Enanta Pharmaceuticals Reports Financial Results for its Fiscal Fourth Quarter and Year Ended September 30, 2023, with Webcast and Conference Call Today at 4:30 p.m. ET

November 20, 2023

- *Initiated a Phase 2a Challenge Study of EDP-323, an L-Protein Inhibitor, in Development as an Oral, Once-Daily Treatment for Respiratory Syncytial Virus (RSV); Expect to Report Data in Q3 2024*
- *Streamlined Business and Significantly Lowered 2024 R&D and G&A Spending Guidance to Support Ongoing Operations*
- *Cash and Marketable Securities Totaled $370 Million at September 30, 2023*

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 20, 2023-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs with an emphasis on treatments for viral infections, today reported financial results for its fiscal fourth quarter and year ended September 30, 2023.

"Throughout fiscal 2023, Enanta remained focused on advancing our two RSV clinical stage programs of best-in-class antivirals with different mechanisms of action. We are pleased to announce the initiation of our Phase 2a challenge study of EDP-323, an L-protein inhibitor, in development as an oral, once-daily treatment for RSV, and look forward to reporting data in the third quarter of 2024," said Jay R. Luly Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. "Further, we are advancing RSVPEDs and RSVHR, our ongoing Phase 2 trials of EDP-938, our N-protein inhibitor, with a data readout from at least one of these studies in the third quarter of 2024, assuming this winter is a normal Northern Hemisphere RSV season. We have also made important adjustments to significantly reduce our 2024 spending and extend our cash runway through fiscal 2027. As a result, we are well positioned financially as we look forward to readouts across our RSV pipeline in 2024 and advancements in new non-virology programs."

Fiscal Fourth Quarter and Year Ended September 30, 2023 Financial Results

Total revenue was $18.9 million for the three months ended September 30, 2023, which consisted of royalty revenue derived from worldwide net sales of AbbVie's hepatitis C virus (HCV) regimen MAVYRET ®/MAVIRET®, compared to royalty revenue of $20.3 million for the three months ended September 30, 2022. For the twelve months ended September 30, 2023, total revenue was $79.2 million compared to $86.2 million for the same period in 2022. The decrease in the quarter and in year-over-year revenue is due to a decline in AbbVie's sales of MAVYRET ®/MAVIRET®.

Beginning with the quarter ended September 30, 2023, 54.5% of Enanta's ongoing royalties from AbbVie's net sales of MAVYRET ®/MAVIRET® are being paid to OMERS, one of Canada's largest defined benefit pension plans, pursuant to a royalty sale transaction in April 2023. For financial reporting purposes, the transaction was 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 royalty payments are paid to OMERS, until a cap of 1.42 times the purchase payment is met, after which point 100% of the cash royalty payments will be retained by Enanta. Non-cash interest expense was $3.2 million for the three months ended September 30, 2023 and $5.1 million for the twelve months ended September 30, 2023.

Research and development expenses were $36.2 million for the three months ended September 30, 2023, compared to $34.8 million for the three months ended September 30, 2022. The increase was due to the timing of clinical trial costs, offset by a decrease in preclinical and manufacturing costs. For the twelve months ended September 30, 2023, research and development expenses were $163.5 million compared to $164.5 million in 2022.

General and administrative expenses totaled $13.8 million for the three months ended September 30, 2023, compared to $12.6 million for the three months ended September 30, 2022. For the twelve months ended September 30, 2023, general and administrative expenses were $52.9 million compared to $45.5 million in 2022. The increases in both periods were primarily due to an increase in legal fees related to the company's patent infringement suit against Pfizer.

Other income, net, totaled $4.7 million for the three months ended September 30, 2023, compared to $0.7 million for the three months ended September 30, 2022. For the twelve months ended September 30, 2023, other income, net, totaled $11.4 million compared to $1.7 million in 2022. The increases in both periods were primarily due to an increase in investment income due to an increase in Enanta's average invested cash balance from the receipt in April 2023 of $200 million from the sale of the company's MAVYRET ®/MAVIRET® royalty, as well as increases in interest rates year-over-year.

Enanta recorded an income tax benefit of $1.4 million for the three months ended September 30, 2023, compared to income tax expense of less than $0.1 million for the three months ended September 30, 2022. Enanta recorded income tax expense of $2.8 million for the twelve months ended September 30, 2023, compared to an income tax benefit of $0.4 million for the three months ended September 30, 2022. Despite recording a loss before taxes during the twelve months ended September 30, 2023, Enanta recorded tax expense driven by the receipt of the $200.0 million from the royalty sale agreement, which is treated as income for Federal and State income tax purposes. This taxable income and its related income tax expense was substantially offset by net operating loss carryforwards, research and development tax credit carryforwards and a deduction for foreign derived intangible income.

