Enanta Pharmaceuticals Reports Financial Results for its Fiscal Fourth Quarter and Year-Ended September 30, 2024

November 25, 2024

- *On Track to Report Topline Results for RSVPEDs, a Phase 2 Study of Zelicapavir in Infants and Children Infected with Respiratory Syncytial Virus (RSV), in December*
- *Announced Positive Topline Results for EDP-323 in a Phase 2a Human Challenge Study of Healthy Adults Infected with RSV*
- *Expands Immunology Portfolio with the Introduction of a New Discovery Program Focused on STAT6 Inhibition and the Nomination of EPS-1421, a Potent and Selective KIT Inhibitor Development Candidate*
- *Operations Supported by Cash and Marketable Securities Totaling $248.2 Million at September 30, 2024, as well as Continuing Retained Royalties*

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 25, 2024-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for virology and immunology indications, today reported financial results for its fiscal fourth quarter and year-ended September 30, 2024.

"Our fiscal fourth quarter was an exciting time for Enanta as we announced positive data from a Phase 2a human challenge study of EDP-323, our RSV L-inhibitor. We believe these results are among the strongest ever reported for an antiviral in an RSV challenge study, and significantly unlock further promise of our RSV program, in addition to advancing our leadership role in the RSV treatment landscape," said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. "With results from our RSVPEDs study of zelicapavir, our RSV N-inhibitor, expected in December, we could potentially have two of the leading clinical candidates for the treatment of RSV with different mechanisms of action, providing us with important optionality. The results of these studies will guide our decisions as we work to develop first-in-disease and best-in-class treatments for patients suffering from RSV."

Dr. Luly added, "We also made notable progress in advancing and expanding our immunology portfolio with the nomination of EPS-1421 as our lead development candidate for our KIT inhibition program. We are excited about the potential for potent and selective, oral, small molecule inhibitors for the treatment of chronic spontaneous urticaria and possibly other mast cell driven diseases. We are also pleased to introduce our second discovery stage program to develop oral STAT6 inhibitors for the treatment of type 2 immune driven diseases, with an initial focus on the treatment of atopic dermatitis, and future expansion opportunities in asthma and other indications. With multiple ongoing programs in both virology and immunology, we are committed to advancing our pipeline to help patients and to create value for shareholders."

Fiscal Fourth Quarter and Year-Ended September 30, 2024 Financial Results

Total revenue was $14.6 million for the three months ended September 30, 2024, 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 $18.9 million for the three months ended September 30, 2023. For the twelve months ended September 30, 2024, total revenue was $67.6 million compared to $79.2 million for the same period in 2023. The decrease in the quarter and in year-over-year revenue is due to a decline in AbbVie's sales of MAVYRET ®/MAVIRET®.

A portion (54.5%) of Enanta's ongoing royalty revenue from AbbVie's net sales of MAVYRET ®/MAVIRET® is paid to OMERS, one of Canada's largest defined benefit pension plans, pursuant to a royalty sale transaction affecting royalties earned after June 2023. For financial reporting purposes, the transaction was treated as debt, with the upfront purchase payment of $200.0 million recorded as a liability. Each quarter, Enanta records 100% of the royalty earned as revenue and then amortizes the debt liability proportionally as 54.5% of the cash royalty payments are paid to OMERS through June 30, 2032, subject to a cap of 1.42 times the purchase payment, after which point 100% of the cash royalty payments will be retained by Enanta. Interest expense was $2.6 million for the three months ended September 30, 2024 and $10.9 million for the twelve months ended September 30, 2024. This compares to interest expense of $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 $30.8 million for the three months ended September 30, 2024, compared to $36.2 million for the three months ended September 30, 2023. For the twelve months ended September 30, 2024, research and development expenses were $131.5 million compared to $163.5 million for the same period in 2023. The decrease in the quarter and in year-over-year research and development expenses is primarily due to a decrease in costs associated with Enanta's COVID-19 program as the company announced previously that plans to pursue any further COVID-19 efforts would be in the context of collaborations. These decreases were partially offset by increased costs associated with Enanta's immunology programs.

