Enanta Pharmaceuticals Reports Financial Results for its Fiscal First Quarter Ended December 31, 2021 with Webcast and Conference Call Today at 4:30 p.m. ET

February 8, 2022
Download this Press Release

- *Expects to Begin Dosing in a First-in-Human Study of EDP-235, an Oral 3CL Protease Inhibitor Specifically Designed for the Treatment of COVID-19, This Month*
- *Completed Enrollment in RSVP, a Phase 2b Study of EDP-938 in Adults With Community-Acquired Respiratory Syncytial Virus (RSV); Expects Topline Data in the Second Quarter of 2022*
- *Plans 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 $27.6 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 first quarter ended December 31, 2021.

“We are excited to begin dosing subjects this month with EDP-235, our SARS-CoV-2 3CL protease inhibitor specifically designed as a once-daily, orally-dosed treatment for COVID-19. As the COVID-19 pandemic continues, demand for a convenient, once-daily therapeutic is stronger than ever, and we look forward to advancing EDP-235 as a COVID-19 treatment option based on its potential best-in-class preclinical profile,” said Jay R. Luly Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “Building on our respiratory virus portfolio, we also made significant progress in our RSV programs. Last quarter we completed enrollment in RSVP, our Phase 2b Study of EDP-938 in adults with community-acquired RSV, and we are eager to report topline data next quarter. Additionally, last month, we were pleased to introduce EDP-323, an RSV L-protein inhibitor that can be used alone or in combination with EDP-938 to potentially broaden the addressable patient populations or their treatment windows, and we plan to initiate a Phase 1 study of EDP-323 in the second half of 2022. Importantly, we remain committed to developing a functional cure for chronic hepatitis B virus patients with EDP-514, our lead core inhibitor, in combination with other mechanisms. We believe that a potent core inhibitor such as EDP-514 will be an important component of a successful combination treatment regimen.”

Fiscal First Quarter Ended December 31, 2021 Financial Results

Total revenue for the three months ended December 31, 2021 was $27.6 million and consisted entirely of royalty revenue from worldwide net sales of MAVYRET®/MAVIRET®, AbbVie’s eight-week treatment for chronic hepatitis C virus (HCV). For the three months ended December 31, 2020, total royalty revenue was $31.7 million on AbbVie’s sales of MAVYRET/MAVIRET. As reported by AbbVie, treated patient volumes remain suppressed compared to pre-COVID levels.

Research and development expenses totaled $48.5 million for the three months ended December 31, 2021, compared to $36.7 million for the three months ended December 31, 2020. The increase was primarily due to the timing of manufacturing in support of the company’s clinical studies in its virology programs.

General and administrative expenses totaled $9.5 million for the three months ended December 31, 2021, compared to $7.4 million for the three months ended December 31, 2020. This increase was primarily due to additional headcount and compensation expense.

Enanta recorded a minor income tax benefit related to the release of a state tax reserve for the three months ended December 31, 2021 compared to an income tax benefit of $3.3 million for the same period in 2020. Enanta recorded a larger income tax benefit in 2020 than in 2021 due to the provision of the CARES Act of 2020, which enabled the company to carry back its tax loss in the 2020 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 December 31, 2021 was $30.1 million, or a loss of $1.48 per diluted common share, compared to a net loss of $8.3 million, or a loss of $0.41 per diluted common share, for the corresponding period in 2020.

Enanta’s cash, cash equivalents and short-term and long-term marketable securities totaled $347.7 million at December 31, 2021. 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

Respiratory Syncytial Virus (RSV)

- EDP-938, an N-protein inhibitor with Fast Track Designation by the U.S. Food and Drug Administration (FDA), is designed to target the two major types of RSV, A and B. It is being evaluated in a broad clinical development program in multiple patient groups, consisting of three ongoing Phase 2 trials: RSVP, RSVPEDs and RSVTx.
- RSVP is a Phase 2b study designed to confirm the results of the challenge study in the setting of community-acquired RSV infection in an otherwise healthy adult population. Enanta recently announced enrollment is complete in this study and

plans to report topline data in the second quarter of calendar 2022.

