible, once-daily oral antiviral for the treatment of COVID-19. EDP-235, as demonstrated by its positive safety, tolerability, and pharmacokinetic properties, is positioned to fill this need and to be an important tool in the global fight against this virus. We look forward to initiating a Phase 2 study in the fourth quarter of this year,” said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “We also continue to advance the rest of our pipeline, with our ongoing and planned RSV studies, including EDP-323, our L-protein inhibitor, in Phase 1 and EDP-938 in a new Phase 2 study in high-risk adults, starting in the fourth quarter of this year. Meanwhile, we remain committed to identifying a third mechanism to combine with EDP-514 and a nucleoside reverse transcriptase inhibitor (NUC), for the treatment of patients with chronic hepatitis B virus infection.”

Fiscal Third Quarter Ended June 30, 2022 Financial Results
Total revenue of $19.5 million for the three months ended June 30, 2022 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 $21.6 million for the three months ended June 30, 2021, which also consisted of royalty revenue from AbbVie.

Research and development expenses totaled $39.1 million for the three months ended June 30, 2022, compared to $47.0 million for the three months ended June 30, 2021. The decrease was due to the timing of activities in the company’s virology and liver disease programs year over year.

General and administrative expenses totaled $12.9 million for the three months ended June 30, 2022, compared to $8.5 million for the three months ended June 30, 2021. The increase was due to an increase in headcount and related compensation expense.

Enanta recorded an income tax benefit of $0.4 million for the three months ended June 30, 2022 due to the release of a state tax reserve during the period, compared to an income tax benefit of $9.4 million for the three months ended June 30, 2021, which was driven by a federal net loss carryback available in fiscal 2021 under the CARES Act of 2020. Enanta is still due a refund of $28.7 million for the tax losses carried back in 2021 to offset taxable income in prior years.

The net loss for the three months ended June 30, 2022 was $31.7 million, or a loss of $1.53 per diluted common share, compared to a net loss of $24.0 million, or a loss of $1.19 per diluted common share, for the corresponding period in 2021.

Enanta’s cash, cash equivalents and marketable securities totaled $292.7 million at June 30, 2022. 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 the next two years.

Pipeline Update and Business Review

Respiratory Virology

COVID-19 (SARS-CoV-2)

- Enanta reported positive data in July for its completed Phase 1 healthy volunteer study of EDP-235, an oral inhibitor of coronavirus 3CL protease, or 3CLpro (also known as Mpro or main protease) specifically designed for the treatment of COVID-19. EDP-235 has Fast Track Designation from the U.S. Food and Drug Administration (FDA).
- Data showed EDP-235 increased approximately proportionally with ascending single and multiple doses of EDP-235, with a half-life consistently ranging from 13 to 22 hours, resulting in a pharmacokinetic profile suitable for once-daily dosing.
- Data demonstrated that EDP-235 had strong exposure multiples over the EC_{90}, which is a measure of potency, specifically the concentration of drug that results in 90% inhibition of viral replication *in vitro*. EDP-235 200mg taken once daily with food resulted in mean trough plasma levels at steady state that were 3-fold and 6-fold over the plasma-protein-adjusted

EC_{90} for the Alpha variant and Delta variant, respectively, while 400mg resulted in levels that were 6-fold and 12-fold over the plasma-protein-adjusted EC_{90} for the respective variants. These exposure multiples were achieved without the need for ritonavir boosting and its associated drug-drug interactions. Further, EDP-235 is projected to have four times higher drug levels in lung tissue compared to plasma, which would be expected to drive the 400mg multiples to 24-fold and 48-fold for the respective variants.

- Overall, EDP-235 was generally safe and well-tolerated up to 400 mg for seven days. Adverse events (AEs) were infrequent, and the majority were mild, with headache and gastrointestinal-related symptoms being the most commonly reported AEs during the MAD phase. There were three study discontinuations: one moderate headache in the 400mg fasted cohort, one severe headache in the 800mg fed cohort and one grade 3 ALT/grade 2 AST elevation in the 800mg fed cohort. All AEs subsequently resolved.
- Based on these positive data, Enanta is moving forward with the clinical development of EDP-235, targeting a fourth quarter initiation of a Phase 2 study exploring doses of 200mg and 400mg once-daily, pending review with the FDA.

