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

August 7, 2023

- *Reported Positive Topline Data from Phase 1 Study of EDP-323, an L-Protein Inhibitor in Development as an Oral, Once-Daily Treatment for Respiratory Syncytial Virus (RSV); Expect to Initiate Phase 2 Human Challenge Study in Early 4Q 2023.*
- *Cash and Marketable Securities Totaled $392.5 Million at June 30, 2023*
- *Royalty Revenue for the Quarter was $18.9 Million*

WATERTOWN, Mass.--(BUSINESS WIRE)--Aug. 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 third quarter ended June 30, 2023.

“Our fiscal third quarter was marked by important progress in our pipeline, most notably across our RSV and COVID-19 programs. In RSV, we were pleased to report positive Phase 1 results for EDP-323 in healthy volunteers, demonstrating favorable safety, tolerability, and pharmacokinetics. These data allow us to build and progress our RSV portfolio through advancement of this second oral RSV antiviral into a Phase 2 human challenge study, with a goal of identifying potential applications for EDP-323 as a monotherapy or combination approach. We believe our RSV antivirals have significant promise and we are advancing our clinical programs with a sense urgency given the substantial unmet need for RSV treatments,” said Jay R. Luly Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “Additionally, in our COVID-19 program, we presented further data in June from the SPRINT trial where EDP-235 treatment resulted in a 1.0 log drop in viral load in the subset of patients who had not been recently infected with SARS-CoV-2 and were treated within three days of symptom onset. With our robust pipeline, including EDP-938, the most advanced RSV N-protein inhibitor in development, and our strong financial position, we are poised to be a leader in the development of therapeutics for life-threatening viruses.”

Fiscal Third Quarter Ended June 30, 2023 Financial Results

Total revenue for the three months ended June 30, 2023 was $18.9 million and consisted of royalty revenue from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET® (glecaprevir/pibrentasvir), compared to $19.5 million for the three months ended June 30, 2022.

Research and development expenses totaled $43.0 million for the three months ended June 30, 2023, compared to $39.1 million for the three months ended June 30, 2022. The increase was primarily due to the timing of clinical trial expenses in the company’s virology programs.

General and administrative expenses totaled $12.6 million for the three months ended June 30, 2023, compared to $12.9 million for the three months ended June 30, 2022.

Enanta recorded income tax expense of $4.2 million for the three months ended June 30, 2023 driven by the receipt of the $200.0 million from the royalty sale agreement which is taxable for federal and state purposes. Enanta was able to utilize federal net operating loss and research and development tax credit carryforwards as well as a deduction for foreign derived intangible income to substantially offset the taxable effect of the royalty sale agreement. For the three months ended June 30, 2022, Enanta recorded an income tax benefit of $0.4 million, which was due to the release of a state tax reserve during the period.

Net loss for the three months ended June 30, 2023 was $39.1 million, or a loss of $1.86 per diluted common share, compared to a net loss of $31.7 million, or a loss of $1.53 per diluted common share, for the corresponding period in 2022.

Enanta’s cash, cash equivalents and short-term and long-term marketable securities totaled $392.5 million at June 30, 2023. In April 2023, Enanta sold 54.5% of its ongoing royalties from AbbVie on sales of MAVYRET®/MAVIRET® after June 30, 2023, for an upfront payment of $200.0 million from OMERS, one of Canada’s largest defined benefit pension plans. For financial reporting purposes, the transaction will be treated as debt, with the upfront purchase payment of $200.0 million recorded as a liability. Enanta will continue to record 100% of the royalty earned as revenue and will then amortize the debt liability proportionally as 54.5% of the cash royalties are paid to OMERS, until a cap of 1.42 times the purchase payment is met, after which point 100% of the cash royalties will be retained by Enanta. Interest expense will be recorded in Enanta’s consolidated statement of operations as other expense based on an imputed interest rate.

Enanta expects that its current cash, cash equivalents and marketable securities and its continuing portion of cash from future royalty revenue, should be sufficient to meet the anticipated cash requirements of its existing business and development programs into the second half of fiscal 2027.

Updated Financial Guidance for Fiscal 2023

- Research and Development Expense: $165 million to $175 million
- General and Administrative Expense: $50 million to $55 million
- 54.5% of royalties on MAVYRET®/MAVIRET® sales in fiscal fourth quarter will be paid to OMERS

Pipeline Update and Business Review

RSV

- EDP-938, an N-protein inhibitor with Fast Track designation from the U.S. Food and Drug Administration (FDA), is supported by data from a Phase 2 RSV human challenge study that demonstrated a significant impact on viral replication and symptom reduction, and is the only published study to show such an effect for an N-inhibitor. EDP-938 also has a favorable and consistent safety profile.
    - Ongoing studies of EDP-938 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 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 RSV infection and symptoms of upper respiratory tract infection.
    - Enanta expects to complete enrollment in one or more of its ongoing Phase 2 studies of EDP-938 in the upcoming Northern Hemisphere RSV season and to report data in fiscal 2024, pending a return to a normal pre-pandemic type of RSV season in the Northern Hemisphere.
- In June, Enanta reported positive topline data from healthy volunteers in its Phase 1 study of EDP-323, an oral, L-protein inhibitor, for the treatment of RSV. EDP-323 has the potential to be used alone or in combination with EDP-938 to address different patient populations or extend the treatment window. Data demonstrated favorable safety, tolerability, and pharmacokinetics (PK) supportive of once-daily dosing, with good exposure multiples, thereby supporting further clinical advancement of EDP-323.
    - Enanta plans to initiate a human challenge study evaluating EDP-323 early in the fourth quarter of 2023 and anticipates having data results in the second quarter of 2024.

