Enanta Pharmaceuticals Reports Financial Results for its Fiscal Second Quarter with Conference Call and Webcast Today at 4:30 p.m. ET

May 8, 2023

- *Reported Positive Topline Data from Phase 2 SPRINT Clinical Study of EDP-235, a 3CL Protease Inhibitor in Development as an Oral, Once-Daily Treatment for COVID-19*
- *Strengthened Balance Sheet Through the Sale of 54.5% of Future MAVYRET®/MAVIRET® Royalties for an Upfront Payment of $200 Million*
- *On Track to Report Phase 1 Data of EDP-323, an L-Protein Inhibitor in Development as an Oral, Once-Daily Treatment for Respiratory Syncytial Virus, in June*
- *Royalty Revenue for the Quarter was $17.8 Million*

WATERTOWN, Mass.--(BUSINESS WIRE)--May 8, 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 second quarter ended March 31, 2023.

“At Enanta, we are focused on transforming the lives of patients with curative therapies, by leveraging our previous successes in the development of small molecules and our deep understanding of virologic diseases,” said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “This vision is supported by positive topline data from our SPRINT Phase 2 study announced today. With EDP-235 and Enanta’s entire pipeline, our goal continues to be to develop cures for life-threatening viral infections. Looking ahead, we are also eager to advance our programs in respiratory syncytial virus with an upcoming data readout for EDP-323, our L-protein inhibitor in development as a once-daily oral treatment, next month. Further, the financial flexibility we now have with the additional funding from our royalty monetization allows us to continue to advance our robust pipeline.”

Fiscal Second Quarter Ended March 31, 2023 Financial Results

Total revenue for the three months ended March 31, 2023 was $17.8 million and consisted of royalty revenue from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET® (glecaprevir/pibrentasvir), compared to $18.7 million for the three months ended March 31, 2022.

Research and development expenses totaled $43.5 million for the three months ended March 31, 2023, compared to $42.1 million for the three months ended March 31, 2022. The increase was primarily due to the timing of clinical trial expenses in our virology programs.

General and administrative expenses totaled $13.8 million for the three months ended March 31, 2023, compared to $10.5 million for the three months ended March 31, 2022. The increase was due to increased stock-related compensation expense and legal fees associated with our patent infringement suit against Pfizer.

Net loss for the three months ended March 31, 2023 was $37.7 million, or a loss of $1.79 per diluted common share, compared to a net loss of $33.6 million, or a loss of $1.63 per diluted common share, for the corresponding period in 2022.

Enanta’s cash, cash equivalents and short-term and long-term marketable securities totaled $225.1 million at March 31, 2023, before giving effect to its April 2023 sale of 54.5% of its ongoing MAVYRET®/MAVIRET® royalties from AbbVie for an upfront payment of $200 million from OMERS, one of Canada’s largest defined benefit pension plans. Enanta expects that its current cash, cash equivalents and marketable securities, as well as the royalty sale and Enanta’s continuing portion of cash from future royalty revenue, will be sufficient to meet the anticipated cash requirements of its existing business and development programs into calendar 2026.

Pipeline Updates

COVID-19 (SARS-CoV-2)

- Today, Enanta announced positive topline data from SPRINT (**S**ARS-Cov-2 **PR**otease **IN**hibitor **T**reatment), a double-blind, placebo-controlled Phase 2 clinical trial of EDP-235, the company’s oral, 3CL protease inhibitor, in non-hospitalized, symptomatic adults with mild or moderate COVID-19 who were not at high risk for severe disease. In the trial, EDP-235 met the primary endpoint and was generally safe and well-tolerated. A dose-dependent improvement in symptoms was observed with EDP-235 treatment compared to placebo, which achieved statistical significance ($p<0.05$) in the 400mg treatment group at multiple time points, starting as early as one day after the first dose. In a prespecified population consisting of patients enrolled within 3 days of symptom onset, a statistically significant improvement was observed with EDP-235 at 400mg at all time points. While no difference was observed in time to improvement of 14 targeted COVID-19 symptoms, an analysis of a subset of these symptoms showed a 2-day shorter time to improvement in patients receiving EDP-235 400mg who were enrolled within 3 days of symptom onset ($p<0.01$). No effect on virologic endpoints as measured in the nose was detected due to the rapid viral decline in the placebo arm of this highly immunologically-experienced, standard risk population.

- Enanta will continue to evaluate data from SPRINT and is focusing on partnership opportunities for Phase 3 and on the potential for a different Phase 2 study in acute or long COVID that could further demonstrate the efficacy of EDP-235.
- Enanta is advancing a 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. The company continues to optimize inhibitors as it progresses this program forward to select a development candidate.