RSV

- EDP-938, an N-protein inhibitor which has Fast Track designation from the FDA, is being evaluated in a broad clinical development program in multiple high-risk patient groups, including pediatric and high-risk adult populations.
- Enanta reported data in May from RSVP, its Phase 2b study evaluating EDP-938 in otherwise healthy adults with community-acquired RSV. RSVP did not meet the primary endpoint of reduction in total symptom score compared to placebo, or the secondary antiviral endpoints. Enanta believes this result was likely because the viral load and symptoms had already peaked and/or were declining at the time of the first dose, indicating RSV infection resolves quickly in this otherwise healthy, low-risk population. However, in this study a statistically significant difference in the number of subjects achieving undetectable RSV RNA at the end of treatment at Day 5 was observed with EDP-938 compared to placebo (p=0.033). EDP-938 demonstrated a favorable safety profile, consistent with that observed in approximately 500 subjects exposed to date in prior studies.
- Ongoing studies include RSVPEDs, a Phase 2 randomized, double-blind, placebo-controlled study in hospitalized and non-hospitalized pediatric RSV patients, and RSVTx, a Phase 2b, randomized, double-blind, placebo-controlled study in adult hematopoietic cell transplant recipients with acute RSV infection and symptoms of upper respiratory tract infection. The company expects these studies to continue beyond 2022, subject to the re-emergence of RSV in broader populations at pre-COVID levels.
- Enanta plans to initiate an additional Phase 2b study of EDP-938 in another high-risk adult population, including the elderly and those with chronic obstructive pulmonary disease, congestive heart failure or asthma, in the fourth quarter of 2022.
- Enanta is also evaluating EDP-323, a novel oral, direct-acting antiviral selectively targeting the RSV L-protein, for the treatment of RSV. EDP-323 has shown sub-nanomolar potency against RSV-A and RSV-B *in vitro* and is not expected to have cross-resistance to other classes of inhibitors. EDP-323 could be used as a monotherapy or in combination with other RSV mechanisms, such as EDP-938, to potentially broaden the addressable patient populations or their treatment windows. Enanta plans to initiate a Phase 1 study of EDP-323 in the fourth quarter of 2022.

Human Metapneumovirus (hMPV)

- Enanta is on track to select a clinical candidate for hMPV in the first half of 2023. hMPV is a pathogen that causes upper and lower respiratory tract infections similar to RSV in young children and the elderly, as well as in immunocompromised patients or those with chronic obstructive pulmonary disease or asthma.

Liver Virology

Hepatitis B Virus (HBV)

- Enanta remains committed to developing a cure for HBV patients and is currently focused on identifying additional compounds with different mechanisms of action to combine with EDP-514, its potent core inhibitor, and a NUC. EDP-514, which has Fast Track designation from the FDA, has displayed a good safety profile and robust antiviral activity in multiple HBV patient populations, with declines in HBV DNA among the best published to date for core inhibitors.

Corporate

- Announced the appointment of Scott T. Rottinghaus, M.D., to the position of Senior Vice President and Chief Medical Officer, effective today. Dr. Rottinghaus joins Enanta from Alexion, AstraZeneca Rare Disease, where he was Vice President and Head of Clinical Development for Hematology and Nephrology. Dr. Rottinghaus is an infectious disease trained physician who has more than 20 years of experience in drug development across a broad range of therapeutic areas. He will lead the development, regulatory, clinical and medical functions in support of Enanta's pipeline.
- Announced the filing of a suit in United States District Court for the District of Massachusetts against Pfizer, Inc. seeking damages for infringement of U.S. Patent No. 11,358,953 (the '953 Patent) in the manufacture, use and sale of Pfizer's COVID-19 antiviral, Paxlovid™ (nirmatrelvir tablets; ritonavir tablets). TheU.S. Patent and Trademark Office awarded the

patent to Enanta in June 2022 based on Enanta's July 2020 patent application describing coronavirus protease inhibitors invented by Enanta scientists. Enanta recognizes the importance of Paxlovid's availability to patients and does not intend to seek an injunction or take other action in this litigation that would impede the production, sale or distribution of Paxlovid. Enanta seeks fair compensation for Pfizer's use of a coronavirus 3CL protease inhibitor claimed in the '953 Patent. Importantly, the '953 Patent is completely separate from the patent estate covering the discovery of EDP-235 and Enanta's ongoing antiviral discovery work for coronaviruses.