COVID-19 (SARS-CoV-2)

- Enanta announced additional analyses of SPRINT (**S**ARS-Cov-2 **PR**otease **IN**hibitor **T**reatment), its Phase 2 clinical trial of EDP-235, an oral, 3CL protease inhibitor in non-hospitalized, symptomatic adults with mild or moderate COVID-19.
    - These analyses demonstrated a virologic effect of EDP-235 in the subset of patients who had not been recently infected, known as nucleocapsid-negative patients, as measured by lack of antibodies to the SARS-CoV-2 nucleocapsid. Specifically, in this nucleocapsid-negative patient subset, an 0.8 log viral load decline was observed at Day 5 with 400 mg of EDP-235 compared to placebo, and a 1.0 log viral load decline in nucleocapsid-negative patients who were treated within three days of symptom onset.
    - These data build upon the positive topline SPRINT data announced in May in which a dose-dependent improvement in symptoms was observed with EDP-235 treatment compared to placebo, which achieved statistical significance ($p<0.05$) in the 400 mg 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 three days of symptom onset, a statistically significant improvement was observed with EDP-235 at 400 mg at all time points. Further, an analysis of a subset of symptoms showed a two day shorter time to symptom improvement in patients receiving EDP-235 400 mg who were enrolled within three days of symptom onset ($p<0.01$). The study also demonstrated that EDP-235 was generally safe and well-tolerated.
- Enanta plans to conduct all future COVID work in the context of a collaboration. To that end, the company is focused on partnering opportunities for progressing EDP-235 into Phase 3 trials and is engaging in regulatory discussions regarding the registrational pathway for such development of EDP-235.

Human Metapneumovirus (hMPV)/RSV

- Enanta's research program targeting both hMPV and RSV with a single agent is ongoing with optimization of 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 each virus. Enanta expects to select a dual hMPV/RSV clinical candidate in the fourth quarter of 2023.

Hepatitis B Virus (HBV)

- Enanta continues to monitor the HBV field to identify alternative compounds for development in combination regimens with a nucleoside reverse transcriptase inhibitor and EDP-514, its potent core inhibitor, which received Fast Track designation from the FDA.

Upcoming Events and Presentations

- Wells Fargo Securities Healthcare Conference, September 7, 2023
- H.C. Wainwright 25th Annual Global Investment Conference, September 12, 2023

- Baird 2023 Global Healthcare Conference, September 13, 2023
- 2023 Cantor Global Healthcare Conference, September 26 – 28, 2023
- 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 20, 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).

Glecaprevir, a protease inhibitor discovered by Enanta, is part of one of the leading treatment regimens for curing chronic hepatitis c virus 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 June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
Revenue	$ 18,892	$ 19,479	$ 60,272	$ 65,843
Operating expenses				
Research and development	42,987	39,090	127,357	129,726
General and administrative	12,618	12,929	39,092	32,913
Total operating expenses	55,605	52,019	166,449	162,639
Loss from operations	(36,713)	(32,540)	(106,177)	(96,796)
Interest expense	(1,997)	—	(1,997)	—
Interest and investment income, net	3,866	393	6,696	942
Loss before income taxes	(34,844)	(32,147)	(101,478)	(95,854)
Income tax (expense) benefit	(4,221)	447	(4,231)	447
Net loss	$ (39,065)	$ (31,700)	$(105,709)	$ (95,407)
Net loss per share				
Basic	$ (1.86)	$ (1.53)	$ (5.05)	$ (4.64)
Diluted	$ (1.86)	$ (1.53)	$ (5.05)	$ (4.64)
Weighted average common shares outstanding				
Basic	21,054	20,710	20,939	20,552

Diluted	21,054	20,710	20,939	20,552

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

	June 30, 2023	September 30, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 95,177	$ 43,994
Short-term marketable securities	291,408	205,238
Accounts receivable	18,892	20,318
Prepaid expenses and other current assets	17,071	13,445
Income tax receivable	25,917	28,718
Total current assets	448,465	311,713
Long-term marketable securities	5,924	29,285
Property and equipment, net	12,014	6,173
Operating lease, right-of-use assets	23,968	23,575
Restricted cash	3,968	3,968
Other long-term assets	830	696
Total assets	$ 495,169	$ 375,410
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 7,932	$ 6,000
Accrued expenses and other current liabilities	18,196	20,936
Liability related to the sale of future royalties	36,693	—
Operating lease liabilities	5,368	2,891
Total current liabilities	68,189	29,827
Liability related to the sale of future royalties, net of current portion	164,979	—
Operating lease liabilities, net of current portion	22,333	22,372
Series 1 nonconvertible preferred stock	1,423	1,423
Other long-term liabilities	426	454
Total liabilities	257,350	54,076
Total stockholders' equity	237,819	321,334
Total liabilities and stockholders' equity	$ 495,169	$ 375,410

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