Respiratory Syncytial Virus (RSV)

- Enanta is progressing a broad clinical program, aimed at targeting populations at high-risk for RSV, and is evaluating EDP-938, an N-protein inhibitor, with three ongoing clinical trials. EDP-938 is supported by data from a previous clinical challenge study showing that the compound significantly inhibited replication of RSV, the only published study to show such an effect for an N-inhibitor. EDP-938 also has a favorable and consistent safety profile.
    - Multiple ongoing studies include RSVPEDs, a Phase 2 randomized, double-blind, placebo-controlled study in hospitalized and non-hospitalized pediatric RSV patients; RSVHR, a Phase 2b randomized, double-blind, placebo-controlled study 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; 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. Enanta is monitoring RSV epidemiology to determine the impact on trial enrollment and timing for data readouts.
- Enanta is on track to report topline Phase 1 data in June from its ongoing study of EDP-323, a novel, oral, direct-acting antiviral selectively targeting the RSV L-protein. This double-blind, placebo-controlled, first-in-human study is designed to enroll healthy subjects to assess EDP-323's safety, tolerability, and pharmacokinetics (PK). EDP-323 has the potential to be used alone or in combination with EDP-938 to potentially broaden the addressable patient populations or the treatment window.
    - In April, at ECCMID, Enanta reported preclinical data highlighting EDP-323's favorable preclinical PK properties, excellent bioavailability with low plasma clearance, and favorable target tissue distribution, supporting a once-daily, oral-dosing regimen for RSV.

Human Metapneumovirus (hMPV)/RSV

- Enanta's research program targeting both hMPV and RSV with a single agent, which the company refers to as a dual inhibitor, is ongoing. 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 mouse models of the respective viruses, demonstrating significant reductions in viral load of each virus. Enanta expects to select a dual hMPV/RSV inhibitor clinical candidate in the fourth quarter of 2023.

Hepatitis B Virus (HBV)

- Enanta remains focused on identifying additional compounds externally 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.

Corporate

- In April, Enanta strengthened its balance sheet with the sale to OMERS of 54.5% of Enanta's future royalty payments from AbbVie Inc. on worldwide sales of MAVYRET/MAVIRET. The upfront purchase price paid to Enanta was $200 million. OMERS right to receive royalty payments is based on net sales of the product beginning in July 2023 through June 2032, with total payments capped at 1.42 times the purchase price. Enanta's retains 45.5% of all royalties until the cap is hit, at which point 100% of all further royalties revert to Enanta.

Upcoming Events and Presentations

- JMP Securities Life Sciences Conference – May 16, 2023
- RBC Capital Markets Global Healthcare Conference – May 17, 2023
- Jefferies Global Healthcare Conference – June 7-9, 2023
- Enanta plans to issue its fiscal third quarter 2023 press release, and hold a conference call regarding those results, on August 7, 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 join by phone, participants can register for the call here. It is recommended that participants register 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 receives 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.

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,	
	2023	2022	2023	2022
Revenue	$ 17,795	$ 18,716	$ 41,380	$ 46,364
Operating expenses				
Research and development	43,468	42,087	84,370	90,636
General and administrative	13,778	10,476	26,474	19,984
Total operating expenses	57,246	52,563	110,844	110,620
Loss from operations	(39,451)	(33,847)	(69,464)	(64,256)
Other income, net	1,837	255	2,830	549
Loss before income taxes	(37,614)	(33,592)	(66,634)	(63,707)
Income tax expense	(44)	—	(10)	—
Net loss	$ (37,658)	$ (33,592)	$ (66,644)	$ (63,707)
Net loss per share				
Basic	$ (1.79)	$ (1.63)	$ (3.19)	$ (3.11)
Diluted	$ (1.79)	$ (1.63)	$ (3.19)	$ (3.11)
Weighted average common shares outstanding				
Basic	21,035	20,551	20,882	20,473
Diluted	21,035	20,551	20,882	20,473

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

	March 31, 2023	September 30, 2022

Assets		
Current assets		
Cash and cash equivalents	$ 73,178	$ 43,994
Short-term marketable securities	136,906	205,238
Accounts receivable	17,795	20,318
Prepaid expenses and other current assets	14,484	13,445
Income tax receivable	28,774	28,718
Total current assets	271,137	311,713
Long-term marketable securities	15,040	29,285
Property and equipment, net	11,050	6,173
Operating lease, right-of-use assets	24,554	23,575
Restricted cash	3,968	3,968
Other long-term assets	696	696
Total assets	$ 326,445	$ 375,410
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 11,761	$ 6,000
Accrued expenses and other current liabilities	15,482	20,936
Operating lease liabilities	4,923	2,891
Total current liabilities	32,166	29,827
Operating lease liabilities, net of current portion	23,073	22,372
Series 1 nonconvertible preferred stock	1,423	1,423
Other long-term liabilities	408	454
Total liabilities	57,070	54,076
Total stockholders' equity	269,375	321,334
Total liabilities and stockholders' equity	$ 326,445	$ 375,410

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