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

February 7, 2023

- *Completes Enrollment in SPRINT, a Phase 2 Clinical Study of EDP-235, a 3CL Protease Inhibitor Designed as an Oral, Once-Daily Treatment for COVID-19; Topline Data Expected in May*
- *Expects Phase 1 Data of EDP-323, an L-Protein Inhibitor in Development as an Oral, Once-Daily Treatment for Respiratory Syncytial Virus (RSV), in 2Q 2023*
- *Expands Robust Pipeline with New Research Programs Developing SARS-CoV-2 Papain-Like Protease Inhibitors and Human Metapneumovirus (hMPV)/RSV Dual-Inhibitors*
- *Revenue for the Quarter was $23.6 Million*

WATERTOWN, Mass.--(BUSINESS WIRE)--Feb. 7, 2023-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections, today reported financial results for its fiscal first quarter ended December 31, 2022.

"We begin 2023 in a strong position and poised for success with multiple upcoming milestones across our pipeline. Notably, we are excited to make important progress in our COVID-19 program with the completion of enrollment in SPRINT, our Phase 2 clinical study of EDP-235, a 3CL protease inhibitor specially designed as an oral, once-daily treatment for SARS-CoV-2 infection," said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. "We look forward to a data readout of SPRINT in May and, pending data, initiating a Phase 3 trial in the second half of this year. Based on the high unmet need that still exists for conveniently prescribed COVID-19 therapies, we are focused on building out our COVID-19 portfolio, with the recent addition of a research program developing SARS-CoV-2 papain-like protease inhibitors. These inhibitors have the potential to be used alone or in combination with 3CL protease inhibitors, such as EDP-235 or other compounds, to provide a range of treatment options for different patient populations. Beyond COVID-19, we look forward to reporting topline data from the Phase 1 study of EDP-323, our RSV L-protein inhibitor, next quarter, and we aim to select a dual inhibitor clinical candidate that targets both hMPV and RSV in the fourth quarter of this year. 2023 is gearing up to be a pivotal year for Enanta, with multiple milestones expected that have the potential to drive value for the company and move us closer to bringing important therapies to patients in need."

Fiscal First Quarter Ended December 31, 2022 Financial Results

Total revenue for the three months ended December 31, 2022 was $23.6 million and consisted primarily of $22.6 million 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, 2021, total royalty revenue was $27.6 million on AbbVie's sales of MAVYRET/MAVIRET. The decline is primarily a result of continued lower treated patient volumes due to the COVID-19 pandemic.

Research and development expenses totaled $40.9 million for the three months ended December 31, 2022, compared to $48.5 million for the three months ended December 31, 2021. The decrease was primarily due to the timing of drug supply manufacturing and preclinical studies in the company's virology program year over year.

General and administrative expenses totaled $12.7 million for the three months ended December 31, 2022, compared to $9.5 million for the three months ended December 31, 2021. This increase was primarily due to an increase in stock-based compensation expense and in headcount.

Net loss for the three months ended December 31, 2022 was $29.0 million, or a loss of $1.39 per diluted common share, compared to a net loss of $30.1 million, or a loss of $1.48 per diluted common share, for the corresponding period in 2021.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $241.4 million at December 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 into the fourth fiscal quarter of 2024.

Pipeline Updates

COVID-19 (SARS-CoV-2)

- Enanta announced today that enrollment is complete in SPRINT (**S**ARS-CoV-2 **PR**otease **IN**hibitor **T**reatment), a Phase 2 clinical study of EDP-235, a 3CL protease inhibitor designed as an oral, once-daily treatment for COVID-19. This randomized, double-blind, placebo-controlled study is evaluating the safety, tolerability, and antiviral activity of EDP-235 compared to placebo. SPRINT was designed to enroll approximately 200 non-hospitalized, symptomatic patients with mild to moderate COVID-19, who were not at increased risk for developing severe disease. During the study, patients received EDP-235 orally at a dose of 200 mg or 400 mg or placebo, once daily for five days, and were assessed for a further 28 days. The primary objective of the study is evaluation of safety and tolerability, and key secondary objectives include analysis of multiple virology measures and pharmacokinetics (PK) to guide dose selection for future trials. Enanta is on schedule to report topline data from SPRINT in May.

- EDP-235 is supported by a robust dataset demonstrating good potency and PK profile, without the need for ritonavir boosting and its associated drug-drug interactions.
    - In January, Enanta announced new preclinical *in vivo* data on EDP-235 highlighting the robust antiviral treatment effect and prevention of COVID-19 transmission in a ferret model. Ferrets were infected with SARS-CoV-2 and then subsequently received either EDP-235 or vehicle. Results demonstrated that EDP-235 treatment of SARS-CoV-2 infected animals resulted in a rapid, robust and sustained decline in viral replication. Additionally, healthy animals did not contract COVID-19 when moved into housing with infected animals that were treated with EDP-235, whereas the healthy animals that were moved into housing with vehicle-treated infected animals did contract the virus. This study continues to support the potential of EDP-235 as an efficacious therapy for COVID-19, and also demonstrates its potential to reduce transmission of the virus.
    - In previously announced Phase 1 data, EDP-235 increased approximately proportionally with ascending single and multiple doses of EDP-235, with a half-life consistent with daily dosing, resulting in a PK profile suitable for once-daily dosing. Data also demonstrated that EDP-235 had strong exposure multiples over the EC90, without the need for ritonavir.
- Enanta plans to present further details of the EDP-235 Phase 1 data, the ferret study and two other preclinical posters at the International Conference on Antiviral Research (ICAR) 2023 in March, as well as other preclinical data at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in April.
- In January, Enanta introduced a new research program focused on the discovery and development of inhibitors of the SARS-CoV-2 papain-like protease (PLpro) for the oral treatment of COVID-19. PLpro is another essential enzyme which plays an important role in viral replication and, in addition, acts to suppress the innate immune response. Inhibition of PLpro blocks viral replication and has the potential to alleviate the suppression of the immune response to SARS-CoV-2 infection. As this mechanism is distinct from 3CL protease inhibition, it could potentially be used alone or in combination with 3CL protease inhibitors. In preclinical research, Enanta's prototype PLpro inhibitors demonstrated nanomolar potency against the Omicron variant in both biochemical and cellular assays, and the company continues to optimize inhibitors as it progresses this program forward toward development candidate selection.