General and administrative expenses totaled $13.7 million for the three months ended September 30, 2024, compared to $13.8 million for the three months ended September 30, 2023. For the twelve months ended September 30, 2024, general and administrative expenses were $57.9 million compared to $52.9 million in 2023. The increase in year-over-year general and administrative expenses was due to an increase in legal fees related to the company's patent infringement suit against Pfizer.

Interest and investment income, net, totaled $3.2 million for the three months ended September 30, 2024, compared to $4.7 million for the three months ended September 30, 2023. The decrease was due to lower cash and investment balances year-over-year. For the twelve months ended September 30, 2024, interest and investment income, net, totaled $14.8 million compared to $11.4 million in 2023. The increase was due to an

increase in average invested cash due to receipt of $200.0 million from OMERS in April 2023 as well as changes in interest rates year-over-year.

Enanta recorded an income tax benefit of $0.4 million for the three months ended September 30, 2024, compared to an income tax benefit of $1.4 million for the three months ended September 30, 2023. Enanta recorded an income tax benefit of $1.7 million for the twelve months ended September 30, 2024, compared to an income tax expense of $2.8 million for the twelve months ended September 30, 2023. The income tax benefit during 2024 was due to interest earned on a pending $28.7 million federal income tax refund. 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 OMERS, which is treated as income for Federal and State income tax purposes.

Net loss for the three months ended September 30, 2024, was $28.8 million, or a loss of $1.36 per diluted common share, compared to a net loss of $28.1 million, or a loss of $1.33 per diluted common share, for the corresponding period in 2023. For the twelve months ended September 30, 2024, net loss was $116.0 million, or a loss of $5.48 per diluted common share, compared to a net loss of $133.8 million, or loss of $6.38 per diluted common share for the corresponding period in 2023.

Enanta's cash, cash equivalents and marketable securities totaled $248.2 million at September 30, 2024. 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 into fiscal 2027.

Virology

RSV

- Enanta is progressing multiple clinical programs comprising a robust antiviral portfolio aimed at treating populations at high-risk for serious outcomes from RSV infection. This includes zelicapavir, Enanta's lead, oral N-protein inhibitor, and EDP-323, its oral L-protein inhibitor, both of which received Fast Track designation from the U.S. Food and Drug Administration (FDA).
    - Zelicapavir is being evaluated in two Phase 2 clinical trials in high-risk pediatric and adult populations.
        - Enrollment is complete in RSVPEDs, a first-in-pediatrics Phase 2, randomized, double-blind, placebo-controlled study of zelicapavir in hospitalized and non-hospitalized RSV patients that are 28 days to three years of age. The company is on track to report topline data in December 2024.
        - RSVHR is a Phase 2b, randomized, double-blind, placebo-controlled study of zelicapavir in adults with RSV infection who are at high risk of complications, including age over 65 years and/or those with congestive heart failure, chronic obstructive pulmonary disease or asthma. Enrollment in RSVHR is progressing, and the company is targeting enrollment completion in the current Northern Hemisphere RSV season.
    - Enanta's second clinical RSV candidate, EDP-323, is a novel oral, direct-acting antiviral selectively targeting the RSV L-protein.
        - In September 2024, Enanta announced positive topline results for EDP-323 in a Phase 2a challenge study of healthy adults infected with RSV. Treatment with EDP-323 achieved statistically significant (p=<0.0001) reductions in both viral load and clinical symptoms compared to placebo. Overall, EDP-323 was generally well-tolerated and demonstrated a favorable safety profile that was comparable to placebo over 5 days of dosing through Day 28 of follow-up. There were no serious adverse events and no discontinuations of EDP-323. With these positive results the company has a potential second approach for treating RSV that may offer a best-in-disease opportunity. Pending RSVPEDs data results, Enanta will provide next steps for EDP-323 and its RSV program.