- RSVPEDs, a Phase 2 randomized, double-blind, placebo-controlled study in 90 hospitalized and non-hospitalized pediatric RSV patients and RSVTx, a Phase 2b, randomized, double-blind, placebo-controlled study in 200 adult hematopoietic cell transplant recipients with acute RSV infection and symptoms of upper respiratory tract infection, are ongoing. Enanta expects these studies to continue into at least 2023.
- Enanta recently introduced its newest clinical candidate for RSV, EDP-323, which is a novel oral, direct-acting antiviral selectively targeting the RSV L-protein, a viral RNA-dependent RNA polymerase that contains multiple enzymatic activities required for RSV replication. 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 expects to initiate a Phase 1 study in healthy volunteers in the second half of 2022.

COVID-19 (SARS-CoV-2)

- Enanta is on track to begin dosing subjects this month in a Phase 1 study of EDP-235, its oral, coronavirus 3CL protease inhibitor (also known as Mpro or main protease) specifically designed for the treatment of COVID-19. 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, 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. EDP-235 has demonstrated potent antiviral activity across a range of currently circulating SARS-CoV-2 variants, including Omicron and Delta. Additionally, EDP-235 is active against all other known human coronaviruses, providing the potential for a pan-coronavirus treatment.

Hepatitis B Virus (HBV)

- Enanta remains focused on identifying additional compounds with different mechanisms of action to develop in combination with EDP-514, its potent core inhibitor, as a functional cure for chronic HBV patients. 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 continues to progress nanomolar inhibitors of hMPV through preclinical development, and clinical candidate selection is planned for the second half of 2022. hMPV is a pathogen that causes upper and lower respiratory tract infections 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 February 8, 2022, through 11:59 p.m. ET on February 15, 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 3458965. 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-K for the fiscal year ended September 30, 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 STATEMENTS OF OPERATIONS
UNAUDITED
(in thousands, except per share amounts)

	Three Months Ended December 31,	
	2021	**2020**
Revenue	$ 27,648	$ 31,743
Operating expenses		
Research and development	48,549	36,665
General and administrative	9,508	7,377
Total operating expenses	58,057	44,042
Loss from operations	(30,409)	(12,299)
Other income, net	258	677
Loss before income taxes	(30,151)	(11,622)
Income tax benefit	36	3,294
Net loss	$ (30,115)	$ (8,328)
Net loss per share		
Basic	$ (1.48)	$ (0.41)
Diluted	$ (1.48)	$ (0.41)
Weighted average common shares outstanding		
Basic	20,388	20,093
Diluted	20,388	20,093

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

	December 31, 2021	**September 30, 2021**
Assets		
Current assets		
Cash and cash equivalents	$ 99,068	$ 57,206
Short-term marketable securities	159,984	186,796
Accounts receivable	27,648	23,576
Prepaid expenses and other current assets	11,506	14,188
Income tax receivable	28,751	37,255
Total current assets	326,957	319,021
Long-term marketable securities	88,668	108,416
Property and equipment, net	5,435	5,943
Operating lease, right-of-use assets	18,834	4,711
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 440,594	$ 438,791
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 7,841	$ 9,540
Accrued expenses and other current liabilities	26,580	22,429
Operating lease liabilities	3,469	4,203

Total current liabilities	37,890	36,172
Operating lease liabilities, net of current portion	15,958	1,126
Series 1 nonconvertible preferred stock	1,506	1,506
Other long-term liabilities	856	558
Total liabilities	56,210	39,362
Total stockholders' equity	384,384	399,429
Total liabilities and stockholders' equity	$ 440,594	$ 438,791

View source version on businesswire.com: https://www.businesswire.com/news/home/20220208005331/en/

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

Source: Enanta Pharmaceuticals, Inc.