Respiratory Syncytial Virus (RSV)

- EDP-938, an N-protein inhibitor, is being evaluated in a broad clinical development program in multiple high-risk patient groups, including pediatric and high-risk adult populations.
    - Ongoing studies include RSVHR, a Phase 2b randomized, double-blind, placebo-controlled study recently initiated in adults with acute RSV infection who are at high risk of complications, including the elderly and/or those with congestive heart failure, chronic obstructive pulmonary disease or asthma; 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.
    - These three studies are expected to continue through 2023 and Enanta is monitoring RSV epidemiology to determine the impact on trial enrollment and timing for data readouts.
- EDP-323, a novel, oral, direct-acting antiviral selectively targeting the RSV L-protein, is being evaluated in a Phase 1 study. This double-blind, placebo-controlled, first-in-human study is designed to enroll approximately 80 healthy subjects to assess the safety, tolerability, and PK of EDP-323. Enanta plans to present preclinical PK data at ECCMID and expects to report topline data from this Phase 1 study in the second quarter of 2023.
    - 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 the treatment window.

Human Metapneumovirus (hMPV)/RSV

- In January, Enanta announced a new research program with broader spectrum antivirals targeting both hMPV and RSV with a single agent, which the company refers to as a dual-inhibitor. In preclinical studies, Enanta's prototype dual inhibitor maintained nanomolar activity against multiple genotypes and strains of hMPV and RSV in a range of cell types. Further, the dual-inhibitor potently inhibited replication of both hMPV and RSV in a dose-dependent manner in respective mouse models, demonstrating a significant reduction in viral load of both viruses. Enanta expects to select a dual hMPV/RSV clinical candidate in the fourth quarter of 2023.

Hepatitis B Virus (HBV)

- Enanta remains focused on identifying additional compounds with different mechanisms of action to combine with EDP-514, its potent core inhibitor, and a nucleoside reverse transcriptase inhibitor. EDP-514 has displayed a good safety profile and robust antiviral activity in multiple HBV patient populations, with significant declines in HBV DNA among the best published to date for core inhibitors.

Upcoming Events and Presentations

- SVB Securities Global Biopharma Conference, February 14, 2023
- Oppenheimer 33rd Annual Healthcare Conference, March 14, 2023
- International Conference on Antiviral Research, March 13 – 17, 2023
- 33rd European Congress of Clinical Microbiology and Infectious Diseases, April 15 – 18, 2023
- Enanta plans to issue its fiscal second quarter financial results press release, and hold a conference call regarding those results, on May 8, 2023.

Conference Call and Webcast Information

Enanta will host a conference call and webcast today at 4:30 p.m. ET. The live webcast can be accessed under "Events & Presentations" in the investors section of Enanta's website. To participate by phone, please register for the call here. It is recommended that participants register a day in advance or at a minimum of 15 minutes before the call. Once registered, participants will receive an email with the dial-in information. The archived webcast will be available on Enanta's website for approximately 30 days following the event.

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. Enanta's research and development programs include clinical candidates for the following disease targets: respiratory syncytial virus (RSV), SARS-CoV-2 (COVID-19) and hepatitis B virus (HBV). Enanta is also conducting research on a single agent targeting both RSV and 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 dual-inhibitor program in hMPV/RSV. 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, 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 December 31,	
	2022	**2021**
Revenue	$ 23,585	$ 27,648
Operating expenses		
Research and development	40,902	48,549
General and administrative	12,696	9,508
Total operating expenses	53,598	58,057
Loss from operations	(30,013)	(30,409)
Other income, net	993	258
Loss before income taxes	(29,020)	(30,151)
Income tax benefit	34	36
Net loss	$ (28,986)	$ (30,115)

Net loss per share		
Basic	$ (1.39)	$ (1.48)
Diluted	$ (1.39)	$ (1.48)
Weighted average common shares outstanding		
Basic	20,816	20,388
Diluted	20,816	20,388

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

	December 31, 2022	September 30, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 42,223	$ 43,994
Short-term marketable securities	172,247	205,238
Accounts receivable	22,585	20,318
Prepaid expenses and other current assets	17,946	13,445
Income tax receivable	28,703	28,718
Total current assets	283,704	311,713
Long-term marketable securities	26,939	29,285
Property and equipment, net	8,682	6,173
Operating lease, right-of-use assets	23,540	23,575
Restricted cash	3,968	3,968
Other long-term assets	701	696
Total assets	$ 347,534	$ 375,410
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,352	$ 6,000
Accrued expenses and other current liabilities	15,163	20,936
Operating lease liabilities	3,486	2,891
Total current liabilities	23,001	29,827
Operating lease liabilities, net of current portion	21,859	22,372
Series 1 nonconvertible preferred stock	1,423	1,423
Other long-term liabilities	414	454
Total liabilities	46,697	54,076
Total stockholders' equity	300,837	321,334
Total liabilities and stockholders' equity	$ 347,534	$ 375,410

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Source: Enanta Pharmaceuticals, Inc.