Net loss for the three months ended September 30, 2023, was $28.1 million, or a loss of $1.33 per diluted common share, compared to a net loss of

$26.3 million, or a loss of $1.27 per diluted common share, for the corresponding period in 2022. For the twelve months ended September 30, 2023, net loss was $133.8 million, or a loss of $6.38 per diluted common share, compared to a net loss of $121.8 million, or loss of $5.91 per diluted common share for the corresponding period in 2022.

Enanta's cash, cash equivalents and marketable securities totaled $370.0 million at September 30, 2023. Enanta expects that its current cash, cash equivalents and short-term marketable securities, as well as its continuing retained portion of royalty revenue, will continue to be sufficient to meet the anticipated cash requirements of its existing business and development programs through fiscal 2027.

Financial Guidance for Fiscal Year 2024

- Research and Development Expense: $100 million to $120 million (reduced from $163.5 million of actual expense in 2023)
- General and Administrative Expense: $45 million to $50 million (reduced from $52 million of actual expense in 2023; guidance includes an increase in legal fees associated with the company's patent infringement lawsuit)

Pipeline Update and Business Review

Virology

RSV

- Enanta is progressing multiple clinical programs aimed at treating populations at high-risk for serious outcomes from RSV infection, and is evaluating EDP-938, an N-protein inhibitor, with two ongoing Phase 2 clinical trials, RSVPEDS and RSVHR.
    - RSVPEDs is a Phase 2 randomized, double-blind, placebo-controlled study in hospitalized and non-hospitalized pediatric RSV patients. The study, which will enroll approximately 90 patients aged 28 days to 36 months, is being conducted in two parts. Because this is the first time the drug is being dosed in pediatrics, the objective of the first part of the study is to evaluate the safety and pharmacokinetics of EDP-938 in multiple ascending doses to select the optimal dose for each age group. The second part of the study will evaluate the antiviral activity of EDP-938 at the selected dose, and symptom scores will be assessed throughout the treatment duration. This part is designed as a small cohort to show a trend toward improved virology metrics for EDP-938 compared to placebo and to give confidence to move forward efficiently into registrational studies.
    - RSVHR is a Phase 2b randomized, double-blind, placebo-controlled study in approximately 180 adults with RSV infection who are at high risk of complications, including the elderly and those with congestive heart failure, chronic obstructive pulmonary disease or asthma. The primary endpoint of RSVHR is time to resolution of RSV lower respiratory tract disease symptoms as assessed by the Respiratory Infection Intensity and Impact Questionnaire (RiiQ™) symptom scale. Secondary endpoints include additional clinical efficacy measures and antiviral activity compared to placebo, pharmacokinetics, and safety of EDP-938.
    - 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, was discontinued in September and resources were reallocated to the enrollment and completion of the other ongoing Phase 2 RSV trials.
    - Enanta expects to complete enrollment in one or both of its ongoing Phase 2 studies of EDP-938 and to report data in the third quarter of 2024, assuming this winter is a normal pre-pandemic RSV season in the Northern Hemisphere. Enanta has expanded its global footprint and has over 75 sites across 15 countries for RSVPEDs and over 130 sites across 16 countries for RSVHR.
    - In October, Enanta presented data at IDWeek™ 2023 highlighting EDP-938's high barrier to the development of clinical resistance as demonstrated in the human challenge study. This is in contrast to the lower barrier to resistance that has been observed for other mechanisms, thereby supporting further development of this first-in-class N-protein inhibitor.
- Enanta today announced the initiation of a Phase 2a human challenge study of EDP-323, an oral, L-protein inhibitor in development for the treatment of RSV. The advancement of EDP-323 into a challenge study is supported by positive Phase 1 data which demonstrated favorable safety, tolerability, and pharmacokinetics (PK) supportive of once-daily dosing, with good exposure multiples. In this randomized, double-blind, placebo-controlled, human challenge study, up to 114 healthy adult subjects will be infected with RSV-A Memphis 37b virus. Primary and secondary outcome measures include safety, changes in viral load measurements and changes in baseline symptoms. Enanta plans to report data from this Phase 2a study in the third quarter of 2024.
    - In September, Enanta presented data for EDP-323 at the 9th European Scientific Working Group on Influenza (ESWI) Conference. These data detailed the positive results observed in the Phase 1 study of healthy subjects.
- Enanta hosted an RSV Key Opinion Leader event in October which highlighted the ongoing need for RSV treatments despite the availability of new vaccines and prophylactic monoclonal antibodies. Guest speakers included Jaime Fergie, MD, FAAP, FIDSA, FSHEA, Medical Director of the Global Institute for Hispanic Health, Professor of Pediatrics at Texas A&M University, and Director of Infectious Diseases at Driscoll Children's Hospital in Texas; and Tom Wilkinson, MA (Cantab), MBBS, PhD, FRCP, FERS, Professor of Respiratory Medicine and Associate Dean at the University of Southampton and a member of the Faculty of Medicine at Southampton General Hospital, United Kingdom. To view the

