Enanta Pharmaceuticals Reports Financial Results for its Fiscal Second Quarter Ended March 31, 2022 With Webcast and Conference Call Today at 4:30 p.m. ET

May 9, 2022

- *Expects Topline Data From RSVP, a Phase 2b Study of EDP-938 in Adults With Community-Acquired Respiratory Syncytial Virus (RSV), This Quarter*
- *Received Fast Track Designation for EDP-235, an Oral 3CL Protease Inhibitor Specifically Designed for the Treatment of COVID-19; Expects Preliminary Data From a Phase 1 Study of EDP-235 This Quarter*
- *On Track to Initiate a Phase 1 Study of EDP-323, an RSV L-Protein Inhibitor, in the Second Half of 2022*
- *Royalty Revenue for the Quarter was $18.7 Million*

WATERTOWN, Mass.--(BUSINESS WIRE)--May 9, 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 second quarter ended March 31, 2022.

“We had a strong start to 2022, making meaningful strides to advance our leadership in the development of therapeutics for viral infections with important progress in our broad pipeline, most notably in our clinical stage RSV and COVID-19 programs,” said Jay R. Luly Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “The progress we made lays the groundwork for an important quarter to come, particularly as we soon approach significant inflection points. During this quarter, we expect to report topline data from our RSVP study, a Phase 2b trial designed to confirm the results of the challenge study, in the setting of community-acquired RSV infection in an otherwise healthy adult population. We are also on track to announce preliminary data from our COVID-19 Phase 1 study of EDP 235 this quarter which, if positive, will allow us to move to the next phase of clinical development in the second half of this year. Additionally, we plan to initiate a Phase 2b study in adults at high-risk for serious RSV infection by year end. With much to look forward to in the coming months, we are excited to continue to advance our mission of transforming the lives of patients by developing curative therapies for viral diseases that have a global impact and high unmet need.”

Fiscal Second Quarter Ended March 31, 2022 Financial Results

Total revenue for the three months ended March 31, 2022 was $18.7 million and consisted of royalty revenue derived primarily from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET® (glecaprevir/pibrentasvir), as treated patient volumes remain suppressed compared to pre-COVID levels. For the three months ended March 31, 2021, total revenue from royalties on AbbVie’s net sales of HCV regimens was $20.1 million.

Research and development expenses totaled $42.1 million for the three months ended March 31, 2022, compared to $41.5 million for the three months ended March 31, 2021. The increase was driven by the timing of manufacturing and clinical trial costs associated with the company’s virology and liver disease programs.

General and administrative expenses totaled $10.5 million for the three months ended March 31, 2022, compared to $8.3 million for the three months ended March 31, 2021. The increase in general and administrative expenses was due to increased headcount and stock-related compensation expense.

Enanta recorded no income tax expense for the three months ended March 31, 2022, compared to an income tax benefit of $7.1 million for the same period of 2021. Enanta recorded an income tax benefit in 2021 due to the provision of the CARES Act of 2020, which enabled the company to carry back its tax loss in the 2021 period to offset taxable income in prior years. This provision does not apply to periods ending after September 30, 2021.

Net loss for the three months ended March 31, 2022 was $33.6 million, or a loss of $1.63 per diluted common share, compared to a net loss of $22.0 million, or a loss of $1.09 per diluted common share, for the corresponding period in 2021.

Enanta’s cash, cash equivalents and short-term and long-term marketable securities totaled $322.5 million at March 31, 2022. 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 at least the next two years.

Pipeline Update and Business Review

RSV

- EDP-938, an N-protein inhibitor with Fast Track designation by the U.S. Food and Drug Administration (FDA), is being evaluated in a broad clinical development program in multiple patient groups, currently consisting of three Phase 2 trials: RSVP, RSVPEDs and RSVTx.
- Enanta is on track to report topline data this quarter for RSVP, a Phase 2b study designed to confirm the results of the company’s challenge study, in the setting of community-acquired RSV infection in an otherwise healthy adult population. These results will provide additional information on the effect of EDP-938 on symptoms and viral load in a low-risk adult population.