Immunology

- Today, Enanta announced the expansion of its immunology portfolio which is focused on designing and developing highly potent and selective, oral small molecule inhibitors for the treatment of inflammatory diseases, by targeting key drivers of the type 2 immune response.
    - KIT Inhibitor EPS-1421:
        - Enanta nominated EPS-1421 as its lead development candidate. EPS-1421 is a novel, potent and selective oral inhibitor of KIT, designed to treat chronic spontaneous urticaria and potentially other indications by depleting mast cells, thereby addressing a primary driver of these diseases.
        - EPS-1421 inhibits KIT with nanomolar potency in both binding and cellular assays and is highly selective for KIT versus other kinases. Further, EPS-1421 has demonstrated good *in vitro* and *in vivo* ADME properties preclinically. The company expects to conduct scale-up activities and IND enabling studies in 2025.
    - STAT6 Inhibitors:
        - The company's second discovery program is aimed at developing oral STAT6 inhibitors for the treatment of type 2 immune driven diseases and will initially focus on atopic dermatitis and potentially other indications by blocking the IL-4/IL-13 signaling pathway, thereby addressing a primary driver of these diseases.
        - Currently, Enanta is advancing novel, potent and selective oral inhibitors of STAT6. The company's prototype inhibitors demonstrate potent activity and high selectivity for STAT6 over other STATs in both biochemical and cellular assays. Enanta continues to evaluate multiple compounds in preclinical studies and expects to conduct lead optimization activities for this program in 2025.

Corporate

- Enanta will not be holding a conference call with today's fiscal fourth quarter and year-end update. The company will provide its next update with the release of the RSVPEDs study results, expected in December 2024.

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 indications in virology and immunology. Enanta's clinical programs are currently focused on respiratory syncytial virus (RSV) and its earlier-stage immunology pipeline aims to develop treatments for inflammatory diseases by targeting key drivers of the type 2 immune response, including KIT and STAT6 inhibition.

Glecaprevir, a protease inhibitor discovered by Enanta, is part of one of the leading treatment regimens for curing chronic hepatitis c virus (HCV) infection and is sold by AbbVie in numerous countries under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir). A portion of Enanta's royalties from HCV products developed under its collaboration with AbbVie contribute ongoing funding to Enanta's operations. 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 and its preclinical programs targeting KIT and STAT6 inhibition. 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 vaccines and competitive treatments for RSV; the discovery and development risks of Enanta's programs in virology and immunology; 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, 2023, 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 September 30,		Twelve Months Ended September 30,	
	2024	2023	2024	2023
Revenue	$ 14,607	$ 18,932	$ 67,635	$ 79,204
Operating expenses				
Research and development	30,778	36,167	131,476	163,524
General and administrative	13,683	13,795	57,850	52,887
Total operating expenses	44,461	49,962	189,326	216,411
Loss from operations	(29,854)	(31,030)	(121,691)	(137,207)
Interest expense	(2,581)	(3,151)	(10,940)	(5,148)
Interest and investment income, net	3,249	4,664	14,843	11,360
Loss before income taxes	(29,186)	(29,517)	(117,788)	(130,995)
Income tax benefit (expense)	363	1,410	1,743	(2,821)
Net loss	$ (28,823)	$ (28,107)	$ (116,045)	$ (133,816)
Net loss per share				
Basic	$ (1.36)	$ (1.33)	$ (5.48)	$ (6.38)
Diluted	$ (1.36)	$ (1.33)	$ (5.48)	$ (6.38)
Weighted average common shares outstanding				
Basic	21,190	21,057	21,157	20,969
Diluted	21,190	21,057	21,157	20,969

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

	September 30, 2024	September 30, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 37,233	$ 85,388
Short-term marketable securities	210,953	284,522
Accounts receivable	6,646	8,614
Prepaid expenses and other current assets	12,413	13,263
Income tax receivable	31,999	31,004
Short-term restricted cash	608	—
Total current assets	299,852	422,791
Property and equipment, net	32,688	11,919
Operating lease, right-of-use assets	40,658	22,794
Long-term restricted cash	3,360	3,968
Other long-term assets	94	803
Total assets	$ 376,652	$ 462,275
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 8,002	$ 4,097
Accrued expenses and other current liabilities	13,547	18,339
Liability related to the sale of future royalties	34,462	35,076
Operating lease liabilities	1,524	5,275
Total current liabilities	57,535	62,787
Liability related to the sale of future royalties, net of current portion	134,779	159,429
Operating lease liabilities, net of current portion	53,943	21,238
Series 1 nonconvertible preferred stock	1,350	1,423
Other long-term liabilities	231	663
Total liabilities	247,838	245,540
Total stockholders' equity	128,814	216,735
Total liabilities and stockholders' equity	$ 376,652	$ 462,275

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