Upcoming Events and Presentations

- Wells Fargo Healthcare Conference (September 8, 2022)
- Baird 2021 Global Healthcare Conference (September 13, 2022)
- 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 21, 2022.

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 833-634-1237 in the U.S. or 412-317-5277 for international callers. No conference identification number is needed for the live call. A replay of the conference call will be available starting at approximately 7:30 p.m. ET on August 8, 2022, through 11:59 p.m. ET on August 22, 2022, by dialing 877-344-7529 in the U.S. or 412-317-0088 for international callers. The access code for the replay is 2895171. 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 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 programs include clinical candidates currently in development for the following disease targets: respiratory syncytial virus (RSV), SARS-CoV-2 (COVID-19) and hepatitis B virus (HBV). 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 part of one of the leading treatment regimens for curing chronic HCV infection and is sold by AbbVie in numerous countries 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, SARS-CoV-2 and HBV and its preclinical program in hMPV. 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 impact of development, regulatory and marketing efforts of others with respect to competitive treatments for RSV, SARS-CoV-2 and HBV; the discovery and development risks of Enanta's programs in RSV, SARS-CoV-2, HBV and hMPV; the competitive impact of development, regulatory and marketing efforts of others in those disease areas; any continuing impact of the COVID-19 pandemic on business operations and clinical trials; 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 Form 10-Q for the fiscal quarter ended March 31, 2022, and any 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.

Tables to Follow

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,	
	2022	2021	2022	2021
Revenue	$ 19,479	$ 21,624	$ 65,843	$ 73,499
Operating expenses				
Research and development	39,090	46,994	129,726	125,165
General and administrative	12,929	8,477	32,913	24,180
Total operating expenses	52,019	55,471	162,639	149,345
Loss from operations	(32,540)	(33,847)	(96,796)	(75,846)

Other income, net	393	439	942	1,661
Loss before income taxes	(32,147)	(33,408)	(95,854)	(74,185)
Income tax benefit	447	9,384	447	19,788
Net loss	$ (31,700)	$ (24,024)	$ (95,407)	$ (54,397)
Net loss per share				
Basic	$ (1.53)	$ (1.19)	$ (4.64)	$ (2.70)
Diluted	$ (1.53)	$ (1.19)	$ (4.64)	$ (2.70)
Weighted average common shares outstanding				
Basic	20,710	20,201	20,552	20,155
Diluted	20,710	20,201	20,552	20,155

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

	June 30, 2022	September 30, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 28,367	$ 57,206
Short-term marketable securities	224,921	186,796
Accounts receivable	19,479	23,576
Prepaid expenses and other current assets	11,540	14,188
Income tax receivable	28,728	37,255
Total current assets	313,035	319,021
Long-term marketable securities	39,427	108,416
Property and equipment, net	4,588	5,943
Operating lease, right-of-use assets	23,493	4,711
Restricted cash	3,968	608
Other long-term assets	703	92
Total assets	$ 385,214	$ 438,791
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,245	$ 9,540
Accrued expenses and other current liabilities	19,191	22,429
Operating lease liabilities	2,599	4,203
Total current liabilities	23,035	36,172
Operating lease liabilities, net of current portion	22,209	1,126
Series 1 nonconvertible preferred stock	1,506	1,506
Other long-term liabilities	441	558
Total liabilities	47,191	39,362
Total stockholders' equity	338,023	399,429
Total liabilities and stockholders' equity	$ 385,214	$ 438,791

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