- Enanta plans to initiate an additional Phase 2b study in a high-risk adult population, including the elderly or those with asthma, chronic obstructive pulmonary disease, or congestive heart failure, by year end.
- Recruitment is ongoing for 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 into 2023.
- Enanta plans to initiate a Phase 1 study for EDP-323, a novel oral, direct-acting antiviral selectively targeting the RSV L-protein, in the second half of 2022. 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.
- Data from the human challenge study of EDP-938 were published this February in *The New England Journal of Medicine*.

COVID-19 (SARS-CoV-2)

- Enanta expects to report preliminary data this quarter for its ongoing 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. If supported by Phase 1 results, the company plans to advance EDP-235 to the next stage of clinical development in the second half of this year.
- In March, the FDA granted Fast Track designation for EDP-235, further highlighting the urgent unmet need that exists for oral COVID-19 treatments.
- Preclinical data demonstrate that EDP-235 potently blocks the replication of SARS-CoV-2 in multiple cellular models, including primary human airway epithelial cells with an EC_{90} of 33 nanomolar, positioning EDP-235 among the most potent direct-acting antivirals currently in development for SARS-CoV-2 infection, with the potential for convenient once-daily dosing. Importantly, in preclinical studies, EDP-235 has shown good exposure after oral administration without ritonavir boosting and favorable distribution into lung cells as well as other key target tissues.
- Enanta also presented data highlighting EDP-235's *in vitro* pharmacology and molecular mechanism of action at the American Society for Biochemistry and Molecular Biology 2022 Annual Meeting. Preclinical data presented at the conference provided further confirmation that EDP-235 is a potent inhibitor of SARS-CoV-2 3CLpro and shows potent antiviral activity against SARS-CoV-2 variants of concern, including Delta and Omicron. EDP-235 also showed potent antiviral activity against most other pathogenic human coronaviruses, potentially making it a pan-coronavirus therapy.

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. 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.

Human Metapneumovirus (hMPV)

- Enanta is on track to select a clinical candidate for hMPV in the second half of 2022. hMPV is a pathogen thatcauses upper and lower respiratory tract infections similar to RSV in young children and the elderly, as well as in immunocompromised patients or those with COPD or asthma.

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 844-467-7101 in the U.S. or 270-215-9353 for international callers. A replay of the conference call will be available starting at approximately 7:30 p.m. ET on May 9, 2022, through 11:59 p.m. ET on May 16, 2022, 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 7061969. 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 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 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 December 31, 2021, 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.

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

	March 31, 2022	September 30, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 40,989	$ 57,206
Short-term marketable securities	239,338	186,796
Accounts receivable	18,716	23,576
Prepaid expenses and other current assets	14,078	14,188
Income tax receivable	28,748	37,255
Total current assets	341,869	319,021
Long-term marketable securities	42,218	108,416
Property and equipment, net	4,815	5,943
Operating lease, right-of-use assets	17,216	4,711
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 406,818	$ 438,791
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 5,985	$ 9,540
Accrued expenses and other current liabilities	21,740	22,429
Operating lease liabilities	3,013	4,203
Total current liabilities	30,738	36,172
Operating lease liabilities, net of current portion	15,115	1,126
Series 1 nonconvertible preferred stock	1,506	1,506
Other long-term liabilities	876	558
Total liabilities	48,235	39,362
Total stockholders' equity	358,583	399,429
Total liabilities and stockholders' equity	$ 406,818	$ 438,791

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,

	2022	2021	2022	2021
Revenue	$ 18,716	$ 20,132	$ 46,364	$ 51,875
Operating expenses				
Research and development	42,087	41,506	90,636	78,171
General and administrative	10,476	8,326	19,984	15,703
Total operating expenses	52,563	49,832	110,620	93,874
Loss from operations	(33,847)	(29,700)	(64,256)	(41,999)
Other income, net	255	545	549	1,222
Loss before income taxes	(33,592)	(29,155)	(63,707)	(40,777)
Income tax benefit	—	7,110	—	10,404
Net loss	$ (33,592)	$ (22,045)	$ (63,707)	$ (30,373)
Net loss per share				
Basic	$ (1.63)	$ (1.09)	$ (3.11)	$ (1.51)
Diluted	$ (1.63)	$ (1.09)	$ (3.11)	$ (1.51)
Weighted average common shares outstanding				
Basic	20,551	20,171	20,473	20,131
Diluted	20,551	20,171	20,473	20,131

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

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