webcast, visit here.

COVID-19 (SARS-CoV-2)

- Enanta plans to pursue any future COVID-19 efforts in the context of a collaboration, including the development of EDP-235, an oral, once-daily, Phase 3 ready 3CL protease inhibitor which has been granted Fast Track designation by the FDA.

Human Metapneumovirus (hMPV)/RSV

- Enanta paused development of its research program targeting both hMPV and RSV with a single agent. Despite promising preclinical data, the company does not plan to move a third RSV candidate into the clinic as long as EDP-938 and EDP-323 continue to progress.

Hepatitis B Virus (HBV)

- Enanta continues to seek an additional mechanism for development in a combination regimen with a nucleoside reverse transcriptase inhibitor and EDP-514, its potent core inhibitor which has Fast Track designation from the FDA, as a functional cure for HBV.

Non-Virology

- Enanta is advancing discovery programs focused on non-virology indications that have a high unmet need and leverage the company's expertise in preclinical small molecule drug discovery and development. The company will announce new therapeutic programs beginning in early 2024.

Upcoming Events and Presentations

- Evercore Healthcare Conference, November 29, 2023
- 42nd Annual JP Morgan Healthcare Conference, January 10, 2024
- Enanta plans to issue its fiscal 2024 first quarter press release, and hold a conference call regarding those results, on February 7, 2024.

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 with an emphasis on treatments for 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).

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; 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 September 30,		Twelve Months Ended September 30,	
	2023	2022	2023	2022
Revenue	$ 18,932	$ 20,317	$ 79,204	$ 86,160
Operating expenses				
Research and development	36,167	34,796	163,524	164,522
General and administrative	13,795	12,569	52,887	45,482
Total operating expenses	49,962	47,365	216,411	210,004
Loss from operations	(31,030)	(27,048)	(137,207)	(123,844)
Interest expense	(3,151)	—	(5,148)	—
Other income, net	4,664	714	11,360	1,656
Loss before income taxes	(29,517)	(26,334)	(130,995)	(122,188)
Income tax benefit (expense)	1,410	(14)	(2,821)	433
Net loss	$ (28,107)	$ (26,348)	$ (133,816)	$ (121,755)
Net loss per share				
Basic	$ (1.33)	$ (1.27)	$ (6.38)	$ (5.91)
Diluted	$ (1.33)	$ (1.27)	$ (6.38)	$ (5.91)
Weighted average common shares outstanding				
Basic	21,057	20,755	20,969	20,603
Diluted	21,057	20,755	20,969	20,603

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

	September 30, 2023	September 30, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 85,388	$ 43,994
Short-term marketable securities	284,522	205,238
Accounts receivable	8,614	20,318
Prepaid expenses and other current assets	13,263	13,445
Income tax receivable	31,004	28,718
Total current assets	422,791	311,713
Long-term marketable securities	—	29,285
Property and equipment, net	11,919	6,173
Operating lease, right-of-use assets	22,794	23,575
Restricted cash	3,968	3,968
Other long-term assets	803	696
Total assets	$ 462,275	$ 375,410
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,097	$ 6,000
Accrued expenses and other current liabilities	18,339	20,936
Liability related to the sale of future royalties	35,076	—
Operating lease liabilities	5,275	2,891
Total current liabilities	62,787	29,827
Liability related to the sale of future royalties, net of current portion	159,429	—
Operating lease liabilities, net of current portion	21,238	22,372
Series 1 nonconvertible preferred stock	1,423	1,423
Other long-term liabilities	663	454
Total liabilities	245,540	54,076
Total stockholders' equity	216,735	321,334
Total liabilities and stockholders' equity	$ 462,275	$ 375,410

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